labcorp

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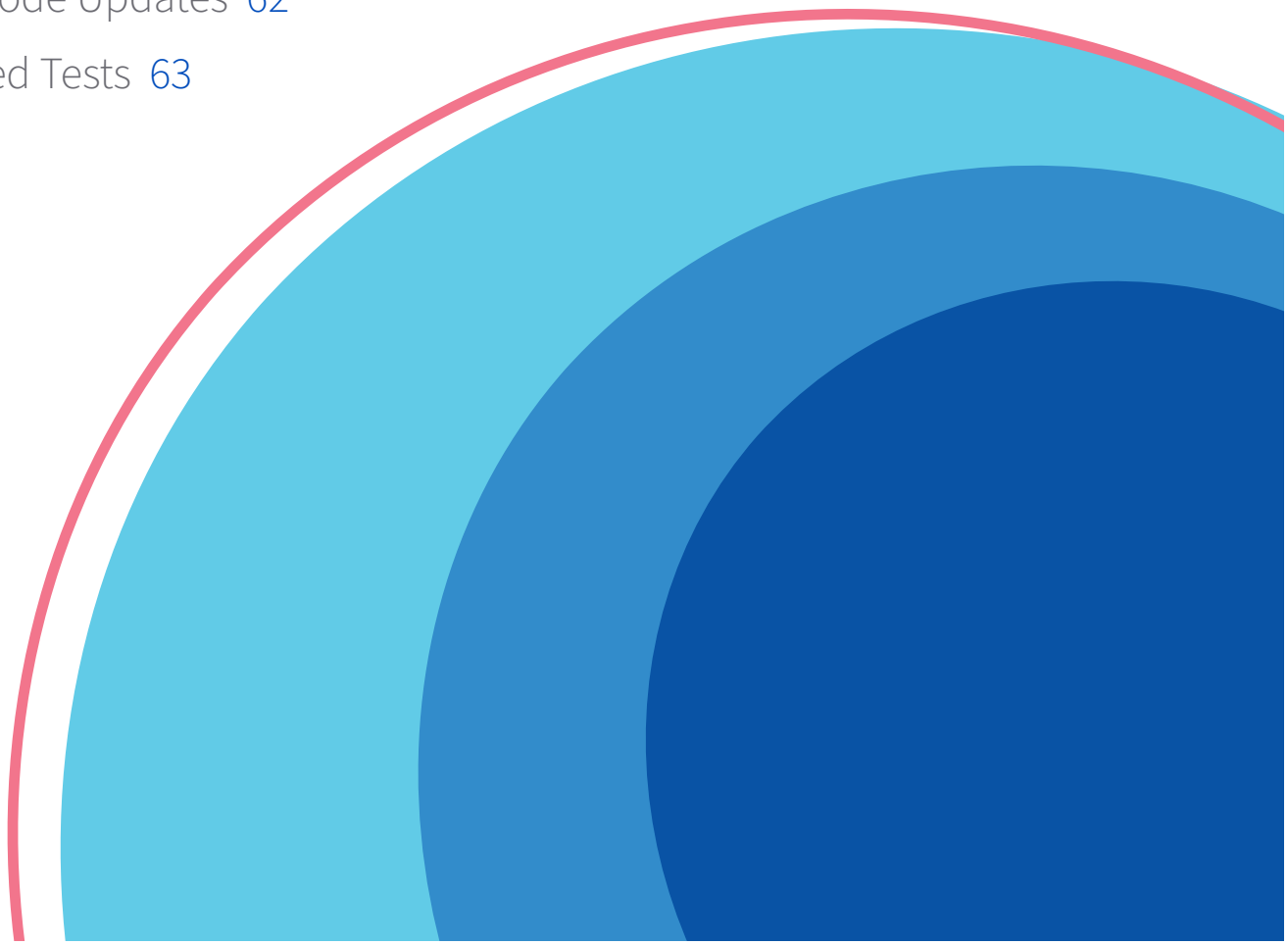
MONTHLY TEST UPDATES

Diagnostics Update

Welcome to the inaugural edition of Diagnostics Update. This new Diagnostics Update replaces the LabHorizons and will continue to be published monthly with a focus on information about new test offerings and test-related changes.



New Tests

Cardiorenal-Glycemic Status 245292

CPT 80061; 82043; 82565; 82570; 83036
Specimen Urine, serum, **and** whole blood
Volume 1 mL urine, 1 mL serum, **and** 4 mL whole blood
Container Urine bottle, gel barrier tube, lavender-top (EDTA) tube
Use According to the National Kidney Foundation, there are approximately 37 million adults in the U.S. who have chronic kidney disease (CKD), and about 90% are unaware of their condition. Diabetes is the leading cause of CKD in the United States. The significant impact of CKD on cardiovascular disease (CVD) risk has been increasingly recognized. Patients with CKD are far more likely to die, predominantly from CVD, than to progress to end-stage renal disease (ESRD). Currently, mainstays of treatment for diabetic kidney disease include control of hypertension, hyperglycemia and dyslipidemia. This panel has been established to aid in the identification and monitoring of hyperglycemia, dyslipidemia and CKD in patients with a history of diabetes and/or kidney disease.

Guidelines and expert panels advocate renal function testing patients with diabetes and/or hypertension at least annually with urinary albumin to creatinine ratio (uACR) and estimated glomerular filtration rate (eGFR). CKD is characterized by gradual loss of kidney function over time, defined as presence of either kidney damage (as indicated by the presence of albuminuria) or declining kidney function (as indicated by the level of GFR) for more than three months.[1]

Non-HDL-C is a calculation (total cholesterol minus HDL-C), and includes the sum of the VLDL-C, LDL-C, and IDL-C. While LDL-C has long been the primary focus of cholesterol reduction efforts, there are several other lipoproteins that also affect cardiovascular health. The advantage of non-HDL-C measurement is that it accounts for cholesterol in the other potentially atherogenic lipoprotein particles, which include VLDL-C, IDL-C, LDL-C, and lipoprotein(a). Recent guidelines suggest that non-HDL levels above 190 mg/dL enhances the risk for CVD.[2]

Hemoglobin A1c values are used to assess glucose control in diabetes, and in 2010, the American Diabetes Associations affirmed the decision of an international expert committee recommendation to use the A1c test to diagnose diabetes with a threshold ≥6.5%.

The Cardiorenal-glycemic Panel can be collected non-fasting.
Methodology See individual test components.
Footnotes

1. *KDIGO 2012 clinical practice guideline for the evaluation and management of chronic kidney disease.* International Society of Nephrology, Kidney International Supplements. 2013 Jan;3(1):1-150.

2. Gruncy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2019 Jun 25;73(24):e285-e350. Epub 2018 Nov 10. PubMed 30423393

Combined Pituitary Hormone Deficiency Genetic Panel 630534

CPT 81404; 81405; 81479
Test Includes *GLI1, HESX1, LHX3, LHX4, OTX2, POU1F1, PROKR2, PROP1, SOX2, SOX3*
Special Instructions This assay currently is not available in New York state.
Expected Turnaround Time 28 days
Specimen Whole blood, oral swab, extracted DNA
Volume 4 mL, 1 swab, **or** 200 ng of DNA
Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA
Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial
Collection Draw blood into EDTA tube; collect swab specimen per guidelines in kit; transfer extracted DNA into sterile screw-capped tube.
Stability

- **Room temperature:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Refrigerated:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Frozen:** Blood: Do **not** freeze; Swab: 60 days; DNA: Indefinitely

Causes for Rejection Frozen blood EDTA tube; insufficient swab cell collection or incorrect oral swab device use; extracted DNA A260:A280 ratio outside of 1.8-2.0 range
Use Diagnostic testing
Limitations This assay will not consistently detect germline mosaicism below 50% or rule out the presence of large chromosomal aberrations, including rearrangements and inversions that do not change copy number of genomic regions. The assay does not detect repeat expansions. Possible intergenic variant interactions are not commented on. False positive or false negative results may occur for reasons that include: insufficient information available about rare genetic variants, sex chromosome abnormalities, pseudogene interference, homologous regions, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples, or erroneous representation of family relationships. Variants that do not alter an amino acid composition of a protein may be difficult to assess for pathogenicity since they may produce abnormalities in structures **not** assessed by conventional analysis paradigms (eg mRNA expression and processing).[1] For mitochondrial DNA variants, low levels of heteroplasmy (<1%) may not be reliably detected by this technique. Mitochondrial variants may be tissue-specific. Interpretation of the clinical significance of gene variations is limited by information about the variant that is available at the time of reporting, and by the quality and quantity of clinical information provided with the sample. As the understanding of human genetic diversity improves, the interpretation of the clinical significance of variants may change.

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Nuclear Gene Copy Number Variant Assessment: Next Generation Sequencing data used to call SNPs and small indels are assessed with Illumina's DRAGEN (Dynamic Read Analysis for GENomics) Bio-IT Platform. Genes listed in ClinVar with intragenic pathogenic deletions are padded with additional intronic probes to allow single exon resolution CNV detection (list based on ClinVar Deletion Database: January 2019 release). For other genes, large deletions (>10 exons) can be detected. The resolution of this analysis can vary depending on region-specific features. Analytical sensitivity is estimated to be >95%.

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New Tests

Footnotes

1. Nackley AG, Shabalina SA, Tchivileva IE, et al. Human catechol-O-methyltransferase haplotypes modulate protein expression by altering mRNA secondary structure. *Science.* 2006 Dec 22;314(5807):1930-1933. PubMed 17185601

2. Richards S, Nazneen A, Bale S, et al. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. *Genet Med.* 2015 May;17(5):405-424. PubMed 25741868

Complete Blood Count (CBC) With Differential, Platelet, Neutrophil to Lymphocyte Ratio (NLR) 005013

CPT 85025
Synonyms CBC/D/Plt+NLR
Expected Turnaround Time Within 1 day
Specimen Whole blood
Volume Fill tube to capacity.
Minimum Volume 0.5 mL (500 µL for pediatric microtainer capillary tubes; fill tube to capacity). **Note:** This volume does **not** allow for repeat testing.
Container Lavender-top (EDTA) tube
Collection Invert tube 8 to 10 times immediately after tube is filled at the time of collection.
Storage Instructions Maintain specimen at room temperature.
Stability

Temperature	Period
Room temperature	1 day
Refrigerated	3 days
Frozen	Unstable
Freeze/thaw cycles	Unstable

Causes for Rejection Hemolysis; clotted specimen; specimen drawn in any anticoagulant other than EDTA; specimen diluted or contaminated with IV fluid; tube not filled with minimum volume; improper labeling; transfer tubes with whole blood; specimen received with plasma removed (plasma is used for other testing)
Use NLR (Neutrophil to Lymphocyte Ratio) is a biomarker that can be used as an indication of subclinical inflammation. NLR is a calculation based on the Absolute Neutrophil Count divided by the Absolute Lymphocyte Count determined by the peripheral blood CBC differential. This calculation, according to recent literature, is useful in assessing the likelihood of severe progression of disease in SARS-CoV-2 positive patients.

CBC:A screening test to evaluate overall health; detect and or identify a wide range of hematologic disorders; assist in managing medications/ chemotherapeutic decisions.
Methodology Automated cell counter with mixed technologies; NLR is a Calculation
Additional Information Assessments of stained smears are performed if results meet specific numeric and/or instrument flagging criteria. Smear review includes assessment of WBC cell populations, presence of WBC and/or RBC inclusions, RBC morphology, and platelet evaluation.

Presence of one or more of the following may be indication for further investigation: hemoglobin <10 g/dL, hemoglobin >18 g/dL, MCV >100 fL, MCV <80 fL, MCHC >37%, WBC >20,000/mm3, WBC <2000/mm3, presence of sickle cells, spherocytes, Pappenheimer bodies, basophilic stippling, stomatocytes, schistocytes (fragmented RBCs), target cells, oval macrocytes, teardrop red blood cells, abnormal cell populations, nucleated red blood cells in other than the newborn, blood parasites (malarial or Babesia organisms or the possibility of parasitic organisms), hypersegmented neutrophils, agranular neutrophils, hyposegmented neutrophils (Pelger-Huët anomaly or pseudo-Pelger-Huët [pelgeroid] cells), mononuclear cells in which apparent nucleoli are prominent (blast-like cells), presence of metamyelocytes, myelocytes, promyelocytes, neutropenia, presence of plasma cells, peculiar atypical lymphocytes, significant increase or decrease in platelets or bizarre platelets.

A six-part differential reported in some lab locations includes IG % and IG absolute counts. IG (immature granulocytes) includes metamyelocytes and myelocytes. It does not include bands or blast cells.[1,2] Promyelocytes and blasts are reported separately to denote the degree of left shift. An elevated percentage of IG has not been found to be clinically significant as a sole clinical predictor of disease. IGs are associated with infections, a variety of inflammatory disorders, cytokine therapy, neoplasia, hemolysis, tissue damage, seizures, metabolic abnormalities, myeloproliferative neoplasms, and with the use of certain medications such as steroids.[3]

Pregnancy-associated leukocytosis may also show increased immature granulocytes without clinical significance. There is a significant increase of normoblastic erythropoiesis and, to a lesser extent, of granulopoiesis during pregnancy, which is associated with an increase in immature cells (shift to the left) of both erythropoietic and granulopoietic tissues. A possible physiologic explanation for the appearance of immature granulocytes in the peripheral blood of pregnant women, increased alkaline phosphate activity in granulocytes, and increased glycogen content of lymphocytes may be found in the excretion curves of hormones during pregnancy. There is a sharp rise in the fifth month then a decrease in the eighth month and a subsequent rise in the ninth month.[4]

Footnotes

1. Fernandes B, Hamaguchi Y. Automated enumeration of immature granulocytes. Am J Clin Pathol. 2007 Sep;128(3):454-463. PubMed 17709320

2. Ansari-Lari M, Kickler TS, Borowitz MJ. Immature granulocyte measurement using the Sysmex XE-2100. Relationship to infection and sepsis. Am J Clin Pathol. 2003 Nov;120(5):795-799. PubMed 14608908

3. Kiechle FL, ed. CAP Today. August 2010, Q&A Section. Accessed December 2020 at http://www.captodayonline.com/Archives/0810/0808_QA.html.

4. Efrati P, Presentey B, Marglaith M, Rozenszajn L. Leukocytes of normal pregnant women. Obstet Gynecol. 1964 Mar;23:429-432. PubMed 14128474 Eckfeldt JH, Levitt MD. Diagnostic enzymes for pancreatic disease. Clin Lab Med. 1989 Dec; 9(4):731-743. PubMed 2480201

Comprehensive Short Stature Genetic Panel 630520

CPT 81442
Synonyms Idiopathic Short Stature
Test Includes *ACAN, BRAF, BTK, CBL, CCDC8, COL10A1, COL11A1, COL11A2, COL1A1, COL2A1, COL9A1, COL9A2, COL9A3, CUL7, EVC, FBN1, FGFR3, GH1, GHR, GHSR, GHRHR, GLI2, GPC3, H19, HESX1, HRAS, IGF1, IGF2, IGF1R, IGFALS, IHH, KRAS, LHX3, LHX4, LZTR1, MAP2K1, MAP2K2, MRAS, NF1, NPPC, NRAS, OBSL1, OTX2, POU1F1, PPP1CB, PROKR2, PROP1, PTPN11, RAF1, RIT1, RRAS, SHOC2, SHOX, SOS1, SOS2, SOX3, SPRED1, SRCAP, STAT5B*
Special Instructions This assay currently is not available in New York state.
Expected Turnaround Time 28 days
Specimen Whole blood, oral swab, extracted DNA
Volume 4 mL, 1 swab, **or** 200 ng of DNA
Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA
Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial
Collection Draw blood into EDTA tube; collect swab specimen per guidelines in kit; transfer extracted DNA into sterile screw-capped tube.
Stability

- **Room temperature:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Refrigerated:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Frozen:** Blood: Do **not** freeze; Swab: 60 days; DNA: Indefinitely

Causes for Rejection Frozen blood EDTA tube; insufficient swab cell collection or incorrect oral swab device use; extracted DNA A260:A280 ratio outside of 1.8-2.0 range
Use Diagnostic testing
Limitations The assay will not consistently detect germline mosaicism below 50% or rule out the presence of large chromosomal aberrations, including rearrangements, inversions that do not change copy number of genomic regions. The assay does not detect repeat expansions. Possible intergenic variant interactions are not commented on. False positive or false negative results may occur for reasons that include: insufficient information available about rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples, or erroneous representation

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of family relationships. Variants that do not alter an amino acid composition of a protein may be difficult to assess for pathogenicity since they may produce abnormalities in structures **not** assessed by conventional analysis paradigms, eg, mRNA expression and processing.[1] Interpretation of the clinical significance of gene variations is limited by information about the variant that is available at the time of reporting, and by the quality and quantity of clinical information provided with the sample. As the understanding of human genetic diversity improves, the interpretation of the clinical significance of variants may change.

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Shox Gene Analysis: This analysis detects single nucleotide variants (SNVs), small indels, and most large deletions/duplications (CNVs) involving more than one exon within the SHOX gene. Regions of interest include all exons and intron/exon junctions (+/-20 nucleotides). For CNVs, upstream and downstream regulatory regions are also included. This analysis does not detect inversions or rearrangements and may not detect the co-occurrence of a deletion and a duplication. Analytical sensitivity is estimated to be >99%.

Results Interpretation: Results should be used in the context of available clinical information and should not be used as the sole basis for patient management or treatment. Genetic counseling is recommended. Variants are assessed according to ACMG criteria.[2] This report contains interpretation of pathogenic and likely pathogenic variants (by ACMG criteria) as well as variants of uncertain significance (VUS) with pathogenic predictions related to the clinical information provided. Variants not reported: (1) Variants classified as benign or likely benign by ACMG Criteria; (2) VUS with benign or likely benign predictions; (3) variants related to carrier status; (4) polymorphisms with implications in drug response (pharmacogenomics variants). We will reanalyze the data periodically at the clinician's request to allow potential reinterpretation based on new research or evidence. GnomAD abbreviations for population frequency data: African/African American (AFR), Latino (AMR), Ashkenazi Jewish (ASJ), East Asian (EAS), Finnish (FIN), Non-Finnish European (NFE), South Asian (SAS), Other (OTH).

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Congenital Hyperinsulinism Genetic Panel 630500

CPT 81403; 81405; 81406(x3); 81407; 81479
Synonyms Hypoglycemia
Test Includes *ABCC8, GCK, GLUD1, HADH, HNF1A, HNF4A, KCNJ11, PGM1, PMM2, SLC16A1, UCP2*
Special Instructions This assay currently is not available in New York state.
Expected Turnaround Time 28 days
Specimen Whole blood, oral swab, extracted DNA
Volume 4 mL, 1 swab, **or** 200 ng of DNA
Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA
Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial
Collection Draw blood into EDTA tube; collect swab specimen per guidelines in kit; transfer extracted DNA into sterile screw-capped tube.
Stability

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Use Diagnostic testing
Limitations The assay will not consistently detect germline mosaicism below 50% or rule out the presence of large chromosomal aberrations, including rearrangements, inversions that do not change copy number of genomic regions. The assay does not detect repeat expansions. Possible intergenic variant interactions are not commented on. False positive or false negative results may occur for reasons that include: insufficient information available about rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples, or erroneous representation of family relationships. Variants that do not alter an amino acid composition of a protein may be difficult to assess for pathogenicity since they may produce abnormalities in structures **not** assessed by conventional analysis paradigms (eg mRNA expression and processing).[1] For mitochondrial DNA variants, low levels of heteroplasmy (<1%) may not be reliably detected by this technique. Mitochondrial variants may be tissue-specific. Interpretation of the clinical significance of gene variations is limited by information about the variant that is available at the time of reporting, and by the quality and quantity of clinical information provided with the sample. As the understanding of human genetic diversity improves, the interpretation of the clinical significance of variants may change.

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Congenital Hypothyroidism Genetic Panel 630264

CPT 81405; 81406; 81479
Synonyms Bamforth-Lazarus Syndrome; Congenital Hypothyroidism; Thyroid Resistance
Test Includes *DUOX2, DUOXA2, FOXE1, IYD, NKX2-5, PAX8, SLC5A5, SLC26A4, TG, THRA, THRB, TPO, TRHR, TSHB, TSHR*
Special Instructions This assay currently is not available in New York state.
Expected Turnaround Time 28 days
Specimen Whole blood, oral swab, extracted DNA
Volume 4 mL, 1 swab, **or** 200 ng of DNA
Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA
Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial
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DDAVP Challenge Profile for Von Willebrand Disease 504836

CPT 80500; 85240(x3); 85245(x3); 85246(x3)
Specimen Citrated plasma, frozen
Volume 2 mL per timepoint
Minimum Volume 1.5 mL per timepoint (**Note:** This volume does **not** allow for repeat testing.)
Container Blue-top (sodium citrate) tube
Collection Centrifuge at 2500 xg for 10 minutes. Separate plasma from cells within 3 hours of venipuncture. Centrifuge plasma a second time and place in

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plastic transport tubes. **Freeze** within 4 hours and keep frozen until testing is performed.
Storage Instructions Plasma, **frozen**

Stability

Temperature	Period
Frozen	6 months
Freeze/thaw cycles	Stable x1

Use This profile is designed to assess the response of DDAVP treatment in patients presenting with Von Willebrand Disease by measuring VWF and factor VIII levels pre-treatment (baseline) and at two time-points (1 hr and 4 hr) post-treatment. Post-treatment VWF levels are evaluated against baseline results to determine whether the response is adequate and sustained. Results should be correlated with clinical symptoms and family history.
Methodology Clotting, platelet agglutination, latex immunoagglutination
Additional Information This profile contains testing for FVIII Activity, VWF Activity and VWF Antigen at three timepoints: baseline, 1 hour and 4 hours post-treatment with DDAVP. It also contains a pathologist Interpretation of all test results.

Growth Hormone Deficiency Genetic Panel 630527

CPT 81404(x2); 81405(x3); 81406; 81479
Synonyms GHD; Isolated Growth Hormone Deficiency
Test Includes *BTK, GH1, GHR, GHRHR, GHSR, HESX1, LHX3, LHX4, OTX2, POU1F1, PROP1*
Special Instructions This assay currently is not available in New York state.
Expected Turnaround Time 28 days
Specimen Whole blood, oral swab, extracted DNA
Volume 4 mL, 1 swab, **or** 200 ng of DNA
Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA
Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial
Collection Draw blood into EDTA tube; collect swab specimen per guidelines in kit; transfer extracted DNA into sterile screw-capped tube.
Stability

- **Room temperature:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Refrigerated:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Frozen:** Blood: Do **not** freeze; Swab: 60 days; DNA: Indefinitely

Causes for Rejection Frozen blood EDTA tube; insufficient swab cell collection or incorrect oral swab device use; extracted DNA A260:A280 ratio outside of 1.8-2.0 range
Use Diagnostic testing
Limitations The assay will not consistently detect germline mosaicism below 50% or rule out the presence of large chromosomal aberrations, including rearrangements, inversions that do not change copy number of genomic regions. The assay does not detect repeat expansions. Possible intergenic variant interactions are not commented on. False positive or false negative results may occur for reasons that include: insufficient information available about rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples, or erroneous representation of family relationships. Variants that do not alter an amino acid composition of a protein may be difficult to assess for pathogenicity since they may produce abnormalities in structures **not** assessed by conventional analysis paradigms (eg mRNA expression and processing).[1] For mitochondrial DNA variants, low levels of heteroplasmy (<1%) may not be reliably detected by this technique. Mitochondrial variants may be tissue-specific. Interpretation of the clinical significance of gene variations is limited by information about the variant that is available at the time of reporting, and by the quality and quantity of clinical information provided with the sample. As the understanding of human genetic diversity improves, the interpretation of the clinical significance of variants may change.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Methodology

Nuclear Gene Single Nucleotide Polymorphism and Small Indel Sequencing Assessment: Genomic regions of interest are selected using a custom capture reagent for target enrichment (Twist Bioscience) and sequenced via the Illumina® Novaseq 6000 next generation sequencing platform. Sequencing reads are aligned with the human genome reference GRCh37/hg19 build. Regions of interest include all exons and intron/exon junctions (+/-10 nucleotides) for each gene analyzed. A minimum of 99% of bases in targeted regions are covered at >30X. Analytical sensitivity is estimated to be >99% for single nucleotide variants, >97% for insertions/deletions less than six base pairs, and >95% for insertions/deletions between six and fifteen base pairs. Uncovered regions with known pathogenic variants are sequenced in a targeted manner (list based on ClinVar Database: July 22, 2019 release).

Nuclear Gene Copy Number Variant Assessment: Next Generation Sequencing data used to call SNPs and small indels are assessed with Illumina's DRAGEN (Dynamic Read Analysis for GENomics) Bio-IT Platform. Genes listed in ClinVar with intragenic pathogenic deletions are padded with additional intronic probes to allow single exon resolution CNV detection (list based on ClinVar Deletion Database: January 2019 release). For other genes, large deletions (>10 exons) can be detected. The resolution of this analysis can vary depending on region-specific features. Analytical sensitivity is estimated to be >95%.

Results Interpretation: Results should be used in the context of available clinical information and should not be used as the sole basis for patient management or treatment. Genetic counseling is recommended. Variants are assessed according to ACMG criteria.[2] This report contains interpretation of pathogenic and likely pathogenic variants (by ACMG criteria) as well as variants of uncertain significance (VUS) with pathogenic predictions related to the clinical information provided. Variants not reported: (1) Variants classified as benign or likely benign by ACMG Criteria; (2) VUS with benign or likely benign predictions; (3) variants related to carrier status; (4) polymorphisms with implications in drug response (pharmacogenomics variants). We will reanalyze the data periodically at the clinician's request to allow potential reinterpretation based on new research or evidence. GnomAD abbreviations for population frequency data: African/African American (AFR), Latino (AMR), Ashkenazi Jewish (ASJ), East Asian (EAS), Finnish (FIN), Non-Finnish European (NFE), South Asian (SAS), Other (OTH).

Footnotes

1. Nackley AG, Shabalina SA, Tchivileva IE, et al. Human catechol-O-methyltransferase haplotypes modulate protein expression by altering mRNA secondary structure. Science. 2006 Dec 22;314(5807):1930-1933. PubMed 17185601

2. Richards S, Nazneen A, Bale S, et al. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Genet Med. 2015 May;17(5):405-424. PubMed 25741868

Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA With Reflex to Cobas® High-risk HPV With HPV Genotypes 16 and 18 When ASC-U, ASC-H, LSIL, HSIL, AGUS 196245

CPT 87491; 87591; 88175
Special Instructions Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

Note: In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, Labcorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)
Expected Turnaround Time 3 - 6 days

New Tests

Specimen Cervical cells collected by one of the methods described below.
Volume ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for *Chlamydia/Gonococcus*)
Minimum Volume A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. Specimens collected with the Gen-Probe® Aptima® swab collection kit must arrive intact.
Container ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for *Chlamydia/Gonococcus*)
Collection ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

Optional Dedicated Specimen for *Chlamydia* and *Gonococcus:* Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly.
Storage Instructions Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be performed within 21 days of collection. ThinPrep® vial may be stored for six months after the date of collection prior to performing the Cobas® HPV test. ThinPrep® specimens should not be frozen. Liquid-based cytology specimens must be tested within seven days for Chlamydia/Gonococcus; if the Aptima® swab transport is used, it must be tested within 60 days.
Patient Preparation Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.
Causes for Rejection Improper collection; inadequate specimen; improper labeling; frozen specimen; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patients; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than six months old in ThinPrep® vial; excessively bloody specimens. **For *Chlamydia* and *Gonococcus:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the blue-shafted collection swab.
Use Diagnose primary or metastatic neoplasm; detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae.* The HPV test specifically identifies types HPV16 and HPV18 while concurrently detecting the rest of the high-risk types 31,33,35,39,45,51,52,56,58,59,66, and 68 without further specific differentiation.
Limitations Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results.

The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap processing or HPV testing. Detection of high-risk HPV is dependent on the number of copies present in the specimen and may be affected by specimen collection methods, patient factors, stage of infection and the presence of interfering substances.

Testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* requires special procedures to be used in the processing of the cytology specimen; therefore, testing for these organisms cannot be added on after the specimen has been submitted. The liquid-based cytology specimen must be processed for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing.

Any time a transport device used for molecular testing is processed, the chance of cross-specimen contamination increases. Aptima® transports can be placed directly on the analyzer, limiting the possibility of cross-specimen contamination.
Methodology Image-guided liquid-based Pap test; nucleic acid amplification (NAA)

Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA with Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U, ASC-H, LSIL, HSIL, AGUS With Reflex to HPV Genotypes 16 and 18,45 199386

CPT 87491; 87591; 88175
Special Instructions Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

Note: In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, Labcorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)
Expected Turnaround Time 3 - 6 days
Specimen Cervical cells in ThinPrep® vial
Volume ThinPrep® vial
Minimum Volume A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen.
Container ThinPrep® vial
Collection

ThinPrep® Vial–Broom or Brush/Spatula:

Broom-like collection technique: Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

Brush/spatula technique: Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

Optional Dedicated Specimen for *Chlamydia* and *Gonococcus:* Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly.
Storage Instructions Maintain specimen at room temperature. Specimens must be processed for testing within 21 days of collection for Pap.
Patient Preparation Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.

New Tests

Causes for Rejection Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than than three months old in ThinPrep® vial. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the collection swab.
Use Diagnose primary or metastatic neoplasm. This test aids in the diagnosis of sexually transmitted HPV infection and in the triage of patients with an abnormal Pap test result. Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae.* High-risk HPV test is used for types 16,18,31,33,35,39,45, 51,52,56,58,59,66, and 68, without differentiation of the individual type. Positive high risk HPV test results reflex the sample for genotyping of types 16 and 18/45.
Limitations Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results. The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result.

Testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* requires special procedures to be used in the processing of the cytology specimen; therefore, testing for these organisms cannot be added on after the specimen has been submitted. The liquid-based cytology specimen must be processed for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing.
Methodology Image-guided liquid-based Pap test; nucleic acid amplification (NAA)

Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas,* NAA With Reflex to Cobas® High-risk HPV With HPV Genotypes 16 and 18 When ASC-U, ASC-H, LSIL, HSIL, AGUS 196255

CPT 87491; 87591; 87661; 88175
Special Instructions Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

Note: In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, Labcorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)
Expected Turnaround Time 3 - 6 days
Specimen Cervical cells collected by one of the methods described below.
Volume ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for *Chlamydia/Gonococcus/Trichomonas*)
Minimum Volume A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. Specimens collected with the Gen-Probe® Aptima® swab collection kit must arrive intact.
Container ThinPrep® vial or ThinPrep® vial with optional Aptima® swab collection kit (for *Chlamydia/Gonococcus/Trichomonas*)
Collection ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

Optional Dedicated Specimen for *Chlamydia, Gonococcus*, and *Trichomonas:* Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly.
Storage Instructions Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be performed within 21 days of collection. ThinPrep® vial may be stored for six months after the date of collection prior to performing the Cobas® HPV test. ThinPrep® specimens should not be frozen. Liquid-based cytology specimens must be tested within seven days for *Chlamydia/Gonococcus/Trichomonas;* if the Aptima® swab transport is used, it must be tested within 60 days.
Patient Preparation Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period. Excessive use of lubricating jelly will interfere with cytologic examination.
Causes for Rejection Improper collection; inadequate specimen; improper labeling; frozen specimen; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patients; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than six months old in ThinPrep® vial; excessively bloody specimens. **For *Chlamydia, Gonococcus,* and *Trichomonas:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the blue-shafted collection swab.
Use Diagnose primary or metastatic neoplasm; detect *Chlamydia trachomatis, Neisseria gonorrhoeae,* and *Trichomonas vaginalis.* The HPV test specifically identifies types HPV16 and HPV18 while concurrently detecting the rest of the high-risk types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 without further specific differentiation.
Limitations Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results.

The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. Detection of high-risk HPV is dependent on the number of copies present in the specimen and may be affected by specimen collection methods, patient factors, stage of infection and the presence of interfering substances.

Testing for *Chlamydia trachomatis, Neisseria gonorrhoeae,* and *Trichomonas vaginalis* requires special procedures to be used in the processing of the cytology specimen; therefore, testing for these organisms cannot be added on after the specimen has been submitted. The liquid-based cytology specimen must be processed for Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis testing.

Any time a transport device used for molecular testing is processed, the chance of cross-specimen contamination increases. Aptima® transports can be placed directly on the analyzer, limiting the possibility of cross-specimen contamination.
Methodology Image-guided liquid-based Pap test; nucleic acid amplification

New Tests

Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA With Reflex to Human Papillomavirus (HPV) (Aptima) When ASC-U, ASC-H, LSIL, HSIL, AGUS With Reflex to HPV Genotypes 16 and 18,45 199337

CPT 87491; 87591; 87661; 88175

Special Instructions Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

Note: In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, Labcorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)

Expected Turnaround Time 3 - 6 days

Specimen Cervical cells in ThinPrep® vial

Volume ThinPrep® vial

Minimum Volume A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen.

Container ThinPrep® vial

Collection

ThinPrep® Vial–Broom or Brush/Spatula:

Broom-like collection technique: Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

Brush/spatula technique: Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

Optional Dedicated Specimen for *Chlamydia* and *Gonococcus:* Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly.

Storage Instructions Maintain specimen at room temperature. Specimens must be processed for testing within 21 days of collection for Pap.

Patient Preparation Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.

Causes for Rejection Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to the manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia, Gonococcus*, and *Trichomonas vaginalis:*** liquid-based cytology specimen more than seven days old, Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs; white-shafted cleaning swab, or any swab other than the collection swab.

Use Diagnose primary or metastatic neoplasm. This test aids in the diagnosis of sexually transmitted HPV infection and in the triage of patients with an abnormal Pap test result. Detect *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis.* High-risk HPV test is used for types 16,18,31,33,35 ,39,45,51,52,56,58,59,66, and 68, without differentiation of the individual type. Positive high risk HPV test results reflex the sample for genotyping of types 16 and 18/45.

Limitations Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results. The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing.

A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result.

Testing for *Chlamydia trachomatis, Neisseria gonorrhoeae,* and *Trichomonas vaginalis requires special procedures to be used in the processing of the cyto*logy specimen; therefore, testing for these organisms cannot be added on after the specimen has been submitted. The liquid-based cytology specimen must be processed for *Chlamydia trachomatis, Neisseria gonorrhoeae,* and *Trichomonas vaginalis* testing.

Methodology Image-guided liquid-based Pap test; nucleic acid amplification (NAA)

Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Cobas® High-risk HPV With HPV Genotypes 16 and 18 When ASC-U, ASC-H, LSIL, HSIL, AGUS 196240

CPT 88175

Special Instructions Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

Note: In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, Labcorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)

Expected Turnaround Time 3 - 6 days

Specimen Cervical cells in ThinPrep® vial

Volume ThinPrep® vial

Minimum Volume A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen.

Container ThinPrep® vial

Collection ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

Storage Instructions Maintain liquid-based cytology specimens at room temperature. Pap processing must be performed within 21 days of collection. ThinPrep® vial may be stored for six months after the date of collection prior to performing the Cobas® HPV test. ThinPrep® specimens should not be frozen.

New Tests

Patient Preparation Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.
Causes for Rejection Improper collection; inadequate specimen; improper labeling; frozen specimen; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patients; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than six months old in ThinPrep® vial; excessively bloody specimens.
Use Diagnose primary or metastatic neoplasm. The HPV test specifically identifies types HPV16 and HPV18 while concurrently detecting the rest of the high-risk types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 without further differentiation.
Limitations Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results.

The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. Detection of high-risk HPV is dependent on the number of copies present in the specimen and may be affected by specimen collection methods, patient factors, stage of infection, and the presence of interfering substances.
Methodology Image-guided liquid-based Pap test; nucleic acid amplification (NAA)

Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U, ASC-H, LSIL, HSIL, AGUS With Reflex to HPV Genotypes 16 and 18,45 199350

CPT 88175
Special Instructions Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

Note: In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, Labcorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)
Expected Turnaround Time 3 - 6 days
Specimen Cervical cells in ThinPrep® vial
Volume ThinPrep® vial
Minimum Volume A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen.
Container ThinPrep® vial
Collection

ThinPrep® Vial–Broom or Brush/Spatula:

Broom-like collection technique: Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

Brush/spatula technique: Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.
Storage Instructions Maintain specimen at room temperature. Specimens must be processed for testing within 21 days of collection for Pap.
Patient Preparation Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.
Causes for Rejection Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial.
Use Diagnose primary or metastatic neoplasm. This test aids in the diagnosis of sexually transmitted HPV infection and in the triage of patients with an abnormal Pap test result. High-risk HPV test is used for types 16,18,31,33,35,39,45, 51,52,56,58,59,66, and 68, without differentiation of the individual type. Positive high risk HPV test results reflex the sample for genotyping of types 16 and 18/45.
Limitations Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results.

The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. Detection of high-risk HPV is dependent on the number of copies present in the specimen and may be affected by specimen collection methods, patient factors, stage of infection, and the presence of interfering substances.
Methodology Image-guided liquid-based Pap test; nucleic acid amplification (NAA)

Hypophosphatasia and Hypophosphatemic Rickets Panel 630292

CPT 81404; 81406; 81479
Synonyms Familial Hypophosphatemic Rickets; HRP; Hypophosphatemic Rickets; Hypophosphatemic Vitamin D-Resistant Rickets (HPDR); Phosphate Diabetes; Vitamin D-Resistant Rickets; X-Linked Dominant Hypophosphatemic Rickets (XLHR); X-Linked Hypophosphatemia; X-Linked Hypophosphatemic Rickets; X-Linked Rickets (XLR); X-Linked Vitamin D-Resistant Rickets (VDRR); XLH
Test Includes *ALPL, CLCN5, CYP2R1,CYP27B1, DMP1, ENPP1, FGF23, PHEX, SLC34A3, VDR*
Special Instructions This assay currently is **not** available in New York state.
Expected Turnaround Time 28 days
Specimen Whole blood, oral swab, extracted DNA
Volume 4 mL, 1 swab, **or** 200 ng of DNA
Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA
Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial
Collection Draw blood into EDTA tube; collect swab specimen per guidelines in kit; transfer extracted DNA into sterile screw-capped tube.
Stability

- **Room temperature:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Refrigerated:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Frozen:** Blood: Do **not** freeze; Swab: 60 days; DNA: Indefinitely

Causes for Rejection Frozen blood EDTA tube; insufficient swab cell collection or incorrect oral swab device use; extracted DNA A260:A280 ratio outside of 1.8-2.0 range
Use Diagnostic testing
Limitations The assay will not consistently detect germline mosaicism below 50% or rule out the presence of large chromosomal aberrations, including rearrangements, inversions that do not change copy number of genomic

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regions. The assay does not detect repeat expansions. Possible intergenic variant interactions are not commented on. False positive or false negative results may occur for reasons that include: insufficient information available about rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples, or erroneous representation of family relationships. Variants that do not alter an amino acid composition of a protein may be difficult to assess for pathogenicity since they may produce abnormalities in structures **not** assessed by conventional analysis paradigms (eg mRNA expression and processing).[1] For mitochondrial DNA variants, low levels of heteroplasmy (<1%) may not be reliably detected by this technique. Mitochondrial variants may be tissue-specific. Interpretation of the clinical significance of gene variations is limited by information about the variant that is available at the time of reporting, and by the quality and quantity of clinical information provided with the sample. As the understanding of human genetic diversity improves, the interpretation of the clinical significance of variants may change.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Methodology

Nuclear Gene Single Nucleotide Polymorphism and Small Indel Sequencing Assessment: Genomic regions of interest are selected using a custom capture reagent for target enrichment (Twist Bioscience) and sequenced via the Illumina® Novaseq 6000 next generation sequencing platform. Sequencing reads are aligned with the human genome reference GRCh37/hg19 build. Regions of interest include all exons and intron/exon junctions (+/-10 nucleotides) for each gene analyzed. A minimum of 99% of bases in targeted regions are covered at >30X. Analytical sensitivity is estimated to be >99% for single nucleotide variants, >97% for insertions/deletions less than six base pairs, and >95% for insertions/deletions between six and fifteen base pairs. Uncovered regions with known pathogenic variants are sequenced in a targeted manner (list based on ClinVar Database: July 22, 2019 release).

Nuclear Gene Copy Number Variant Assessment: Next Generation Sequencing data used to call SNPs and small indels are assessed with Illumina's DRAGEN (Dynamic Read Analysis for GENomics) Bio-IT Platform. Genes listed in ClinVar with intragenic pathogenic deletions are padded with additional intronic probes to allow single exon resolution CNV detection (list based on ClinVar Deletion Database: January 2019 release). For other genes, large deletions (>10 exons) can be detected. The resolution of this analysis can vary depending on region-specific features. Analytical sensitivity is estimated to be >95%.

Results Interpretation: Results should be used in the context of available clinical information and should not be used as the sole basis for patient management or treatment. Genetic counseling is recommended. Variants are assessed according to ACMG criteria.[2] This report contains interpretation of pathogenic and likely pathogenic variants (by ACMG criteria) as well as variants of uncertain significance (VUS) with pathogenic predictions related to the clinical information provided. Variants not reported: (1) Variants classified as benign or likely benign by ACMG Criteria; (2) VUS with benign or likely benign predictions; (3) variants related to carrier status; (4) polymorphisms with implications in drug response (pharmacogenomics variants). We will reanalyze the data periodically at the clinician's request to allow potential reinterpretation based on new research or evidence. GnomAD abbreviations for population frequency data: African/African American (AFR), Latino (AMR), Ashkenazi Jewish (ASJ), East Asian (EAS), Finnish (FIN), Non-Finnish European (NFE), South Asian (SAS), Other (OTH).

Footnotes

1. Nackley AG, Shabalina SA, Tchivileva IE, et al. Human catechol-O-methyltransferase haplotypes modulate protein expression by altering mRNA secondary structure. Science. 2006 Dec 22;314(5807):1930-1933. PubMed 17185601

2. Richards S, Nazneen A, Bale S, et al. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Genet Med. 2015 May;17(5):405-424. PubMed 25741868

Kallmann Syndrome Genetic Panel 630542

CPT 81405; 81406; 81407; 81479
Synonyms Hypogonadotropic Hypogonadism
Test Includes *ANOS1, AXL, CCDC141, CHD7, DUSP6, FEZF1, FGF8, FGF17, FGFR1, FLRT3, GNRH1, HS6ST1, IL17RD, KISS1R, NSMF, PROK2, PROKR2, SEMA3A, SEMA7A, SOX10, SPRY4, TAC3, TACR3, WDR11*
Special Instructions This assay currently is **not** available in New York state.
Expected Turnaround Time 28 days
Specimen Whole blood, oral swab, extracted DNA
Volume 4 mL, 1 swab, **or** 200 ng of DNA
Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA
Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial
Collection Draw blood into EDTA tube; collect swab specimen per guidelines in kit; transfer extracted DNA into sterile screw-capped tube.
Stability
- **Room temperature:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Refrigerated:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Frozen:** Blood: Do **not** freeze; Swab: 60 days; DNA: Indefinitely

Causes for Rejection Frozen blood EDTA tube; insufficient swab cell collection or incorrect oral swab device use; extracted DNA A260:A280 ratio outside of 1.8-2.0 range
Use Diagnostic testing
Limitations The assay will not consistently detect germline mosaicism below 50% or rule out the presence of large chromosomal aberrations, including rearrangements, inversions that do not change copy number of genomic regions. The assay does not detect repeat expansions. Possible intergenic variant interactions are not commented on. False positive or false negative results may occur for reasons that include: insufficient information available about rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples, or erroneous representation of family relationships. Variants that do not alter an amino acid composition of a protein may be difficult to assess for pathogenicity since they may produce abnormalities in structures **not** assessed by conventional analysis paradigms (eg mRNA expression and processing).[1] For mitochondrial DNA variants, low levels of heteroplasmy (<1%) may not be reliably detected by this technique. Mitochondrial variants may be tissue-specific. Interpretation of the clinical significance of gene variations is limited by information about the variant that is available at the time of reporting, and by the quality and quantity of clinical information provided with the sample. As the understanding of human genetic diversity improves, the interpretation of the clinical significance of variants may change.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Methodology

Nuclear Gene Single Nucleotide Polymorphism and Small Indel Sequencing Assessment: Genomic regions of interest are selected using a custom capture reagent for target enrichment (Twist Bioscience) and sequenced via the Illumina® Novaseq 6000 next generation sequencing platform. Sequencing reads are aligned with the human genome reference GRCh37/hg19 build. Regions of interest include all exons and intron/exon junctions (+/-10 nucleotides) for each gene analyzed. A minimum of 99% of bases in targeted regions are covered at >30X. Analytical sensitivity is estimated to be >99% for single nucleotide variants, >97% for insertions/deletions less than six base pairs, and >95% for insertions/deletions between six and fifteen base pairs. Uncovered regions with known pathogenic variants are sequenced in a targeted manner (list based on ClinVar Database: July 22, 2019 release).

Nuclear Gene Copy Number Variant Assessment: Next Generation Sequencing data used to call SNPs and small indels are assessed with Illumina's DRAGEN (Dynamic Read Analysis for GENomics) Bio-IT Platform. Genes listed in ClinVar with intragenic pathogenic deletions are padded with additional

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intronic probes to allow single exon resolution CNV detection (list based on ClinVar Deletion Database: January 2019 release). For other genes, large deletions (>10 exons) can be detected. The resolution of this analysis can vary depending on region-specific features. Analytical sensitivity is estimated to be >95%.

Results Interpretation: Results should be used in the context of available clinical information and should not be used as the sole basis for patient management or treatment. Genetic counseling is recommended. Variants are assessed according to ACMG criteria.[2] This report contains interpretation of pathogenic and likely pathogenic variants (by ACMG criteria) as well as variants of uncertain significance (VUS) with pathogenic predictions related to the clinical information provided. Variants not reported: (1) Variants classified as benign or likely benign by ACMG Criteria; (2) VUS with benign or likely benign predictions; (3) variants related to carrier status; (4) polymorphisms with implications in drug response (pharmacogenomics variants). We will reanalyze the data periodically at the clinician's request to allow potential reinterpretation based on new research or evidence. GnomAD abbreviations for population frequency data: African/African American (AFR), Latino (AMR), Ashkenazi Jewish (ASJ), East Asian (EAS), Finnish (FIN), Non-Finnish European (NFE), South Asian (SAS), Other (OTH).

Footnotes

1. Nackley AG, Shabalina SA, Tchivileva IE, et al. Human catechol-O-methyltransferase haplotypes modulate protein expression by altering mRNA secondary structure. Science. 2006 Dec 22;314(5807):1930-1933. PubMed 17185601

2. Richards S, Nazneen A, Bale S, et al. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Genet Med. 2015 May;17(5):405-424. PubMed 25741868

Lipid Panel With Apolipoprotein B (ApoB) 123544

CPT 80061; 82172
Test Includes Cholesterol, total; Apolipoprotein B (ApoB); high-density lipoprotein (HDL) cholesterol; low-density lipoprotein (LDL) cholesterol (calculation); non-high-density lipoprotein (non-HDL) cholesterol (calculation = total cholesterol minus HDLC); triglycerides
Expected Turnaround Time 1 - 3 days
Specimen Serum or plasma
Volume 1 mL
Minimum Volume 0.5 mL (**Note:** This volume does **not** allow for repeat testing.)
Container Spun NMR LipoTube (preferred); serum from a plain red-top tube, plasma from a lavender-top (EDTA-no gel), or green-top (heparin-no gel) tube is acceptable.
Collection Collect specimen in NMR LipoTube (black-and-yellow-top tube), which is the preferred container. Plain red-top, green-top (heparin-no gel), or lavender-top (EDTA-no gel) tubes are also acceptable. Serum or plasma drawn in gel-barrier collection tubes other than the NMR LipoTube should not be used.

The NMR LipoTube is the only acceptable gel-barrier tube. Gently invert tube 8 to 10 times to mix contents and allow specimen to clot for 30 minutes upright at room temperature prior to centrifugation (Plasma tubes should not clot). Centrifuge specimen within two hours of collection at 1800 to 2200xg for 10 to 15 minutes to separate serum/plasma from the red cells and to avoid red cell contamination during shipment.

Note: All specimens should be centrifuged by the client, prior to shipment to Labcorp, to ensure sample integrity. Immediately after centrifugation, pipette separated red-top serum or green-top/lavender-top plasma into a transport tube and label accordingly (serum, heparin plasma, EDTA plasma).
Storage Instructions Refrigerate.
Stability

Temperature	Period
Room temperature	LipoTube Serum: 7 days; Plain Serum: 5 days; EDTA Plasma: 7 days; Sodium Heparin Plasma: 6 days
Refrigerated	All tubes: 14 days
Frozen	All tubes: 14 days (**Note:** Triglyceride values in frozen samples with high values >400 mg/dL may be decreased more than 10% when frozen.)
Freeze/thaw cycles	ApoB serum tubes: Stable x4; NMR LipoTubes: Stable x1; All other tubes: Stable x5

Patient Preparation Patient fasting is not required; however, in conditions where triglyceride values provide a priori diagnostic information, such as screening for familial hypercholesterolemia or early onset heart disease, pancreatitis, or confirming hypertriglyceridemia, the patient should be counseled to fast 12 to 14 hours prior to blood draw.
Causes for Rejection Unspun specimens; plasma/serum contaminated with red cells; citrated plasma (light blue-top tube); gross hemolysis; specimen received in gel-barrier collection tube other than the LipoTube
Use This "Extended Lipid Panel" quantifies the components of a typical lipid panel (TC, HDL-C and TG) along with ApoB by nuclear magnetic resonance (NMR) spectroscopy using the Vantera NMR Clinical Analyzer. Results from the Extended Lipid Panel Assay can be used by physicians to assist in CVD risk assessment. The principal protein component of LDL particles, ApoB, has been shown to be associated with CVD and is also an important CVD risk factor.
Limitations If triglyceride level is >800 mg/dL, LDL cholesterol will not be calculated.
Methodology Nuclear magnetic resonance (NMR)

Lipid Panel With Apolipoprotein B (ApoB), GlycA (Inflammation), Diabetes Risk Index (DRI) 123567

CPT 80061; 81599; 82172; 0024U
Test Includes Cholesterol, total; Apolipoprotein B (ApoB); DRI; GlycA; high-density lipoprotein (HDL) cholesterol; low-density lipoprotein (LDL) cholesterol (calculation); non-high-density lipoprotein (non-HDL) cholesterol (calculation = total cholesterol minus HDLC); triglycerides
Special Instructions Not approved for NY state clients.
Expected Turnaround Time 1 - 3 days
Specimen Serum, shipped refrigerated or plasma
Volume 1 mL
Minimum Volume 0.5 mL (**Note:** This volume does **not** allow for repeat testing.)
Container Plain red-top tube (preferred); NMR LipoTube (black-and- yellow-top tube), lavender-top (EDTA-no gel) tube, or green-top (heparin-no gel) tube is acceptable.
Collection Collect specimen in plain red-top tube (no gel), which is the preferred specimen. Hold tube upright at room temperature for 45 minutes and allow to clot. Centrifuge specimen after clotting according to manufacturer's specifications. Transfer to a transport tube for storage at (2°C to 8°C) until shipped.

For NMR LipoTube (black-and-yellow-top tube), keep upright at room

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temperature for 30 minutes and allow to clot. Centrifuge at 1800 to 2200xg for 10 to 15 minutes immediately after clotting. If the sample cannot be centrifuged immediately, it must be refrigerated at (2°C to 8°C) and centrifuged within 24 hours of collection. The NMR tube should then be stored at (2°C to 8°C) until shipped.

Separate plasma from lavender-top (EDTA-no gel) tube or green-top (heparin-no gel) tube immediately after collection and transfer to a plastic transport tube for shipment to the laboratory.

Serum or plasma drawn in gel-barrier collection tubes other than the NMR LipoTube should not be used.

Storage Instructions Refrigerate.

Stability

Temperature	Period
Room temperature	LipoTube Serum: 1 day; Plain Serum: 1 day; EDTA Plasma: 8 hours; Sodium Heparin Plasma: 8 hours
Refrigerated	LipoTube Serum: 8 days; Plain Serum: 8 days; EDTA Plasma: 8 days; Sodium Heparin Plasma: 7 days
Frozen	All tubes: 14days (**Note:** Triglyceride values in frozen samples with high values >400 mg/dL may be decreased more than 10% when frozen.)

Patient Preparation Patient fasting is not required; however, in conditions where triglyceride values provide a priori diagnostic information, such as screening for familial hypercholesterolemia or early onset heart disease, pancreatitis, or confirming hypertriglyceridemia, the patient should be counseled to fast 12 to 14 hours prior to blood draw.

Causes for Rejection Unspun LipoTube or unseparated plain red-top or EDTA tube; serum or plasma specimen drawn in gel-barrier collection tube other than the NMR LipoTube; citrated plasma (light blue-top tube); hemolysis (may reduce GlycA concentrations more than 10%)

Use This "Extended Lipid Panel" quantifies the components of a typical lipid panel (TC, HDL-C and TG) along with ApoB by nuclear magnetic resonance (NMR) spectroscopy using the Vantera NMR Clinical Analyzer. Results from the Extended Lipid Panel Assay can be used by physicians to assist in CVD risk assessment. The principal protein component of LDL particles, ApoB, has been shown to be associated with CVD and is also an important CVD risk factor.

GlycA is hypothesized to be a nonspecific measure of global inflammation status. Unlike existing biomarkers of inflammation that are discrete molecular species, such as CRP or inflammatory cytokines, GlycA is a composite biomarker that integrates the protein levels and glycosylation states of several of the most abundant acute- phase proteins in serum. This allows for a more stable measure of systemic inflammation with lower intra-individual variability of GlycA than hsCRP. While guidelines recommend two serial measurements be taken at least two weeks apart when using hsCRP for CV disease risk assessment, only one measurement is necessary for evaluation of a patient's CV risk using the GlycA test.

The Diabetes Risk Index (DRI) is intended for use in adult subjects for the quantitative determination of a risk score in serum or plasma. The DRI score (1-100) may be used as an aid in stratifying the risk of developing type 2 diabetes in individuals with normo-glycemia or prediabetes. The Diabetes Risk Index (DRI) is a nuclear magnetic resonance spectroscopy (NMR)-derived multimarker score (values 1-100) that predicts a patient's risk of developing type 2 diabetes mellitus (T2D) independent of glycemic status. DRI derives its performance from the weighted addition of the Lipoprotein Insulin Resistance Index (LP-IR) scores with simultaneously-measured levels of branched-chain amino acids (BCAA).[1-6]

Limitations If triglyceride level is >800 mg/dL, LDL cholesterol will not be calculated.

GlycA measurements from EDTA plasma specimens are, on average, 3% to 5% lower than from serum samples. GlycA measurements from NMR LipoTube specimens are, on average, 5% to 6% higher than from serum samples collected in red-top tubes. DRI measurements from plasma specimens are on average 8 points lower than from serum specimens.

GlycA is an indicator for a wide range of disease processes and should not be interpreted without a complete clinical history. Recent medical events resulting in tissue injury, infections, or inflammation, which may cause elevated GlycA levels, should also be considered when interpreting results. Hemolysis may reduce GlycA concentrations more than 10%.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Methodology Nuclear magnetic resonance (NMR)

Footnotes

1. Shalaurova I, Connelly MA, Garvey WT, Otvos JD. Lipoprotein insulin resistance index: a lipoprotein particle-derived measure of insulin resistance. *Metab Syndr Relat Disord.* 2014 Oct; 12(8):422-429. PubMed 24959989

2. Mackey RH, Mora S, Bertoni AG, et al. Lipoprotein particles and incident type 2 diabetes in the multi-ethnic study of atherosclerosis. *Diabetes Care.* 2015 Apr; 38(4):628-636. PubMed 25592196

3. Harada PHN, Demler OV, Dugani SB, et al. Lipoprotein insulin resistance score and risk of incident diabetes during extended follow-up of 20 years: The Women's Health Study. *J Clin Lipidol.* 2017 Sep-Oct;11(5):1257-1267.e2. PubMed 28733174

4. Flores-Guerrero JL, Connelly MA, Shalaurova I, et al. Lipoprotein insulin resistance index, a high-throughput measure of insulin resistance, is associated with incident type II diabetes mellitus in the Prevention of Renal and Vascular End-Stage Disease study. *J Clin Lipidol.* 2019 Jan-Feb;13(1):129-137.e1. PubMed 30591414

5. Wolak-Dinsmore J, Gruppen EG, Shalaurova I, et al. A novel NMR-based assay to measure circulating concentrations of branched-chain amino acids: Elevation in subjects with type 2 diabetes mellitus and association with carotid intima media thickness. *Clin Biochem.* 2018 Apr;54:92-99. PubMed 29432757

6. Flores-Guerrero JL, Oste MCJ, Kieneker LM, et al. Plasma Branched-Chain Amino Acids and Risk of Incident Type 2 Diabetes: Results from the PREVEND Prospective Cohort Study. *J Clin Med.* 2018 Dec 4;7(12):513. PubMed 30518023

Lipid Panel With Diabetes Risk Index (DRI) 123525

CPT 80061; 81599

Test Includes Cholesterol, total; DRI; high-density lipoprotein (HDL) cholesterol; low-density lipoprotein (LDL) cholesterol (calculation); non-high-density lipoprotein (non-HDL) cholesterol (calculation = total cholesterol minus HDLC); triglycerides

Special Instructions Not approved for NY state clients.

Expected Turnaround Time 1 - 3 days

Specimen Serum, shipped refrigerated or plasma

Volume 1 mL

Minimum Volume 0.5 mL (**Note:** This volume does **not** allow for repeat testing.)

Container Plain red-top tube (preferred); NMR LipoTube (black-and- yellow-top tube), lavender-top (EDTA-no gel) tube, or green-top (heparin-no gel) tube is acceptable.

Collection Collect specimen in plain red-top tube (no gel), which is the preferred specimen. Hold tube upright at room temperature for 45 minutes and allow to clot. Centrifuge specimen after clotting according to manufacturer's specifications. Transfer to a transport tube for storage at (2°C to 8°C) until shipped.

For NMR LipoTube (black-and-yellow-top tube), keep upright at room temperature for 30 minutes and allow to clot. Centrifuge at 1800 to 2200xg for 10 to 15 minutes immediately after clotting. If the sample cannot be centrifuged immediately, it must be refrigerated at (2°C to 8°C) and centrifuged within 24 hours of collection. The NMR tube should then be stored at (2°C to 8°C) until shipped.

Separate plasma from lavender-top (EDTA-no gel) tube or green-top (heparin-no gel) tube immediately after collection and transfer to a plastic transport tube for shipment to the laboratory.

Serum or plasma drawn in gel-barrier collection tubes other than the NMR LipoTube should not be used.

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Storage Instructions Refrigerate.
Stability

Temperature	Period
Room temperature	LipoTube Serum: 1 day; Plain Serum: 1 day; EDTA Plasma: 8 hours; Sodium Heparin Plasma: 8 hours
Refrigerated	LipoTube Serum: 8 days; Plain Serum: 8 days; EDTA Plasma: 8 days; Sodium Heparin Plasma: 7 days
Frozen	All tubes: 15 days (**Note:** Triglyceride values in frozen samples with high values >400 mg/dL may be decreased more than 10% when frozen.)
Freeze/thaw cycles	LipoTube Serum: Stable x5; Plain Serum: Stable x1; EDTA Plasma: Stable x5; Sodium Heparin Plasma: Stable x2

Patient Preparation Patient fasting is not required; however, in conditions where triglyceride values provide a priori diagnostic information, such as screening for familial hypercholesterolemia or early onset heart disease, pancreatitis, or confirming hypertriglyceridemia, the patient should be counseled to fast 12 to 14 hours prior to blood draw.
Causes for Rejection Unspun LipoTube or unseparated plain red-top or EDTA tube; serum or plasma specimen drawn in gel-barrier collection tube other than the NMR LipoTube
Use The Diabetes Risk Index (DRI) is intended for use in adult subjects for the quantitative determination of a risk score in serum or plasma. The DRI score (1-100) may be used as an aid in stratifying the risk of developing type 2 diabetes in individuals with normo-glycemia or prediabetes. The Diabetes Risk Index (DRI) is a nuclear magnetic resonance spectroscopy (NMR)-derived multimarker score (values 1-100) that predicts a patient's risk of developing type 2 diabetes mellitus (T2D) independent of glycemic status. DRI derives its performance from the weighted addition of the Lipoprotein Insulin Resistance Index (LP-IR) scores with simultaneously-measured levels of branched-chain amino acids (BCAA).[1-6]

For clinical use, DRI can be divided into three groups, corresponding to a low, intermediate, and high risk of developing T2D, with cutpoints corresponding closely to the 40th and 80th percentile values in the Multi-Ethnic Study of Atherosclerosis (MESA) reference population, using gender-specific cutpoints. Therefore, the low DRI category would include men and women with DRI scores less than 50 and 40, respectively. The intermediate DRI category would include men with DRI 50-65 and women with DRI 40-55. The high DRI group would consist of men and women with DRI >65 and >55, respectively.
Limitations If triglyceride level is >800 mg/dL, LDL cholesterol will not be calculated.

DRI measurements from plasma specimens are on average 8 points lower than from serum specimens.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.
Methodology Nuclear magnetic resonance (NMR)
Additional Information LP-IR is a marker of insulin resistance, and as such the LP-IR score predicts a patient's likelihood of future development of T2D.1-4 LP-IR is a multimarker index (values 0-100) based on the concentrations of particular lipoprotein subclasses [very large and large triglyceride-rich lipoprotein particles (VLL-TRLP), small low density lipoprotein particles (S-LDLP), large high density lipoprotein particles (L-HDLP), and mean TRL, LDL, and HDL particle sizes (TRLZ, LDLZ, HDLZ)]. The medical decision limits established for LPIR are <50 (low), 50-80 (intermediate), and >80 (high) with these cutpoints corresponding to the 25th and 75th percentiles in a normal population. DRI builds on the effective insulin resistance assessment by LP-IR and adds the measurement of BCAA. Similar to LP-IR, BCAA have also been shown to predict incident T2DM.5,6 The analytes contributing to DRI are measured by mathematical deconvolution of the methyl signal region of the plasma/serum NMR spectrum. This algorithm is different from the NMR LipoProfile test in that the methyl region is extended downfield to include signals from the BCAA (valine and leucine).
Footnotes

1. Shalaurova I, Connelly MA, Garvey WT, Otvos JD. Lipoprotein insulin resistance index: a lipoprotein particle-derived measure of insulin resistance. *Metab Syndr Relat Disord.* 2014 Oct; 12(8):422-429. PubMed 24959989

2. Mackey RH, Mora S, Bertoni AG, et al. Lipoprotein particles and incident type 2 diabetes in the multi-ethnic study of atherosclerosis. *Diabetes Care.* 2015 Apr; 38(4):628-636. PubMed 25592196

3. Harada PHN, Demler OV, Dugani SB, et al. Lipoprotein insulin resistance score and risk of incident diabetes during extended follow-up of 20 years: The Women's Health Study. *J Clin Lipidol.* 2017 Sep-Oct;11(5):1257-1267.e2. PubMed 28733174

4. Flores-Guerrero JL, Connelly MA, Shalaurova I, et al. Lipoprotein insulin resistance index, a high-throughput measure of insulin resistance, is associated with incident type II diabetes mellitus in the Prevention of Renal and Vascular End-Stage Disease study. *J Clin Lipidol.* 2019 Jan-Feb;13(1):129-137.e1. PubMed 30591414

5. Wolak-Dinsmore J, Gruppen EG, Shalaurova I, et al. A novel NMR-based assay to measure circulating concentrations of branched-chain amino acids: Elevation in subjects with type 2 diabetes mellitus and association with carotid intima media thickness. *Clin Biochem.* 2018 Apr;54:92-99. PubMed 29432757

6. Flores-Guerrero JL, Oste MCJ, Kieneker LM, et al. Plasma Branched-Chain Amino Acids and Risk of Incident Type 2 Diabetes: Results from the PREVEND Prospective Cohort Study. *J Clin Med.* 2018 Dec 4;7(12):513. PubMed 30518023

Lipid Panel With GlycA (Inflammation) 123510

CPT 80061; 0024U
Test Includes Cholesterol, total; GlycA; high-density lipoprotein (HDL) cholesterol; low-density lipoprotein (LDL) cholesterol (calculation); non-high-density lipoprotein (non-HDL) cholesterol (calculation = total cholesterol minus HDLC); triglycerides
Expected Turnaround Time 1 - 3 days
Specimen Serum, shipped refrigerated or plasma
Volume 1 mL
Minimum Volume 0.5 mL (**Note:** This volume does **not** allow for repeat testing.)
Container Plain red-top tube (preferred); NMR LipoTube (black-and- yellow-top tube), lavender-top (EDTA-no gel) tube, or green-top (heparin-no gel) tube is acceptable.
Collection Collect specimen in plain red-top tube (no gel), which is the preferred specimen. Hold tube upright at room temperature for 45 minutes and allow to clot. Centrifuge specimen after clotting according to manufacturer's specifications. Transfer to a transport tube for storage at (2°C to 8°C) until shipped.

For NMR LipoTube (black-and-yellow-top tube), keep upright at room temperature for 30 minutes and allow to clot. Centrifuge at 1800 to 2200xg for 10 to 15 minutes immediately after clotting. If the sample cannot be centrifuged immediately, it must be refrigerated at (2°C to 8°C) and centrifuged within 24 hours of collection. The NMR tube should then be stored at (2°C to 8°C) until shipped.

Separate plasma from lavender-top (EDTA-no gel) tube or green-top (heparin-no gel) tube immediately after collection and transfer to a plastic transport tube for shipment to the laboratory.

Serum or plasma drawn in gel-barrier collection tubes other than the NMR LipoTube should not be used.
Storage Instructions Refrigerate.
Stability

Temperature	Period
Room temperature	60 hours
Refrigerated	14 days
Frozen	14 days (**Note:** Triglyceride values in frozen samples with high values >400 mg/dL may be decreased more than 10% when frozen.)
Freeze/thaw cycles	Stable x3

Patient Preparation Patient fasting is not required; however, in conditions where triglyceride values provide a priori diagnostic information, such as screening for familial hypercholesterolemia or early onset heart disease, pancreatitis, or confirming hypertriglyceridemia, the patient should be counseled to fast 12 to 14 hours prior to blood draw.
Causes for Rejection Unspun LipoTube or unseparated plain red-top or EDTA tube; serum or plasma specimen drawn in gel-barrier collection tube other than the NMR LipoTube; hemolysis (may reduce GlycA concentrations more than 10%)
Use As an (1) aid in the identification and stratification of individuals at risk

New Tests

for future cardiovascular (CV) disease, (2) independent marker of prognosis for recurrent cardiovascular events in patients with stable coronary disease or acute coronary syndrome, (3) aid in the assessment of disease activity and risk of CV disease in adult Rheumatoid Arthritis (RA) and psoriasis patients, when used in conjunction with standard clinical assessment and for monitoring of anti-inflammatory treatment.

Limitations If triglyceride level is >800 mg/dL, LDL cholesterol will not be calculated.

GlycA measurements from EDTA plasma specimens are, on average, 3% to 5% lower than from serum samples. GlycA measurements from NMR LipoTube specimens are, on average, 5% to 6% higher than from serum samples collected in red-top tubes.

GlycA is an indicator for a wide range of disease processes and should not be interpreted without a complete clinical history. Recent medical events resulting in tissue injury, infections, or inflammation, which may cause elevated GlycA levels, should also be considered when interpreting results. Hemolysis may reduce GlycA concentrations more than 10%.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Methodology Nuclear magnetic resonance (NMR)

Additional Information The GlycA test quantifies an NMR signal that appears in a region of the NMR LipoProfile® test spectrum separate from that used for lipoprotein particle analysis. Data indicate that this signal is a marker of systemic inflammation, suggesting it may have clinical utility similar or complementary to high sensitivity C-reactive protein(hsCRP), fibrinogen, and other biomarkers of inflammation.[1,2] The NMR signal, named "GlycA," originates from the N-acetyl methyl groups of the N-acetylglucosamine moieties on the carbohydrate portions of circulating glycoproteins.[1,3] The measured amplitude of this signal reflects the extent of plasma protein glycosylation (not to be confused with nonenzymatic glycation reflecting glucose levels). Most acute phase proteins, released from the liver during an inflammatory response, are glycosylated, and some are glycosylated differentially as a function of inflammation. Acute-phase proteins, such as alpha-1-acid glycoprotein (also known as orosomucoid), haptoglobin, alpha-1- antitrypsin, alpha-1-antichymotrypsin, and transferrin circulate at high enough concentrations to make major contributions to the GlycA signal.[1] Therefore, GlycA is hypothesized to be a nonspecific measure of global inflammation status. Unlike existing biomarkers of inflammation that are discrete molecular species, such as CRP or inflammatory cytokines, GlycA is a composite biomarker that integrates the protein levels and glycosylation states of several of the most abundant acute-phase proteins in serum. This allows for a more stable measure of systemic inflammation with lower intra-individual variability of GlycA than hsCRP.[1] While guidelines recommend two serial measurements be taken at least two weeks apart when using hsCRP for CV disease risk assessment, only one measurement is necessary for evaluation of a patient's CV risk using the GlycA test.

Footnotes

1. Otvos JD, Shalaurova I, Wolak-Dinsmore J, et al. GlycA: A Novel Nuclear Magnetic Resonance Biomarker of Systemic Inflammation. *Clin Chem.* 2015 May;61(5):714-723. PubMed 25779987

2. Akinkuolie AO, Buring JE, Ridker PM, Mora S. A novel protein glycan biomarker and future cardiovascular disease events. *J Am Heart Assoc.* 2014 Sep 23;3(5):e001221. PubMed 25249300

3. Bell JD, Sadler PJ, Macleod AF, Turner PR, La Ville A. 1H NMR studies of human blood plasma. Assignment of resonances for lipoproteins. *FEBS Lett.* 1987 Jul 13;219(1):239-243. PubMed 3595877

References

Akinkuolie AO, Glynn RJ, Ridker PM, Mora S. Protein glycan side-chains, rosuvastatin therapy, and incident vascular events; An analysis from the JUPITER trial. *Circulation.* 2014;130:A17731. doi:10.1161/circ.130.suppl_2.17731

Bell JD, Brown JC, Nicholson JK, Sadler PJ. Assignment of resonances for 'acute phase' glycoproteins in high resolution proton NMR spectra of human blood plasma. *FEBS Lett.* 1987 May 11;215(2):311-315. PubMed 2438159

Chung CP, Ormseth MJ, Connelly MA, et al. GlycA, a novel marker of inflammation, is elevated in systemic lupus erythematosus. *Lupus.* 2016 Mar;25(3):296-300. PubMed 26637290

Dungan K, Binkley P, Osei K. GlycA is a novel marker of inflammation among non-critically ill hospitalized patients with type 2 diabetes. *Inflammation.* 2015;38(3):1357-1363. PubMed 25586483

Lauridsen MB, Bliddal H, Christensen R, et al. 1H NMR spectroscopy-based interventional metabolic phenotyping: a cohort study of rheumatoid arthritis patients. *J Proteome Res.* 2010 Sep 3;9(9):4545-4553. PubMed 20701312

Lawler P, Akinkuolie AO, Buring JE, Ridker P, Glynn R, Mora S. A novel biomarker of circulating glycoproteins and cardiovascular and all-cause mortality among 39,521 initially healthy adults. *J Am Coll Cardiol.* 2015;65(10):A1358.10.1016/S0735-1097(15)61358-4

McGarrah R, Craig D, Haynes C, Dowdy ZE, Shah S, Kraus W. High-density lipoprotein subclass measurements improve mortality risk prediction, discrimination and reclassification in a cardiac catheterization cohort. *Artherosclerosis.* 2016 Mar;246:229-235. PubMed 26803432

Ormseth MJ, Chung CP, Oeser AM, et al. Utility of a novel inflammatory marker, GlycA, for assessment of rheumatoid arthritis disease activity and coronary atherosclerosis. *Arthritis Res Ther.* 2015 May 9;17:117. PubMed 25956924

Lipid Panel With GlycA (Inflammation) and Diabetes Risk Index (DRI) 123559

CPT 80061; 81599; 0024U

Test Includes Cholesterol, total; DRI; GlycA; high-density lipoprotein (HDL) cholesterol; low-density lipoprotein (LDL) cholesterol (calculation); non-high-density lipoprotein (non-HDL) cholesterol (calculation = total cholesterol minus HDLC); triglycerides

Special Instructions Not approved for NY state clients.

Expected Turnaround Time 1 - 3 days

Specimen Serum, shipped refrigerated or plasma

Volume 1 mL

Minimum Volume 0.5 mL (**Note:** This volume does **not** allow for repeat testing.)

Container Plain red-top tube (preferred); NMR LipoTube (black-and- yellow-top tube), lavender-top (EDTA-no gel) tube, or green-top (heparin-no gel) tube is acceptable.

Collection Collect specimen in plain red-top tube (no gel), which is the preferred specimen. Hold tube upright at room temperature for 45 minutes and allow to clot. Centrifuge specimen after clotting according to manufacturer's specifications. Transfer to a transport tube for storage at (2°C to 8°C) until shipped.

For NMR LipoTube (black-and-yellow-top tube), keep upright at room temperature for 30 minutes and allow to clot. Centrifuge at 1800 to 2200xg for 10 to 15 minutes immediately after clotting. If the sample cannot be centrifuged immediately, it must be refrigerated at (2°C to 8°C) and centrifuged within 24 hours of collection. The NMR tube should then be stored at (2°C to 8°C) until shipped.

Separate plasma from lavender-top (EDTA-no gel) tube or green-top (heparin-no gel) tube immediately after collection and transfer to a plastic transport tube for shipment to the laboratory.

Serum or plasma drawn in gel-barrier collection tubes other than the NMR LipoTube should not be used.

Storage Instructions Refrigerate.

Stability

Temperature	Period
Room temperature	LipoTube Serum: 1 day; Plain Serum: 1 day; EDTA Plasma: 8 hours; Sodium Heparin Plasma: 8 hours
Refrigerated	LipoTube Serum: 8 days; Plain Serum: 8 days; EDTA Plasma: 8 days; Sodium Heparin Plasma: 7 days
Frozen	All tubes: 14days (**Note:** Triglyceride values in frozen samples with high values >400 mg/dL may be decreased more than 10% when frozen.)

Patient Preparation Patient fasting is not required; however, in conditions where triglyceride values provide a priori diagnostic information, such as screening for familial hypercholesterolemia or early onset heart disease, pancreatitis, or confirming hypertriglyceridemia, the patient should be counseled to fast 12 to 14 hours prior to blood draw.

Causes for Rejection Unspun LipoTube or unseparated plain red-top or EDTA

New Tests

tube; serum or plasma specimen drawn in gel-barrier collection tube other than the NMR LipoTube; hemolysis (may reduce GlycA concentrations more than 10%)

Use GlycA is hypothesized to be a nonspecific measure of global inflammation status. Unlike existing biomarkers of inflammation that are discrete molecular species, such as CRP or inflammatory cytokines, GlycA is a composite biomarker that integrates the protein levels and glycosylation states of several of the most abundant acute- phase proteins in serum. This allows for a more stable measure of systemic inflammation with lower intra-individual variability of GlycA than hsCRP. While guidelines recommend two serial measurements be taken at least two weeks apart when using hsCRP for CV disease risk assessment, only one measurement is necessary for evaluation of a patient's CV risk using the GlycA test.

The Diabetes Risk Index (DRI) is intended for use in adult subjects for the quantitative determination of a risk score in serum or plasma. The DRI score (1-100) may be used as an aid in stratifying the risk of developing type 2 diabetes in individuals with normo-glycemia or prediabetes. The Diabetes Risk Index (DRI) is a nuclear magnetic resonance spectroscopy (NMR)-derived multimarker score (values 1-100) that predicts a patient's risk of developing type 2 diabetes mellitus (T2D) independent of glycemic status. DRI derives its performance from the weighted addition of the Lipoprotein Insulin Resistance Index (LP-IR) scores with simultaneously-measured levels of branched-chain amino acids (BCAA).[1-6]

Limitations If triglyceride level is >800 mg/dL, LDL cholesterol will not be calculated.

GlycA measurements from EDTA plasma specimens are, on average, 3% to 5% lower than from serum samples. GlycA measurements from NMR LipoTube specimens are, on average, 5% to 6% higher than from serum samples collected in red-top tubes. DRI measurements from plasma specimens are on average 8 points lower than from serum specimens.

GlycA is an indicator for a wide range of disease processes and should not be interpreted without a complete clinical history. Recent medical events resulting in tissue injury, infections, or inflammation, which may cause elevated GlycA levels, should also be considered when interpreting results. Hemolysis may reduce GlycA concentrations more than 10%. DRI measurements from plasma specimens are on average 8 points lower than from serum specimens.

DRI measurements from plasma specimens are on average 8 points lower than from serum specimens.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Methodology Nuclear magnetic resonance (NMR)

Footnotes

1. Shalaurova I, Connelly MA, Garvey WT, Otvos JD. Lipoprotein insulin resistance index: a lipoprotein particle-derived measure of insulin resistance. *Metab Syndr Relat Disord.* 2014 Oct; 12(8):422-429. PubMed 24959989

2. Mackey RH, Mora S, Bertoni AG, et al. Lipoprotein particles and incident type 2 diabetes in the multi-ethnic study of atherosclerosis. *Diabetes Care.* 2015 Apr; 38(4):628-636. PubMed 25592196

3. Harada PHN, Demler OV, Dugani SB, et al. Lipoprotein insulin resistance score and risk of incident diabetes during extended follow-up of 20 years: The Women's Health Study. *J Clin Lipidol.* 2017 Sep-Oct;11(5):1257-1267.e2. PubMed 28733174

4. Flores-Guerrero JL, Connelly MA, Shalaurova I, et al. Lipoprotein insulin resistance index, a high-throughput measure of insulin resistance, is associated with incident type II diabetes mellitus in the Prevention of Renal and Vascular End-Stage Disease study. *J Clin Lipidol.* 2019 Jan-Feb;13(1):129-137.e1. PubMed 30591414

5. Wolak-Dinsmore J, Gruppen EG, Shalaurova I, et al. A novel NMR-based assay to measure circulating concentrations of branched-chain amino acids: Elevation in subjects with type 2 diabetes mellitus and association with carotid intima media thickness. *Clin Biochem.* 2018 Apr;54:92-99. PubMed 29432757

6. Flores-Guerrero JL, Oste MCJ, Kieneker LM, et al. Plasma Branched-Chain Amino Acids and Risk of Incident Type 2 Diabetes: Results from the PREVEND Prospective Cohort Study. *J Clin Med.* 2018 Dec 4;7(12):513. PubMed 30518023

Maturity-Onset Diabetes of the Young (MODY) Expanded Genetic Panel 630513

CPT 81403; 81404(x3); 81405(x2); 81406(x2); 81407; 81479

Synonyms MODY

Test Includes *ABCC8, APPL1, BLK, CEL, GCK, HNF1A, HNF1B, HNF4A, INS, KCNJ11, KLF11, NEUROD1, PAX4, PDX1*

Special Instructions This assay currently is **not** available in New York state.

Expected Turnaround Time 28 days

Specimen Whole blood, oral swab, extracted DNA

Volume 4 mL, 1 swab, **or** 200 ng of DNA

Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA

Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial

Collection Draw blood into EDTA tube; collect swab specimen per guidelines in kit; transfer extracted DNA into sterile screw-capped tube.

Stability

- **Room temperature:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Refrigerated:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Frozen:** Blood: Do **not** freeze; Swab: 60 days; DNA: Indefinitely

Causes for Rejection Frozen blood EDTA tube; insufficient swab cell collection or incorrect oral swab device use; extracted DNA A260:A280 ratio outside of 1.8-2.0 range

Use Diagnostic testing

Limitations The assay will not consistently detect germline mosaicism below 50% or rule out the presence of large chromosomal aberrations, including rearrangements, inversions that do not change copy number of genomic regions. The assay does not detect repeat expansions. Possible intergenic variant interactions are not commented on. False positive or false negative results may occur for reasons that include: insufficient information available about rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples, or erroneous representation of family relationships. Variants that do not alter an amino acid composition of a protein may be difficult to assess for pathogenicity since they may produce abnormalities in structures **not** assessed by conventional analysis paradigms (eg mRNA expression and processing).[1] For mitochondrial DNA variants, low levels of heteroplasmy (<1%) may not be reliably detected by this technique. Mitochondrial variants may be tissue-specific. Interpretation of the clinical significance of gene variations is limited by information about the variant that is available at the time of reporting, and by the quality and quantity of clinical information provided with the sample. As the understanding of human genetic diversity improves, the interpretation of the clinical significance of variants may change.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Methodology

Nuclear Gene Single Nucleotide Polymorphism and Small Indel Sequencing Assessment: Genomic regions of interest are selected using a custom capture reagent for target enrichment (Twist Bioscience) and sequenced via the Illumina® Novaseq 6000 next generation sequencing platform. Sequencing reads are aligned with the human genome reference GRCh37/hg19 build. Regions of interest include all exons and intron/exon junctions (+/-10 nucleotides) for each gene analyzed. A minimum of 99% of bases in targeted regions are covered at >30X. Analytical sensitivity is estimated to be >99% for single nucleotide variants, >97% for insertions/deletions less than six base pairs, and >95% for insertions/deletions between six and fifteen base pairs. Uncovered regions with known pathogenic variants are sequenced in a targeted manner (list based on ClinVar Database: July 22, 2019 release).

New Tests

Nuclear Gene Copy Number Variant Assessment: Next Generation Sequencing data used to call SNPs and small indels are assessed with Illumina's DRAGEN (Dynamic Read Analysis for GENomics) Bio-IT Platform. Genes listed in ClinVar with intragenic pathogenic deletions are padded with additional intronic probes to allow single exon resolution CNV detection (list based on ClinVar Deletion Database: January 2019 release). For other genes, large deletions (>10 exons) can be detected. The resolution of this analysis can vary depending on region-specific features. Analytical sensitivity is estimated to be >95%.

Results Interpretation: Results should be used in the context of available clinical information and should not be used as the sole basis for patient management or treatment. Genetic counseling is recommended. Variants are assessed according to ACMG criteria.[2] This report contains interpretation of pathogenic and likely pathogenic variants (by ACMG criteria) as well as variants of uncertain significance (VUS) with pathogenic predictions related to the clinical information provided. Variants not reported: (1) Variants classified as benign or likely benign by ACMG Criteria; (2) VUS with benign or likely benign predictions; (3) variants related to carrier status; (4) polymorphisms with implications in drug response (pharmacogenomics variants). We will reanalyze the data periodically at the clinician's request to allow potential reinterpretation based on new research or evidence. GnomAD abbreviations for population frequency data: African/African American (AFR), Latino (AMR), Ashkenazi Jewish (ASJ), East Asian (EAS), Finnish (FIN), Non-Finnish European (NFE), South Asian (SAS), Other (OTH).

Footnotes

1. Nackley AG, Shabalina SA, Tchivileva IE, et al. Human catechol-O-methyltransferase haplotypes modulate protein expression by altering mRNA secondary structure. Science. 2006 Dec 22;314(5807):1930-1933. PubMed 17185601

2. Richards S, Nazneen A, Bale S, et al. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Genet Med. 2015 May;17(5):405-424. PubMed 25741868

Monogenic Hypertension Genetic Panel 630258

CPT 81404; 81405; 81406(x2); 81479
Synonyms Familial Hyperaldosteronism; Gordon syndrome; Liddle syndrome; Pseudohypoaldosteronism
Test Includes *CUL3, CYP11B1, CYP11B2, HSD11B2, KCNJ5, KLHL3, NR3C2, SCNN1B, SCNN1G, WNK1, WNK4*
Special Instructions This assay currently is **not** available in New York state.
Expected Turnaround Time 28 days
Specimen Whole blood, oral swab, extracted DNA
Volume 4 mL, 1 swab, **or** 200 ng of DNA
Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA
Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial
Collection Draw blood into EDTA tube; collect swab specimen per guidelines in kit; transfer extracted DNA into sterile screw-capped tube.
Stability

- **Room temperature:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Refrigerated:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Frozen:** Blood: Do **not** freeze; Swab: 60 days; DNA: Indefinitely

Causes for Rejection Frozen blood EDTA tube; insufficient swab cell collection or incorrect oral swab device use; extracted DNA A260:A280 ratio outside of 1.8-2.0 range
Use Diagnostic testing
Limitations The assay will not consistently detect germline mosaicism below 50% or rule out the presence of large chromosomal aberrations, including rearrangements, inversions that do not change copy number of genomic regions. The assay does not detect repeat expansions. Possible intergenic variant interactions are not commented on. False positive or false negative results may occur for reasons that include: insufficient information available about rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples, or erroneous representation of family relationships. Variants that do not alter an amino acid composition of a protein may be difficult to assess for pathogenicity since they may produce abnormalities in structures **not** assessed by conventional analysis paradigms (eg mRNA expression and processing).[1] For mitochondrial DNA variants, low levels of heteroplasmy (<1%) may not be reliably detected by this technique. Mitochondrial variants may be tissue-specific. Interpretation of the clinical significance of gene variations is limited by information about the variant that is available at the time of reporting, and by the quality and quantity of clinical information provided with the sample. As the understanding of human genetic diversity improves, the interpretation of the clinical significance of variants may change.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Methodology

Nuclear Gene Single Nucleotide Polymorphism and Small Indel Sequencing Assessment: Genomic regions of interest are selected using a custom capture reagent for target enrichment (Twist Bioscience) and sequenced via the Illumina® Novaseq 6000 next generation sequencing platform. Sequencing reads are aligned with the human genome reference GRCh37/hg19 build. Regions of interest include all exons and intron/exon junctions (+/-10 nucleotides) for each gene analyzed. A minimum of 99% of bases in targeted regions are covered at >30X. Analytical sensitivity is estimated to be >99% for single nucleotide variants, >97% for insertions/deletions less than six base pairs, and >95% for insertions/deletions between six and fifteen base pairs. Uncovered regions with known pathogenic variants are sequenced in a targeted manner (list based on ClinVar Database: July 22, 2019 release).

Nuclear Gene Copy Number Variant Assessment: Next Generation Sequencing data used to call SNPs and small indels are assessed with Illumina's DRAGEN (Dynamic Read Analysis for GENomics) Bio-IT Platform. Genes listed in ClinVar with intragenic pathogenic deletions are padded with additional intronic probes to allow single exon resolution CNV detection (list based on ClinVar Deletion Database: January 2019 release). For other genes, large deletions (>10 exons) can be detected. The resolution of this analysis can vary depending on region-specific features. Analytical sensitivity is estimated to be >95%.

Results Interpretation: Results should be used in the context of available clinical information and should not be used as the sole basis for patient management or treatment. Genetic counseling is recommended. Variants are assessed according to ACMG criteria.[2] This report contains interpretation of pathogenic and likely pathogenic variants (by ACMG criteria) as well as variants of uncertain significance (VUS) with pathogenic predictions related to the clinical information provided. Variants not reported: (1) Variants classified as benign or likely benign by ACMG Criteria; (2) VUS with benign or likely benign predictions; (3) variants related to carrier status; (4) polymorphisms with implications in drug response (pharmacogenomics variants). We will reanalyze the data periodically at the clinician's request to allow potential reinterpretation based on new research or evidence. GnomAD abbreviations for population frequency data: African/African American (AFR), Latino (AMR), Ashkenazi Jewish (ASJ), East Asian (EAS), Finnish (FIN), Non-Finnish European (NFE), South Asian (SAS), Other (OTH).

Footnotes

1. Nackley AG, Shabalina SA, Tchivileva IE, et al. Human catechol-O-methyltransferase haplotypes modulate protein expression by altering mRNA secondary structure. Science. 2006 Dec 22;314(5807):1930-1933. PubMed 17185601

2. Richards S, Nazneen A, Bale S, et al. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Genet Med. 2015 May;17(5):405-424. PubMed 25741868

Osteogenesis Imperfecta Genetic Panel 630543

CPT 81406; 81408(x2); 81479
Synonyms Juvenile Primary Osteoporosis; OI
Test Includes *BMP1, COL1A1, COL1A2, CREB3L1, CRTAP, FKBP10, IFITM5, LRP5, MBTPS2, P3H1, PLOD2, PPIB, SERPINF1, SERPINH1*
Special Instructions This assay currently is **not** available in New York state.
Expected Turnaround Time 28 days

New Tests

Specimen Whole blood, oral swab, extracted DNA
Volume 4 mL, 1 swab, **or** 200 ng of DNA
Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA
Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial
Collection Draw blood into EDTA tube; collect swab specimen per guidelines in kit; transfer extracted DNA into sterile screw-capped tube.
Stability
- **Room temperature:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Refrigerated:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Frozen:** Blood: Do **not** freeze; Swab: 60 days; DNA: Indefinitely

Causes for Rejection Frozen blood EDTA tube; insufficient swab cell collection or incorrect oral swab device use; extracted DNA A260:A280 ratio outside of 1.8-2.0 range
Use Diagnostic testing
Limitations The assay will not consistently detect germline mosaicism below 50% or rule out the presence of large chromosomal aberrations, including rearrangements, inversions that do not change copy number of genomic regions. The assay does not detect repeat expansions. Possible intergenic variant interactions are not commented on. False positive or false negative results may occur for reasons that include: insufficient information available about rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples, or erroneous representation of family relationships. Variants that do not alter an amino acid composition of a protein may be difficult to assess for pathogenicity since they may produce abnormalities in structures **not** assessed by conventional analysis paradigms (eg mRNA expression and processing).[1] For mitochondrial DNA variants, low levels of heteroplasmy (<1%) may not be reliably detected by this technique. Mitochondrial variants may be tissue-specific. Interpretation of the clinical significance of gene variations is limited by information about the variant that is available at the time of reporting, and by the quality and quantity of clinical information provided with the sample. As the understanding of human genetic diversity improves, the interpretation of the clinical significance of variants may change.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.
Methodology

Nuclear Gene Single Nucleotide Polymorphism and Small Indel Sequencing Assessment: Genomic regions of interest are selected using a custom capture reagent for target enrichment (Twist Bioscience) and sequenced via the Illumina® Novaseq 6000 next generation sequencing platform. Sequencing reads are aligned with the human genome reference GRCh37/hg19 build. Regions of interest include all exons and intron/exon junctions (+/-10 nucleotides) for each gene analyzed. A minimum of 99% of bases in targeted regions are covered at >30X. Analytical sensitivity is estimated to be >99% for single nucleotide variants, >97% for insertions/deletions less than six base pairs, and >95% for insertions/deletions between six and fifteen base pairs. Uncovered regions with known pathogenic variants are sequenced in a targeted manner (list based on ClinVar Database: July 22, 2019 release).

Nuclear Gene Copy Number Variant Assessment: Next Generation Sequencing data used to call SNPs and small indels are assessed with Illumina's DRAGEN (Dynamic Read Analysis for GENomics) Bio-IT Platform. Genes listed in ClinVar with intragenic pathogenic deletions are padded with additional intronic probes to allow single exon resolution CNV detection (list based on ClinVar Deletion Database: January 2019 release). For other genes, large deletions (>10 exons) can be detected. The resolution of this analysis can vary depending on region-specific features. Analytical sensitivity is estimated to be >95%.

Results Interpretation: Results should be used in the context of available clinical information and should not be used as the sole basis for patient management or treatment. Genetic counseling is recommended. Variants are assessed according to ACMG criteria.[2] This report contains interpretation of pathogenic and likely pathogenic variants (by ACMG criteria) as well as variants of uncertain significance (VUS) with pathogenic predictions related to the clinical information provided. Variants not reported: (1) Variants classified as benign or likely benign by ACMG Criteria; (2) VUS with benign or likely benign predictions; (3) variants related to carrier status; (4) polymorphisms with implications in drug response (pharmacogenomics variants). We will reanalyze the data periodically at the clinician's request to allow potential reinterpretation based on new research or evidence. GnomAD abbreviations for population frequency data: African/African American (AFR), Latino (AMR), Ashkenazi Jewish (ASJ), East Asian (EAS), Finnish (FIN), Non-Finnish European (NFE), South Asian (SAS), Other (OTH).
Footnotes

1. Nackley AG, Shabalina SA, Tchivileva IE, et al. Human catechol-O-methyltransferase haplotypes modulate protein expression by altering mRNA secondary structure. Science. 2006 Dec 22;314(5807):1930-1933. PubMed 17185601

2. Richards S, Nazneen A, Bale S, et al. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Genet Med. 2015 May;17(5):405-424. PubMed 25741868

PHEX Gene Sequencing 630494

CPT 81406
Synonyms Familial Hypophosphatemic Rickets; Hypophosphatemic Rickets; Hypophosphatemic Vitamin D-Resistant Rickets (HPDR); Phosphate Diabetes; Vitamin D-Resistant Rickets; X-Linked Dominant Hypophosphatemic Rickets (XLHR); X-Linked Hypophosphatemia; X-Linked Hypophosphatemic Rickets; X-Linked Rickets (XLR); X-Linked Vitamin D-Resistant Rickets (VDRR); XLH
Test Includes PHEX
Special Instructions This assay currently is **not** available in New York state.
Expected Turnaround Time 28 days
Specimen Whole blood, oral swab, extracted DNA
Volume 4 mL, 1 swab, **or** 200 ng of DNA
Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA
Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial
Collection Draw blood into EDTA tube; collect swab specimen per guidelines in kit; transfer extracted DNA into sterile screw-capped tube.
Stability
- **Room temperature:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Refrigerated:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Frozen:** Blood: Do **not** freeze; Swab: 60 days; DNA: Indefinitely

Causes for Rejection Frozen blood EDTA tube; insufficient swab cell collection or incorrect oral swab device use; extracted DNA A260:A280 ratio outside of 1.8-2.0 range
Use Diagnostic testing
Limitations The assay will not consistently detect germline mosaicism below 50% or rule out the presence of large chromosomal aberrations, including rearrangements, inversions that do not change copy number of genomic regions. The assay does not detect repeat expansions. Possible intergenic variant interactions are not commented on. False positive or false negative results may occur for reasons that include: insufficient information available about rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples, or erroneous representation of family relationships. Variants that do not alter an amino acid composition of a protein may be difficult to assess for pathogenicity since they may produce abnormalities in structures **not** assessed by conventional analysis paradigms (eg mRNA expression and processing).[1] For mitochondrial DNA variants, low levels of heteroplasmy (<1%) may not be reliably detected by this technique. Mitochondrial variants may be tissue-specific. Interpretation of the clinical significance of gene variations is limited by information about the variant that is available at the time of reporting, and by the quality and quantity of clinical information provided with the sample. As the understanding of human genetic diversity improves, the interpretation of the clinical significance of variants may change.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.
Methodology

Nuclear Gene Single Nucleotide Polymorphism and Small Indel Sequencing Assessment: Genomic regions of interest are selected using

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a custom capture reagent for target enrichment (Twist Bioscience) and sequenced via the Illumina® Novaseq 6000 next generation sequencing platform. Sequencing reads are aligned with the human genome reference GRCh37/hg19 build. Regions of interest include all exons and intron/exon junctions (+/-10 nucleotides) for each gene analyzed. A minimum of 99% of bases in targeted regions are covered at >30X. Analytical sensitivity is estimated to be >99% for single nucleotide variants, >97% for insertions/deletions less than six base pairs, and >95% for insertions/deletions between six and fifteen base pairs. Uncovered regions with known pathogenic variants are sequenced in a targeted manner (list based on ClinVar Database: July 22, 2019 release).

Nuclear Gene Copy Number Variant Assessment: Next Generation Sequencing data used to call SNPs and small indels are assessed with Illumina's DRAGEN (Dynamic Read Analysis for GENomics) Bio-IT Platform. Genes listed in ClinVar with intragenic pathogenic deletions are padded with additional intronic probes to allow single exon resolution CNV detection (list based on ClinVar Deletion Database: January 2019 release). For other genes, large deletions (>10 exons) can be detected. The resolution of this analysis can vary depending on region-specific features. Analytical sensitivity is estimated to be >95%.

Results Interpretation: Results should be used in the context of available clinical information and should not be used as the sole basis for patient management or treatment. Genetic counseling is recommended. Variants are assessed according to ACMG criteria.[2] This report contains interpretation of pathogenic and likely pathogenic variants (by ACMG criteria) as well as variants of uncertain significance (VUS) with pathogenic predictions related to the clinical information provided. Variants not reported: (1) Variants classified as benign or likely benign by ACMG Criteria; (2) VUS with benign or likely benign predictions; (3) variants related to carrier status; (4) polymorphisms with implications in drug response (pharmacogenomics variants). We will reanalyze the data periodically at the clinician's request to allow potential reinterpretation based on new research or evidence. GnomAD abbreviations for population frequency data: African/African American (AFR), Latino (AMR), Ashkenazi Jewish (ASJ), East Asian (EAS), Finnish (FIN), Non-Finnish European (NFE), South Asian (SAS), Other (OTH).

Footnotes

1. Nackley AG, Shabalina SA, Tchivileva IE, et al. Human catechol-O-methyltransferase haplotypes modulate protein expression by altering mRNA secondary structure. Science. 2006 Dec 22;314(5807):1930-1933. PubMed 17185601

2. Richards S, Nazneen A, Bale S, et al. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Genet Med. 2015 May;17(5):405-424. PubMed 25741868

SARS-CoV-2 Antibody, IgM, Spike 164034

CPT 86769
Synonyms COVID-19; Severe Acute Respiratory Syndrome (SARS)
Expected Turnaround Time 3 - 5 days
Specimen Serum
Volume 0.5 mL
Minimum Volume 0.4 mL (**Note:** This volume does **not** allow for repeat testing.)
Container Gel-barrier tube or serum from red-top tube or serum transfer tube
Collection Standard aseptic procedures
Storage Instructions Room temperature
Stability

Temperature	Period
Room temperature	3 days
Refrigerated	7 days
Frozen	7 days
Freeze/thaw cycles	Stable x3

Patient Preparation No special preparation required.
Causes for Rejection Gross hemolysis; visible microbial contamination; specimen type other than serum
Use Qualitative detection of IgM antibodies to SARS-CoV-2, the virus that causes COVID-19 to help identify individuals who have been exposed to the virus. Serologic results should not be used as the sole basis to diagnosis or exclude recent SARS-CoV-2 infection. This test is recommended in individuals at least 10 days post symptom onset or following exposure to individuals with confirmed COVID-19.
Limitations This test has not been reviewed by the FDA.

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Methodology Immunoassay
Additional Information The incubation period for COVID-19 ranges from 5 to 7 days. The antibody response to SARS-CoV-2 is not typical as there does not appear to be an early IgM response. Early published literature suggests that detectable IgM-class antibodies against SARS-CoV-2 develop around the same time as IgG- and IgA-class antibodies at approximately 8 to 11 days following onset of symptoms. Correlation with epidemiologic risk factors and other clinical and laboratory findings is recommended. A positive serological result is not diagnostic but indicates that an individual has likely been infected with SARS-CoV-2 and produced an immune response to the virus. It is not known at this time whether detectable antibody corelates with immunity. A negative serologic result indicates that an individual has not developed detectable antibodies at the time of testing. While contingent on a variety of factors, this could be due to testing too early in the course of infection, the absence of exposure to the virus, or the lack of an adequate immune response, which can be due to conditions or treatments that suppress immune function.

FDA-authorized Fact sheets for patients and providers can be accessed at the following link: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

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Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff: March 2020. US Food & Drug Administration web site. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency. Accessed March 2020.

Woo PC, Lau SK, Wong BH, et al. Differential Sensitivities of Severe Acute Respiratory Syndrome (SARS) Coronavirus Spike Polypeptide Enzyme-Linked Immunosorbent Assay (ELISA) and SARS Coronavirus Nucleocapsid Protein ELISA for Serodiagnosis of SARS Coronavirus Pneumonia. *J Clin Microbiol.* 2005 Jul;43(7):3054-3058. PubMed 16000415

Yu F, Le MQ, Inoue S, et al. Recombinant truncated nucleocapsid protein as antigen in a novel immunoglobulin M capture enzyme-linked immunosorbent assay for diagnosis of severe acute respiratory syndrome coronavirus infection. *Clin Vaccine Immunol.* 2007 Feb;14(2):146-149. PubMed 17202310

SARS-CoV-2 Semi-Quantitative Total Antibody 164090

CPT 86769
Synonyms SARS-CoV-2 Antibody Titer
Expected Turnaround Time 2 - 5 days
Specimen Serum or plasma
Volume 1.5 mL
Minimum Volume 0.7 mL (**Note:** This volume does **not** allow for repeat testing.)
Container Gel-barrier tube, red-top tube, or serum transfer tube, or plasma from lithium heaprin tube, EDTA, or sodium citrate tube
Storage Instructions Room temperature

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Stability

Temperature	Period
Room temperature	14 days
Refrigerated	14 days
Frozen	14 days
Freeze/thaw cycles	Stable x3

Causes for Rejection Gross hemolysis; visible microbial contamination
Use Evaluation of SARS-CoV-2 Quantitative Total Antibody.

Serologic assays can plan an important role in understanding viral epidemiology in the general population and identifying groups at higher risk of infection. This assay uses a recombinant protein representing the RBD of the S antigen for the quantitative determination of antibodies against SARS-CoV-2. Quantification of the antibody response can help to determine the specific antibody titer and aid in longitudinal monitoring of the dynamics of the antibody response in individual patients.

Limitations The results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

A negative test result does not rule out the possibility of an infection with SARS-CoV-2. Serum or plasma samples from the very early (pre-seroconversion) phase can yield negative findings. Therefore, this test cannot be used to diagnose an acute infection. It has also been reported that certain patients with confirmed infection do not develop SARS-CoV-2 antibodies. Furthermore, waning of antibody titers has been reported in some individuals within a range of months after infection, a feature which has also been reported for other coronaviruses.

This test has not been FDA cleared or approved. This test has been authorized by FDA under an Emergency Use Authorization (EUA). This test is only authorized for the duration of the declaration that circumstances existj ustifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b) (1), unless the authorization is terminated or revoked sooner. This test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens.

Methodology Electrochemiluminescence Immunoassay (ECLIA)
Additional Information FDA-authorized Fact sheets for patients and providers can be accessed at the following link: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

Thyroid Hormone Resistance Beta (THRB) Gene Sequencing
630540

CPT 81405
Synonyms Thyroid Resistance
Test Includes THRB
Special Instructions This assay currently is **not** available in New York state.
Expected Turnaround Time 28 days
Specimen Whole blood, oral swab, extracted DNA
Volume 4 mL, 1 swab, **or** 200 ng of DNA
Minimum Volume 1 mL, 1 swab, **or** 100 ng of DNA
Container Lavender-top (EDTA) tube; OCD-100 DNA Genotek device **only;** extracted DNA; sterile screw-capped vial
Collection Draw blood into EDTA tube; collect swab specimen per guidelines in kit; transfer extracted DNA into sterile screw-capped tube.
Stability

- **Room temperature:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Refrigerated:** Blood: 5 days; Swab: 60 days; DNA: 30 days
- **Frozen:** Blood: Do **not** freeze; Swab: 60 days; DNA: Indefinitely

Causes for Rejection Frozen blood EDTA tube; insufficient swab cell collection or incorrect oral swab device use; extracted DNA A260:A280 ratio outside of 1.8-2.0 range
Use Diagnostic testing
Limitations The assay will not consistently detect germline mosaicism below 50% or rule out the presence of large chromosomal aberrations, including rearrangements, inversions that do not change copy number of genomic regions. The assay does not detect repeat expansions. Possible intergenic variant interactions are not commented on. False positive or false negative results may occur for reasons that include: insufficient information available about rare genetic variants, sex chromosome abnormalities, pseudogene interference, blood transfusions, bone marrow transplantation, somatic or tissue-specific mosaicism, mislabeled samples, or erroneous representation of family relationships. Variants that do not alter an amino acid composition of a protein may be difficult to assess for pathogenicity since they may produce abnormalities in structures **not** assessed by conventional analysis paradigms (eg mRNA expression and processing).[1] For mitochondrial DNA variants, low levels of heteroplasmy (<1%) may not be reliably detected by this technique. Mitochondrial variants may be tissue-specific. Interpretation of the clinical significance of gene variations is limited by information about the variant that is available at the time of reporting, and by the quality and quantity of clinical information provided with the sample. As the understanding of human genetic diversity improves, the interpretation of the clinical significance of variants may change.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Methodology

Nuclear Gene Single Nucleotide Polymorphism and Small Indel Sequencing Assessment: Genomic regions of interest are selected using a custom capture reagent for target enrichment (Twist Bioscience) and sequenced via the Illumina® Novaseq 6000 next generation sequencing platform. Sequencing reads are aligned with the human genome reference GRCh37/hg19 build. Regions of interest include all exons and intron/exon junctions (+/-10 nucleotides) for each gene analyzed. A minimum of 99% of bases in targeted regions are covered at >30X. Analytical sensitivity is estimated to be >99% for single nucleotide variants, >97% for insertions/deletions less than six base pairs, and >95% for insertions/deletions between six and fifteen base pairs. Uncovered regions with known pathogenic variants are sequenced in a targeted manner (list based on ClinVar Database: July 22, 2019 release).

Nuclear Gene Copy Number Variant Assessment: Next Generation Sequencing data used to call SNPs and small indels are assessed with Illumina's DRAGEN (Dynamic Read Analysis for GENomics) Bio-IT Platform. Genes listed in ClinVar with intragenic pathogenic deletions are padded with additional intronic probes to allow single exon resolution CNV detection (list based on ClinVar Deletion Database: January 2019 release). For other genes, large deletions (>10 exons) can be detected. The resolution of this analysis can vary depending on region-specific features. Analytical sensitivity is estimated to be >95%.

Results Interpretation: Results should be used in the context of available clinical information and should not be used as the sole basis for patient management or treatment. Genetic counseling is recommended. Variants are assessed according to ACMG criteria.[2] This report contains interpretation of pathogenic and likely pathogenic variants (by ACMG criteria) as well as variants of uncertain significance (VUS) with pathogenic predictions related to the clinical information provided. Variants not reported: (1) Variants classified as benign or likely benign by ACMG Criteria; (2) VUS with benign or likely benign predictions; (3) variants related to carrier status; (4) polymorphisms with implications in drug response (pharmacogenomics variants). We will reanalyze the data periodically at the clinician's request to allow potential reinterpretation based on new research or evidence. GnomAD abbreviations for population frequency data: African/African American (AFR), Latino (AMR), Ashkenazi Jewish (ASJ), East Asian (EAS), Finnish (FIN), Non-Finnish European (NFE), South Asian (SAS), Other (OTH).

Footnotes

1. Nackley AG, Shabalina SA, Tchivileva IE, et al. Human catechol-O-methyltransferase haplotypes modulate protein expression by altering mRNA secondary structure. Science. 2006 Dec 22;314(5807):1930-1933. PubMed 17185601

2. Richards S, Nazneen A, Bale S, et al. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Genet Med. 2015 May;17(5):405-424. PubMed 25741868

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Acetylcholine Receptor (AChR) Antibodies, Complete Panel With Reflex to MuSK Antibodies	**165595**	**Use** Test for the laboratory diagnosis of myasthenia gravis (MG) **Limitations** In rare cases AChR antibodies can be found in patients with other autoimmune disorders or with thymoma without MG.[1] The causative autoantibody cannot be identified in up to 10 percent of patients with MG. This panel is RUO/IUO Yes due to the following test: Acetylcholine Receptor (AChR)-blocking Antibodies [085926]. Results for this test are for research purposes only by the assay's manufacturer. The performance characteristics of this product have not been established. Results should not be used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure. **Additional Information** Myasthenia gravis (MG) is an acquired disorder of neuromuscular transmission that is characterized by skeletal muscle weakness and fatigability on exertion that is exacerbated by repeated muscle activity.[2-7] This autoimmune disease is caused by antibodies directed toward receptors embedded in the motor endplate of the neuromuscular junction. Progressive weakness of the ocular muscles manifesting as asymmetric ptosis and variable diplopia are the presenting symptoms in 60% of patients.[5,7] Many patients progress to more generalized weakness of peripheral limb muscles and muscles required for body posture, including facial and neck muscles. Bulbar muscle weakness compromises speaking (dysarthria), chewing and swallowing (dysphagia) and respiratory muscle weakness can lead to a myasthenic crisis where patients need to be ventilated artificially.[8] Clinical symptoms may be restricted to one muscle group, in particular the eye muscles (ocular MG), or may become generalized (generalized MG).[5-8] Patients with MG frequently have thymic abnormalities (thymic hyperplasia or thymoma).[9] Ten to 15 percent of patients with MG patients have thymoma, and up to 50% of thymoma patients develop MG.[9] It is thought that the thymus plays a role in MG pathogenesis and these patients respond well to the surgical removal of the thymus gland.[10] Neonatal MG can occur as a result of trans-placental transit of antibodies from an affected mother to the fetus, or in some cases, due to antibody to the fetal form of AChR.[11-13] In the latter case, the mother may be unaffected. It should be noted that the AChR antibody assays employed by Labcorp contain a mixture of adult and embryonic AChRs allowing for the detection of autoantibodies to both proteins. In most cases affected babies are born with a diminished ability to suck and generalized hypotonia. Decrease in utero feta movement caused by MG can also result in arthrogryposis multiplex congenital, a condition where the neonate suffers from contractures in more than two joints and in multiple body areas. The majority of patients with MG have antibodies to the acetylcholine receptor (AChR) and, less frequently, to the other proteins at postsynaptic membrane of the neuromuscular junction.[14-16] AChR antibodies impede neuromuscular transmission by a range of pathogenic mechanisms including the alteration of tissue architecture and/or by causing a reduction the density of functionality of AChRs.[1,17-21] Three functionally different types of antibodies against muscle AChR can be measured.[1,21-24] • AChR binding antibodies attach to the AChR activate the complement system result in in destruction and focal lysis of the neuromuscular junction leading to the destruction of AChR and AChR-related protein at the end-plate.[1,20] • AChR blocking antibodies functionally block the binding of the neurotransmitter acetylcholine to the receptor.[20] These antibodies usually occur in association with AChR-binding antibodies and have a higher prevalence in generalized MG compared with ocular MG.[20] • AChR modulation antibodies crosslink receptor subunits in such as way as to cause the receptors to be internalized and degraded in a process known as antigenic modulation.[20,22,25-27] Modulating antibodies are implicated with an increased risk of thymoma and the majority of patients with thymoma have modulating antibodies.[28] Test for serum autoantibodies are highly sensitive and specific for generalized MG but lack sensitivity when there is pure ocular involvement.[1,14,29-30] Approximately 85% of patients with generalized MG have detectable muscle AChR antibodies (of one or more types), while fewer patients with ocular MH have the antibodies (50-60%).[4,30] In general, an elevated level of any one of the AChR-binding antibodies in a patient with compatible clinical features confirms the diagnosis of MG. Approximately 15 percent of individuals with confirmed myasthenia gravis have no measurable AChR binding, blocking, or modulating antibodies. Thirty-five percent of these patients (six percent of all MG patients) will have antibodies directed against a muscle-specific tyrosine kinase (MuSK).[10,31] Autoantibodies levels do not generally correlate with disease severity. However, in individual patients, serial antibody titers tend to correlate with disease status.[18,19,32-34] Autoantibodies directed against the contractile elements of striated muscle are found in 30% of adult patients with myasthenia gravis and in 80% of those with thymoma.[35-37] Striational antibodies are associated with the late-onset MG subgroup and are rarely found in AChR antibody-negative MG. **Footnotes** 1. Meriggioli MN, Sanders DB. Muscle autoantibodies in myasthenia gravis: beyond diagnosis? *Expert Rev Clin Immunol.* 2012 Jul;8(5):427-438. PubMed 22882218 2. Berrih-Aknin S, Le Panse R. 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NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Acetylcholine Receptor (AChR) Antibodies, Complete Panel With Reflex to MuSK Antibodies (continued)	**165595**	**Footnotes (continued)** 6. Hehir MK, Silvestri NJ. Generalized Myasthenia Gravis: Classification, Clinical Presentation, Natural History, and Epidemiology. *Neurol Clin.* 2018 May;36(2):253-260. PubMed 29655448 7. Juel VC, Massey JM. Myasthenia gravis. *Orphanet J Rare Dis.* 2007 Nov 6;2:44. PubMed 17986328 8. Skeie GO, Apostolski S, Evoli A, et al. Guidelines for treatment of autoimmune neuromuscular transmission disorders. *Eur J Neurol.* 2010 Jul;17(7):893-902. PubMed 20402760 9. Bernard C, Frih H, Pasquet F, et al. Thymoma associated with autoimmune diseases: 85 cases and literature review. *Autoimmun Rev.* 2016 Jan;15(1):82-92. PubMed 26408958 10. Randomized Trial of Thymectomy in Myasthenia Gravis. Published Erratum. *N Engl J Med.* 2017 May 25;376(21):2097. PubMed 28471717 11. Gilhus NE. 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NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Acetylcholine Receptor (AChR) Antibodies, Complete Profile	**086007**	**Use** Test for the laboratory diagnosis of myasthenia gravis (MG) **Limitations** In rare cases AChR antibodies can be found in patients with other autoimmune disorders or with thymoma without MG.[1] The causative autoantibody cannot be identified in up to 10 percent of patients with MG. This panel is RUO/IUO Yes due to the following test: Acetylcholine Receptor (AChR)-blocking Antibodies [085926]. Results for this test are for research purposes only by the assay's manufacturer. The performance characteristics of this product have not been established. Results should not be used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure. **Additional Information** Myasthenia gravis (MG) is an acquired disorder of neuromuscular transmission that is characterized by skeletal muscle weakness and fatigability on exertion that is exacerbated by repeated muscle activity.[2-7] This autoimmune disease is caused by antibodies directed toward receptors embedded in the motor endplate of the neuromuscular junction. Progressive weakness of the ocular muscles manifesting as asymmetric ptosis and variable diplopia are the presenting symptoms in 60% of patients.[5,7] Many patients progress to more generalized weakness of peripheral limb muscles and muscles required for body posture, including facial and neck muscles. Bulbar muscle weakness compromises speaking (dysarthria), chewing and swallowing (dysphagia) and respiratory muscle weakness can lead to a myasthenic crisis where patients need to be ventilated artificially.[8] Clinical symptoms may be restricted to one muscle group, in particular the eye muscles (ocular MG), or may become generalized (generalized MG).[5-8] Patients with MG frequently have thymic abnormalities (thymic hyperplasia or thymoma).[9] Ten to 15 percent of patients with MG patients have thymoma, and up to 50% of thymoma patients develop MG.[9] It is thought that the thymus plays a role in MG pathogenesis and these patients respond well to the surgical removal of the thymus gland.[10] Neonatal MG can occur as a result of trans-placental transit of antibodies from an affected mother to the fetus, or in some cases, due to antibody to the fetal form of AChR.[11-13] In the latter case, the mother may be unaffected. It should be noted that the AChR antibody assays employed by Labcorp contain a mixture of adult and embryonic AChRs allowing for the detection of autoantibodies to both proteins. In most cases affected babies are born with a diminished ability to suck and generalized hypotonia. Decrease in utero feta movement caused by MG can also result in arthrogryposis multiplex congenital, a condition where the neonate suffers from contractures in more than two joints and in multiple body areas. The majority of patients with MG have antibodies to the acetylcholine receptor (AChR) and, less frequently, to the other proteins at postsynaptic membrane of the neuromuscular junction.[14-16] AChR antibodies impede neuromuscular transmission by a range of pathogenic mechanisms including the alteration of tissue architecture and/or by causing a reduction the density of functionality of AChRs.[1,17-21] Three functionally different types of antibodies against muscle AChR can be measured.[1,21-24] • AChR binding antibodies attach to the AChR activate the complement system result in in destruction and focal lysis of the neuromuscular junction leading to the destruction of AChR and AChR-related protein at the end-plate.[1,20] • AChR blocking antibodies functionally block the binding of the neurotransmitter acetylcholine to the receptor.[20] These antibodies usually occur in association with AChR-binding antibodies and have a higher prevalence in generalized MG compared with ocular MG.[20] • AChR modulation antibodies crosslink receptor subunits in such as way as to cause the receptors to be internalized and degraded in a process known as antigenic modulation.[20,22,25-27] Modulating antibodies are implicated with an increased risk of thymoma and the majority of patients with thymoma have modulating antibodies.[28] Test for serum autoantibodies are highly sensitive and specific for generalized MG but lack sensitivity when there is pure ocular involvement.[1,14,29-30] Approximately 85% of patients with generalized MG have detectable muscle AChR antibodies (of one or more types), while fewer patients with ocular MH have the antibodies (50-60%).[4,30] In general, an elevated level of any one of the AChR-binding antibodies in a patient with compatible clinical features confirms the diagnosis of MG. Approximately 15 percent of individuals with confirmed myasthenia gravis have no measurable AChR binding, blocking, or modulating antibodies. Thirty-five percent of these patients (six percent of all MG patients) will have antibodies directed against a muscle-specific tyrosine kinase (MuSK).[10,31] Autoantibodies levels do not generally correlate with disease severity. However, in individual patients, serial antibody titers tend to correlate with disease status.[18,19,32-34] Autoantibodies directed against the contractile elements of striated muscle are found in 30% of adult patients with myasthenia gravis and in 80% of those with thymoma.[35-37] Striational antibodies are associated with the late-onset MG subgroup and are rarely found in AChR antibody-negative MG. **Footnotes** 1. Meriggioli MN, Sanders DB. Muscle autoantibodies in myasthenia gravis: beyond diagnosis? *Expert Rev Clin Immunol.* 2012 Jul;8(5):427-438. PubMed 22882218 2. Berrih-Aknin S, Le Panse R. 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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Acetylcholine Receptor (AChR) Antibodies, Complete Profile (continued)	**086007**	**Footnotes (continued)** 6. Hehir MK, Silvestri NJ. Generalized Myasthenia Gravis: Classification, Clinical Presentation, Natural History, and Epidemiology. *Neurol Clin.* 2018 May;36(2):253-260. PubMed 29655448 7. Juel VC, Massey JM. Myasthenia gravis. *Orphanet J Rare Dis.* 2007 Nov 6;2:44. PubMed 17986328 8. Skeie GO, Apostolski S, Evoli A, et al. Guidelines for treatment of autoimmune neuromuscular transmission disorders. *Eur J Neurol.* 2010 Jul;17(7):893-902. PubMed 20402760 9. Bernard C, Frih H, Pasquet F, et al. Thymoma associated with autoimmune diseases: 85 cases and literature review. *Autoimmun Rev.* 2016 Jan;15(1):82-92. PubMed 26408958 10. Randomized Trial of Thymectomy in Myasthenia Gravis. Published Erratum. *N Engl J Med.* 2017 May 25;376(21):2097. PubMed 28471717 11. Gilhus NE. 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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Acetylcholine Receptor (AChR)-binding Antibodies	**085902**	**Use** Test for the laboratory diagnosis of myasthenia gravis (MG) **Limitations** In rare cases AChR antibodies can be found in patients with other autoimmune disorders or with thymoma without MG.[1] The causative autoantibody cannot be identified in up to 10 percent of patients with MG. **Additional Information** Myasthenia gravis (MG) is an acquired disorder of neuromuscular transmission that is characterized by skeletal muscle weakness and fatigability on exertion that is exacerbated by repeated muscle activity.[2-7] This autoimmune disease is caused by antibodies directed toward receptors embedded in the motor endplate of the neuromuscular junction. Progressive weakness of the ocular muscles manifesting as asymmetric ptosis and variable diplopia are the presenting symptoms in 60% of patients.[5,7] Many patients progress to more generalized weakness of peripheral limb muscles and muscles required for body posture, including facial and neck muscles. Bulbar muscle weakness compromises speaking (dysarthria), chewing and swallowing (dysphagia) and respiratory muscle weakness can lead to a myasthenic crisis where patients need to be ventilated artificially.[8] Clinical symptoms may be restricted to one muscle group, in particular the eye muscles (ocular MG), or may become generalized (generalized MG).[5-8] Patients with MG frequently have thymic abnormalities (thymic hyperplasia or thymoma).[9] Ten to 15 percent of patients with MG patients have thymoma, and up to 50% of thymoma patients develop MG.[9] It is thought that the thymus plays a role in MG pathogenesis and these patients respond well to the surgical removal of the thymus gland.[10] Neonatal MG can occur as a result of trans-placental transit of antibodies from an affected mother to the fetus, or in some cases, due to antibody to the fetal form of AChR.[11-13] In the latter case, the mother may be unaffected. It should be noted that the AChR antibody assays employed by Labcorp contain a mixture of adult and embryonic AChRs allowing for the detection of autoantibodies to both proteins. In most cases affected babies are born with a diminished ability to suck and generalized hypotonia. Decrease in utero feta movement caused by MG can also result in arthrogryposis multiplex congenital, a condition where the neonate suffers from contractures in more than two joints and in multiple body areas. 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Approximately 15 percent of individuals with confirmed myasthenia gravis have no measurable AChR binding, blocking, or modulating antibodies. Thirty-five percent of these patients (six percent of all MG patients) will have antibodies directed against a muscle-specific tyrosine kinase (MuSK).[10,31] Autoantibodies levels do not generally correlate with disease severity. However, in individual patients, serial antibody titers tend to correlate with disease status.[18,19,32-34] Autoantibodies directed against the contractile elements of striated muscle are found in 30% of adult patients with myasthenia gravis and in 80% of those with thymoma.[35-37] Striational antibodies are associated with the late-onset MG subgroup and are rarely found in AChR antibody-negative MG. **Footnotes** 1. Meriggioli MN, Sanders DB. Muscle autoantibodies in myasthenia gravis: beyond diagnosis? *Expert Rev Clin Immunol.* 2012 Jul;8(5):427-438. PubMed 22882218 2. Berrih-Aknin S, Le Panse R. 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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Acetylcholine Receptor (AChR)-binding Antibodies (continued)	**085902**	**Footnotes (continued)** 12. Midelfart Hoff J, Midelfart A. Maternal myasthenia gravis: a cause for arthrogryposis multiplex congenita. *J Child Orthop.* 2015 Dec;9(6):433-435. PubMed 26482518 13. Riemersma S, Vincent A, Beeson D, et al. Association of arthrogryposis multiplex congenita with maternal antibodies inhibiting fetal acetylcholine receptor function. *J Clin Invest.* 1996 Nov 15;98(10):2358-2363. PubMed 8941654 14. Vincent A. Unravelling the pathogenesis of myasthenia gravis. *Nat Rev Immunol.* 2002 Oct;2(10):797-804. PubMed 12360217 15. Vincent A, Newsom-Davis J. Acetylcholine receptor antibody as a diagnostic test for myasthenia gravis: results in 153 validated cases and 2967 diagnostic assays. *J Neurol Neurosurg Psychiatry.* 1985 Dec;48(12):1246-1252. PubMed 4087000 16. Zisimopoulou P, Evangelakou P, Tzartos J, et al. 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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Acetylcholine Receptor (AChR) Binding Antibodies With Reflex to MuSK Antibodies	**165592**	**Use** Test for the laboratory diagnosis of myasthenia gravis (MG) **Limitations** In rare cases AChR antibodies can be found in patients with other autoimmune disorders or with thymoma without MG.[1] The causative autoantibody cannot be identified in up to 10 percent of patients with MG. **Additional Information** Myasthenia gravis (MG) is an acquired disorder of neuromuscular transmission that is characterized by skeletal muscle weakness and fatigability on exertion that is exacerbated by repeated muscle activity.[2-7] This autoimmune disease is caused by antibodies directed toward receptors embedded in the motor endplate of the neuromuscular junction. Progressive weakness of the ocular muscles manifesting as asymmetric ptosis and variable diplopia are the presenting symptoms in 60% of patients.[5,7] Many patients progress to more generalized weakness of peripheral limb muscles and muscles required for body posture, including facial and neck muscles. 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Juel VC, Massey JM. Myasthenia gravis. *Orphanet J Rare Dis.* 2007 Nov 6;2:44. PubMed 17986328 8. Skeie GO, Apostolski S, Evoli A, et al. Guidelines for treatment of autoimmune neuromuscular transmission disorders. *Eur J Neurol.* 2010 Jul;17(7):893-902. PubMed 20402760 9. Bernard C, Frih H, Pasquet F, et al. Thymoma associated with autoimmune diseases: 85 cases and literature review. *Autoimmun Rev.* 2016 Jan;15(1):82-92. PubMed 26408958 10. Randomized Trial of Thymectomy in Myasthenia Gravis. Published Erratum. *N Engl J Med.* 2017 May 25;376(21):2097. PubMed 28471717 11. Gilhus NE. Myasthenia Gravis Can Have Consequences for Pregnancy and the Developing Child. *Front Neurol.* 2020 Jun 12;11:554. PubMed 32595594

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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Acetylcholine Receptor (AChR) Binding Antibodies With Reflex to MuSK Antibodies (continued)	**165592**	**Footnotes (continued)** 12. Midelfart Hoff J, Midelfart A. Maternal myasthenia gravis: a cause for arthrogryposis multiplex congenita. *J Child Orthop.* 2015 Dec;9(6):433-435. PubMed 26482518 13. Riemersma S, Vincent A, Beeson D, et al. Association of arthrogryposis multiplex congenita with maternal antibodies inhibiting fetal acetylcholine receptor function. *J Clin Invest.* 1996 Nov 15;98(10):2358-2363. PubMed 8941654 14. Vincent A. Unravelling the pathogenesis of myasthenia gravis. *Nat Rev Immunol.* 2002 Oct;2(10):797-804. PubMed 12360217 15. Vincent A, Newsom-Davis J. Acetylcholine receptor antibody as a diagnostic test for myasthenia gravis: results in 153 validated cases and 2967 diagnostic assays. *J Neurol Neurosurg Psychiatry.* 1985 Dec;48(12):1246-1252. PubMed 4087000 16. Zisimopoulou P, Evangelakou P, Tzartos J, et al. 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Striational autoantibodies: quantitative detection by enzyme immunoassay in myasthenia gravis, thymoma, and recipients of D-penicillamine or allogeneic bone marrow. *Mayo Clin Proc.* 1988 May;63(5):474-481. PubMed 3283472 36. Romi F, Skeie GO, Gilhus NE, Aarli JA. Striational antibodies in myasthenia gravis: reactivity and possible clinical significance. *Arch Neurol.* 2005 Mar;62(3):442-446. PubMed 15767509 37. Vernino S, Lennon VA. Autoantibody profiles and neurological correlations of thymoma. *Clin Cancer Res.* 2004 Nov 1;10(21):7270-7275 PubMed 15534101
Acetylcholine Receptor (AChR)-blocking Antibodies	**085926**	**Use** Test for the laboratory diagnosis of myasthenia gravis (MG) **Limitations** In rare cases AChR antibodies can be found in patients with other autoimmune disorders or with thymoma without MG.[1] The causative autoantibody cannot be identified in up to 10 percent of patients with MG. Results for this test are for research purposes only by the assay's manufacturer. The performance characteristics of this product have not been established. Results should not be used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure.

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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Acetylcholine Receptor (AChR)-blocking Antibodies (continued)	**085926**	**Additional Information** Myasthenia gravis (MG) is an acquired disorder of neuromuscular transmission that is characterized by skeletal muscle weakness and fatigability on exertion that is exacerbated by repeated muscle activity.[2-7] This autoimmune disease is caused by antibodies directed toward receptors embedded in the motor endplate of the neuromuscular junction. Progressive weakness of the ocular muscles manifesting as asymmetric ptosis and variable diplopia are the presenting symptoms in 60% of patients.[5,7] Many patients progress to more generalized weakness of peripheral limb muscles and muscles required for body posture, including facial and neck muscles. Bulbar muscle weakness compromises speaking (dysarthria), chewing and swallowing (dysphagia) and respiratory muscle weakness can lead to a myasthenic crisis where patients need to be ventilated artificially.[8] Clinical symptoms may be restricted to one muscle group, in particular the eye muscles (ocular MG), or may become generalized (generalized MG).[5-8] Patients with MG frequently have thymic abnormalities (thymic hyperplasia or thymoma).[9] Ten to 15 percent of patients with MG patients have thymoma, and up to 50% of thymoma patients develop MG.[9] It is thought that the thymus plays a role in MG pathogenesis and these patients respond well to the surgical removal of the thymus gland.[10] Neonatal MG can occur as a result of trans-placental transit of antibodies from an affected mother to the fetus, or in some cases, due to antibody to the fetal form of AChR.[11-13] In the latter case, the mother may be unaffected. It should be noted that the AChR antibody assays employed by Labcorp contain a mixture of adult and embryonic AChRs allowing for the detection of autoantibodies to both proteins. In most cases affected babies are born with a diminished ability to suck and generalized hypotonia. Decrease in utero feta movement caused by MG can also result in arthrogryposis multiplex congenital, a condition where the neonate suffers from contractures in more than two joints and in multiple body areas. The majority of patients with MG have antibodies to the acetylcholine receptor (AChR) and, less frequently, to the other proteins at postsynaptic membrane of the neuromuscular junction.[14-16] AChR antibodies impede neuromuscular transmission by a range of pathogenic mechanisms including the alteration of tissue architecture and/or by causing a reduction the density of functionality of AChRs.[1,17-21] Three functionally different types of antibodies against muscle AChR can be measured.[1,21-24] • AChR binding antibodies attach to the AChR activate the complement system result in in destruction and focal lysis of the neuromuscular junction leading to the destruction of AChR and AChR-related protein at the end-plate.[1,20] • AChR blocking antibodies functionally block the binding of the neurotransmitter acetylcholine to the receptor.[20] These antibodies usually occur in association with AChR-binding antibodies and have a higher prevalence in generalized MG compared with ocular MG.[20] • AChR modulation antibodies crosslink receptor subunits in such as way as to cause the receptors to be internalized and degraded in a process known as antigenic modulation.[20,22,25-27] Modulating antibodies are implicated with an increased risk of thymoma and the majority of patients with thymoma have modulating antibodies.[28] Test for serum autoantibodies are highly sensitive and specific for generalized MG but lack sensitivity when there is pure ocular involvement.[1,14,29-30] Approximately 85% of patients with generalized MG have detectable muscle AChR antibodies (of one or more types), while fewer patients with ocular MH have the antibodies (50-60%).[4,30] In general, an elevated level of any one of the AChR-binding antibodies in a patient with compatible clinical features confirms the diagnosis of MG. Approximately 15 percent of individuals with confirmed myasthenia gravis have no measurable AChR binding, blocking, or modulating antibodies. Thirty-five percent of these patients (six percent of all MG patients) will have antibodies directed against a muscle-specific tyrosine kinase (MuSK).[10,31] Autoantibodies levels do not generally correlate with disease severity. However, in individual patients, serial antibody titers tend to correlate with disease status.[18,19,32-34] Autoantibodies directed against the contractile elements of striated muscle are found in 30% of adult patients with myasthenia gravis and in 80% of those with thymoma.[35-37] Striational antibodies are associated with the late-onset MG subgroup and are rarely found in AChR antibody-negative MG. **Footnotes** 1. Meriggioli MN, Sanders DB. Muscle autoantibodies in myasthenia gravis: beyond diagnosis? *Expert Rev Clin Immunol.* 2012 Jul;8(5):427-438. PubMed 22882218 2. Berrih-Aknin S, Le Panse R. 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Acetylcholine Receptor (AChR)-blocking Antibodies (continued)	**085926**	**Footnotes (continued)** 12. Midelfart Hoff J, Midelfart A. Maternal myasthenia gravis: a cause for arthrogryposis multiplex congenita. *J Child Orthop.* 2015 Dec;9(6):433-435. PubMed 26482518 13. Riemersma S, Vincent A, Beeson D, et al. Association of arthrogryposis multiplex congenita with maternal antibodies inhibiting fetal acetylcholine receptor function. *J Clin Invest.* 1996 Nov 15;98(10):2358-2363. PubMed 8941654 14. Vincent A. Unravelling the pathogenesis of myasthenia gravis. *Nat Rev Immunol.* 2002 Oct;2(10):797-804. PubMed 12360217 15. Vincent A, Newsom-Davis J. Acetylcholine receptor antibody as a diagnostic test for myasthenia gravis: results in 153 validated cases and 2967 diagnostic assays. *J Neurol Neurosurg Psychiatry.* 1985 Dec;48(12):1246-1252. PubMed 4087000 16. Zisimopoulou P, Evangelakou P, Tzartos J, et al. 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Acid-fast (Mycobacteria) Smear and Culture With Reflex to Identification	**183753**	**Container** Sterile container with tight screw-cap seal or green-top (sodium heparin) tube or Isolator™ or Para Pak White
Acid-fast (Mycobacteria) Smear and Culture With Reflex to Identification and Susceptibility Testing	**183764**	**Container** Sterile container with tight screw-cap seal or green-top (sodium heparin) tube or Isolator™ or Para Pak White
NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.		

Test Updates

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Synonyms ANA on Synovial Fluid; ANA Synovial Fluid; Anti Nuclear Antibodies on Synovial Fluid; Indirect Immunofluorescence
Test Inlcudes This test reflexes to ANA Titer and Pattern Synovial Fluid if ANA by IFA is positive in order to rule out false positive ANA by IFA.
Specimen Synovial fluid only
Container Transport tube or other container
Collection Collect synovial fluid aseptically into tube or other container.
Casues for Rejection Grossly hemolyzed; bacterial contamination; lipemic specimen; icteric specimen; non-synovial body fluids</td></tr>
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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
***Chlamydia/Gonococcus*, NAA**	**183194**	**Container** Gen-Probe® Aptima® swab or Aptima® urine specimen transport; ThinPrep® liquid cytology vial **Collection Option 1: Gen-Probe® Aptima® Endocervical, Male Urethral, or Vaginal Swab** ***Endocervical swab:*** Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shaft swab in the package with red printing). Discard this swab. Insert the specimen collection swab (blue-shaft swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of the contents. Recap the swab specimen transport tube tightly. ***Male urethral swab:*** The patient should not have urinated for at least one hour prior to specimen collection. Insert the specimen collection swab (blue-shaft swab in the package with the green printing) 2 to 4 cm into the urethra. Gently rotate the swab clockwise for two to three seconds in the urethra to ensure adequate sampling. Withdraw the swab carefully. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of contents. Recap the swab specimen transport tube tightly. ***Vaginal swab: Care provider specimen:*** Collect vaginal fluid sample using the Gen-Probe® Aptima® vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. ***Patient self-collection:*** Partially open the package of the Gen-Probe® Aptima® vaginal swab kit. Do **not** touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima® swab specimen collection kit. Remove the swab. Carefully insert the swab into the vagina about two inches past the introitus and gently rotate the swab for 10 to 30 seconds, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube, and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. **Option 2: Urine Specimen:** The patient should not have urinated for at least one hour prior to specimen collection. Direct patient to provide a **first-catch urine** (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity; lesser volumes may not adequately rinse organisms into the specimen. Female patients should **not** cleanse the labial area prior to providing the specimen. Add urine to the Aptima® Combo 2 urine collection device. The final volume must be between the two black lines on the device (about 2 mL). **Option 3: Liquid-based Cytology Specimen** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to further release cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Specimen with incorrect patient identification; unlabeled specimen; inappropriate specimen transport conditions; specimen leaked in transit; specimen in expired transport or incorrect transport device; specimens with inappropriate source for test requested; specimen with fixative or additives; APTIMA® urine transport >30 days from collection; APTIMA® urine transport with incorrect specimen volume; <15 mL urine submitted in sterile container; receipt of urine in sterile container >72 hours from collection; APTIMA® swab transport >60 days from collection; APTIMA® swab specimens with incorrect specimen volume; APTIMA® swab specimen without a swab; cleaning swab (white-shaft swab) in APTIMA® swab transport; any non-Gen-Probe® swab submitted in APTIMA® transport device; wooden-shafted swab in transport device; transport device with multiple swabs; female urethral swab; bloody or grossly mucoid specimens; bacterial swabs; specimen in ProbeTec™ UPT transport; ProbeTec™ Q-swabs; BD ProbeTec™ ET male urethral swab; swab specimen in universal transport media or viral transport media; SurePath™ vial

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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
***Chlamydia/Gonococcus*, NAA With Confirmation**	**183616**	**Container** Gen-Probe® Aptima® swab or Aptima® urine specimen transport; ThinPrep® liquid cytology vial **Collection Option 1: Gen-Probe® Aptima® Endocervical, Male Urethral, or Vaginal Swab** ***Endocervical swab:*** Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shaft swab in the package with red printing). Discard this swab. Insert the specimen collection swab (blue-shaft swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of the contents. Recap the swab specimen transport tube tightly. ***Male urethral swab:*** The patient should not have urinated for at least one hour prior to specimen collection. Insert the specimen collection swab (blue-shaft swab in the package with the green printing) 2 to 4 cm into the urethra. Gently rotate the swab clockwise for two to three seconds in the urethra to ensure adequate sampling. Withdraw the swab carefully. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of contents. Recap the swab specimen transport tube tightly. ***Vaginal swab: Care provider specimen:*** Collect vaginal fluid sample using the Gen-Probe® Aptima® vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. ***Patient self-collection:*** Partially open the package of the Gen-Probe® Aptima® vaginal swab kit. Do **not** touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima® swab specimen collection kit. Remove the swab. Carefully insert the swab into the vagina about two inches past the introitus and gently rotate the swab for 10 to 30 seconds, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube, and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. **Option 2: Urine Specimen:** The patient should not have urinated for at least one hour prior to specimen collection. Direct patient to provide a **first-catch urine** (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity; lesser volumes may not adequately rinse organisms into the specimen. Female patients should **not** cleanse the labial area prior to providing the specimen. Add urine to the Aptima® Combo 2 urine collection device. The final volume must be between the two black lines on the device (about 2 mL). **Option 3: Liquid-based Cytology Specimen** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to further release cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Specimen with incorrect patient identification; unlabeled specimen; inappropriate specimen transport conditions; specimen leaked in transit; specimen in expired transport or incorrect transport device; specimens with inappropriate source for test requested; specimen with fixative or additives; APTIMA® urine transport >30 days from collection; APTIMA® urine transport with incorrect specimen volume; <15 mL urine submitted in sterile container; receipt of urine in sterile container >72 hours from collection; APTIMA® swab transport >60 days from collection; APTIMA® swab specimens with incorrect specimen volume; APTIMA® swab specimen without a swab; cleaning swab (white-shaft swab) in APTIMA® swab transport; any non-Gen-Probe® swab submitted in APTIMA® transport device; wooden-shafted swab in transport device; transport device with multiple swabs; female urethral swab; bloody or grossly mucoid specimens; bacterial swabs; specimen in ProbeTec™ UPT transport; ProbeTec™ Q-swabs; BD ProbeTec™ ET male urethral swab; swab specimen in universal transport media or viral transport media; SurePath™ vial
***Chlamydia/Gonococcus*, NAA With Reflex to *Trichomonas vaginalis*, NAA**	**183198**	**Container** Gen-Probe® Aptima® swab or Aptima® urine specimen transport; ThinPrep® liquid cytology vial **Causes for Rejection** Specimen with incorrect patient identification; unlabeled specimen; inappropriate specimen transport conditions; specimens received after prolonged delay (usually >72 hours); specimen leaked in transit; specimen in expired transport or incorrect transport device; specimens with inappropriate source for test requested; specimen with fixative or additives; Aptima® urine transport >30 days from collection; Aptima® urine transport with incorrect specimen volume; <15 mL urine submitted in sterile container; receipt of urine in sterile container >24 hours from collection; Aptima® swab transport >60 days from collection; Aptima® swab specimens with incorrect specimen volume; Aptima® swab specimen without a swab; cleaning swab (white-shaft swab) in Aptima® swab transport; any non–Gen-Probe® swab submitted in Aptima® transport device; wooden-shaft swab in transport device; transport device with multiple swabs; female urethral swab; bloody or grossly mucoid specimens; bacterial swabs; specimen in ProbeTec™ UPT transport; ProbeTec™ Q-swabs; UTM-RT; SurePath™ vial

NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
***Chlamydia trachomatis*, NAA**	**188078**	**Container** Gen-Probe® Aptima® swab or Aptima® urine specimen transport; ThinPrep® liquid cytology vial **Collection Option 1: Gen-Probe® Aptima® Endocervical, Male Urethral, or Vaginal Swab** ***Endocervical swab:*** Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shaft swab in the package with red printing). Discard this swab. Insert the specimen collection swab (blue-shaft swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of the contents. Recap the swab specimen transport tube tightly. ***Male urethral swab:*** The patient should not have urinated for at least one hour prior to specimen collection. Insert the specimen collection swab (blue-shaft swab in the package with the green printing) 2 to 4 cm into the urethra. Gently rotate the swab clockwise for two to three seconds in the urethra to ensure adequate sampling. Withdraw the swab carefully. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of contents. Recap the swab specimen transport tube tightly. ***Vaginal swab: Care provider specimen:*** Collect vaginal fluid sample using the Gen-Probe® Aptima® vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. ***Patient self-collection:*** Partially open the package of the Gen-Probe® Aptima® vaginal swab kit. Do **not** touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima® swab specimen collection kit. Remove the swab. Carefully insert the swab into the vagina about two inches past the introitus and gently rotate the swab for 10 to 30 seconds, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube, and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. **Option 2: Urine Specimen:** The patient should not have urinated for at least one hour prior to specimen collection. Direct patient to provide a **first-catch urine** (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity; lesser volumes may not adequately rinse organisms into the specimen. Female patients should **not** cleanse the labial area prior to providing the specimen. Add urine to the Aptima® Combo 2 urine collection device. The final volume must be between the two black lines on the device (about 2 mL) **Option 3: Liquid-based Cytology Specimen** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to further release cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Specimen with incorrect patient identification; unlabeled specimen; inappropriate specimen transport conditions; specimen leaked in transit; specimen in expired transport or incorrect transport device; specimens with inappropriate source for test requested; specimen with fixative or additives; APTIMA® urine transport >30 days from collection; APTIMA® urine transport with incorrect specimen volume; <15 mL urine submitted in sterile container; receipt of urine in sterile container >72 hours from collection; APTIMA® swab transport >60 days from collection; APTIMA® swab specimens with incorrect specimen volume; APTIMA® swab specimen without a swab; cleaning swab (white-shaft swab) in APTIMA® swab transport; any non-Gen-Probe® swab submitted in APTIMA® transport device; wooden-shafted swab in transport device; transport device with multiple swabs; female urethral swab; bloody or grossly mucoid specimens; bacterial swabs; specimen in ProbeTec™ UPT transport; ProbeTec™ Q-swabs; BD ProbeTec™ ET male urethral swab; swab specimen in universal transport media or viral transport media; SurePath™ vial.

NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
***Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and Herpes Simplex Virus (HSV) Types 1 and 2, NAA**	**188065**	**Container** Aptima® unisex or Aptima® vaginal swab transport or ThinPrep™ liquid cytology vial **Collection Vaginal swab: *Care provider specimen:*** Collect vaginal fluid sample using the GenProbe® Aptima® vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. ***Patient self-collection:*** Partially open the package of the GenProbe® Aptima® vaginal swab kit. Do **not** touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima® swab specimen collection kit. Remove the swab. Carefully insert the swab into the vagina about two inches past the vaginal opening and gently rotate the swab for 10 to 30 seconds, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. **Endocervical swab in Aptima®:** Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shafted swab in the package with red printing). **Discard this swab.** Insert the specimen collection swab (blue-shafted swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the scoreline using care to avoid splashing of the contents. Recap the swab specimen transport tube tightly. **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to further release cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Urine specimen; specimen transported under inappropriate conditions; bacterial swabs; unlabeled specimen or discrepancy between specimen label and test request form; Aptima® COMBO 2 (AC2) swab specimen transport tube with two swabs or swab not supplied by Gen-Probe® or no swab; ProbeTec™ swabs; female urethral swab; SurePath™ vial. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** Aptima® swab transports >60 days from collection. **For HSV:** Aptima® swab transports >7 days from collection. **Note:** Specimens collected from children younger than 13 years of age or specimens submitted without the age of the patient or date of birth may be tested and will be reported with a disclaimer.
***Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*, NAA**	**183160**	**Container** Gen-Probe® Aptima® swab or Aptima® urine specimen transport; ThinPrep® liquid cytology vial **Causes for Rejection** Specimen with incorrect patient identification; unlabeled specimen; inappropriate specimen transport conditions; specimens received after prolonged delay (usually >72 hours); specimen leaked in transit; specimen in expired transport or incorrect transport device; specimens with inappropriate source for test requested; specimen with fixative or additives; Aptima® urine transport >30 days from collection; Aptima® urine transport with incorrect specimen volume; <15 mL urine submitted in sterile container; receipt of urine in sterile container >24 hours from collection; Aptima® swab transport >60 days from collection; Aptima® swab specimens with incorrect specimen volume; Aptima® swab specimen without a swab; cleaning swab (white-shaft swab) in Aptima® swab transport; any non–Gen-Probe® swab submitted in Aptima® transport device; wooden-shaft swab in transport device; transport device with multiple swabs; female urethral swab; bloody or grossly mucoid specimens; bacterial swabs; specimen in ProbeTec™ UPT transport; ProbeTec™ Q-swabs; UTM-RT; SurePath™ vial
NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.		

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
***Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis,* and Herpes Simplex Virus (HSV) Types 1 and 2, NAA**	**188070**	**Container** Aptima® unisex or Aptima® vaginal swab transport or ThinPrep™ liquid cytology vial **Collection Vaginal swab: *Care provider specimen:*** Collect vaginal fluid sample using the GenProbe® Aptima® vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. ***Patient self-collection:*** Partially open the package of the GenProbe® Aptima® vaginal swab kit. Do **not** touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima® swab specimen collection kit. Remove the swab. Carefully insert the swab into the vagina about two inches past the vaginal opening and gently rotate the swab for 10 to 30 seconds, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. **Endocervical swab in Aptima®:** Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shafted swab in the package with red printing). **Discard this swab.** Insert the specimen collection swab (blue-shafted swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the scoreline using care to avoid splashing of the contents. Recap the swab specimen transport tube tightly. **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to further release cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Urine specimen; specimen transported under inappropriate conditions; bacterial swabs; unlabeled specimen or discrepancy between specimen label and test request form; Aptima® COMBO 2 (AC2) swab specimen transport tube with two swabs or swab not supplied by Gen-Probe® or no swab; ProbeTec™ swabs; female urethral swab; SurePath™ vial. **For *Chlamydia trachomatis, Neisseria gonorrhoeae,* and *Trichomonas vaginalis:*** Aptima® swab transports >60 days from collection. **For HSV:** Aptima® swab transports >7 days from collection. **Note:** Specimens collected from children younger than 13 years of age or specimens submitted without the age of the patient or date of birth may be tested and will be reported with a disclaimer.
Chromosome Analysis, AFP, AChE, Amniotic Fluid With Reflex to Fetal Hemoglobin (Hb F)	**511580**	**Special Instructions** (added) If prior NIPT studies have been performed, include copy of the report.
Chromosome Analysis, Amniotic Fluid	**052040**	**Special Instructions** (added) If prior NIPT studies have been performed, include copy of the report.
Chromosome Analysis, Amniotic Fluid With Reflex to SNP Microarray (Reveal®)	**052104**	**Special Instructions** (added) If prior NIPT studies have been performed, include copy of the report.
Chromosome Analysis and AFP, Amniotic Fluid	**510185**	**Special Instructions** (added) If prior NIPT studies have been performed, include copy of the report.
Chromosome Analysis, Chorionic Villi Biopsy	**510988**	**Special Instructions** (added) If prior NIPT studies have been performed, include copy of the report.
Chromosome Analysis, Chorionic Villi Biopsy With Reflex to SNP Microarray (Reveal®)	**511033**	**Special Instructions** (added) If prior NIPT studies have been performed, include copy of the report.
Chromosome Analysis, Products of Conception (POC) With Reflex to SNP Microarray (Reveal®)	**052065**	**Special Instructions** (added) If prior NIPT studies have been performed, include copy of the report.
Chromosome Analysis, Tissue Biopsies (Products of Conception, Skin)	**052052**	**Special Instructions** (added) If prior NIPT studies have been performed, include copy of the report.
Chromosome Five-cell Count Plus Microarray (Reveal®), Amniotic Fluid	**511590**	**Special Instructions** (added) If prior NIPT studies have been performed, include copy of the report.
Chromosome Five-cell Count Plus Microarray (Reveal®), CVS	**511555**	**Special Instructions** (added) If prior NIPT studies have been performed, include copy of the report.
***Clostridium difficile* Toxins A and B, EIA**	**086207**	**Causes for Rejection** Specimens from patients less than two years of age; inappropriate specimen transport conditions (eg, room temperature) or transport device; unlabeled specimen or name discrepancy between specimen and request label; specimen received after prolonged delay (usually more than 72 hours); specimens other than stool; leaking specimen; specimen received in denture cup, "Cool Whip" container, margarine container, or similar container

NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

<table>
<tr><th>Test Name</th><th>Test No.</th><th>Field/Change (Only fields that change are included here.)</th></tr>
<tr><td>Copper, Serum or Plasma</td><td>001586</td><td>Reference Interval
<table>
<tr><th>Age</th><th>Male</th></tr>
<tr><td>0 to 4 m</td><td>38–122</td></tr>
<tr><td>5 to 6 m</td><td>55–131</td></tr>
<tr><td>7 to 10 m</td><td>64–142</td></tr>
<tr><td>11 m to 5 y</td><td>81–152</td></tr>
<tr><td>6 to 10 y</td><td>80–141</td></tr>
<tr><td>11 to 15 y</td><td>67–128</td></tr>
<tr><td>16 to 30 y</td><td>63–121</td></tr>
<tr><td>>30 y</td><td>69–132</td></tr>
<tr><th>Age</th><th>Female</th></tr>
<tr><td>0 to 4 m</td><td>38–122</td></tr>
<tr><td>5 to 6 m</td><td>55–131</td></tr>
<tr><td>7 to 10 m</td><td>64–142</td></tr>
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<tr><td>11 to 15 y</td><td>67–128</td></tr>
<tr><td>16 to 18 y</td><td>71–146</td></tr>
<tr><td>>18 y</td><td>80–158</td></tr>
</table></td></tr>
<tr><td>Cystine, Quantitative, Urine</td><td>700195</td><td>Storage Instructions Freeze.</td></tr>
<tr><td>Cytochrome P450 2C9 Genotyping</td><td>511893</td><td>Volume 5 mL whole blood or Labcorp buccal swab kit
Collection Collect specimen in a lavender-top (EDTA) or yellow-top (ACD) tube or use a buccal swab kit. Ship whole blood specimen at room temperature or frozen. Ship buccal swab collection kit at room temperature.
Storage Instructions Maintain whole blood specimen at room temperature or refrigerated for 7 days, frozen for 2 years. Maintain buccal swabs at room temperature or refrigerated for 2 months.
Causes for Rejection Hemolysis; quantity not sufficient for analysis; improper container; single buccal swab; wet buccal swab</td></tr>
<tr><td>Cytochrome P450 2C9 Genotyping Siponimod</td><td>512215</td><td>Specimen Whole blood or Labcorp buccal swab kit (buccal swab collection kit contains instructions for use of a buccal swab)
Volume 5 mL whole blood or Labcorp buccal swab kit
Minimum Volume 3 mL whole blood or two buccal swabs
Container Lavender-top (EDTA) tube or yellow-top (ACD) tube or buccal swab kit
Collection Collect specimen in a lavender-top (EDTA) tube or yellow-top (ACD) tube or use a buccal swab kit. Ship whole blood specimen at room temperature or frozen. Ship buccal swab collection kit at room temperature.
Storage Instructions Maintain whole blood specimen at room temperature or refrigerated for 7 days, frozen for 2 years. Maintain buccal swabs at room temperture or refrigerated for 2 months.
Causes for Rejection Hemolysis; quantity not sufficient for analysis; improper container; single buccal swab; wet buccal swab</td></tr>
<tr><td>Cytochrome P450 2C19 Genotyping</td><td>511675</td><td>Volume 5 mL
Collection Collect specimen in alavender-top (EDTA) or yellow-top (ACD) tube. Ship whole blood specimen at room temperature or frozen.
Storage Instructions Maintain whole blood specimen at room temperature or refrigerated for 7 days, frozen for 2 years.
Causes for Rejection Hemolysis; quantity not sufficient for analysis; improper container, buccal swab</td></tr>
<tr><td>Cytochrome P450 2D6/2C19 Genotyping</td><td>511905</td><td>Volume 5 mL
Collection Collect specimen in alavender-top (EDTA) or yellow-top (ACD) tube. Ship whole blood specimen at room temperature or frozen.
Storage Instructions Maintain whole blood specimen at room temperature or refrigerated for 7 days, frozen for 2 years.
Causes for Rejection Hemolysis; quantity not sufficient for analysis; improper container, buccal swab</td></tr>
<tr><td>Cytochrome P450 2D6 Genotyping</td><td>511230</td><td>Volume 5 mL
Collection Collect specimen in alavender-top (EDTA) or yellow-top (ACD) tube. Ship whole blood specimen at room temperature or frozen.
Storage Instructions Maintain whole blood specimen at room temperature or refrigerated for 7 days, frozen for 2 years.
Causes for Rejection Hemolysis; quantity not sufficient for analysis; improper container, buccal swab</td></tr>
<tr><td>Cytochrome P450 3A4/3A5 Genotyping</td><td>504155</td><td>Volume 5 mL whole blood or Labcorp buccal swab kit
Collection Collect specimen in a lavender-top (EDTA) or yellow-top (ACD) tube or use a buccal swab kit. Ship whole blood specimen at room temperature or frozen. Ship buccal swab collection kit at room temperature.
Storage Instructions Maintain whole blood specimen at room temperature or refrigerated for 7 days, frozen for 2 years. Maintain buccal swabs at room temperature or refrigerated for 2 months.
Causes for Rejection Hemolysis; quantity not sufficient for analysis; improper container; single buccal swab; wet buccal swab</td></tr>
<tr><td>Engraftment Monitoring, Pre</td><td>168138</td><td>Container Lavender-top (EDTA) tube, yellow-top (ACD) tube, or Labcorp buccal swab kit. When submitting buccal swabs, please telephone 800-533-1037.</td></tr>
<tr><td colspan="3">NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.</td></tr>
</table>

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Foscarnet Resistance HSV (Phenotype)	**138362**	**Specimen** Actively-growing isolate (preferred) **or** eye, genital, oral, urethral, vesicle, or throat swab (from which HSV isolation will be attempted) **Volume** One cell culture tube **or** one swab in viral transport media **Container** Isolate growing in a permissive cell line (ie MRC-5 or A549) or primary sample in viral transport media (VTM) **Storage Instructions** Maintain isolate at room temperature. Refrigerate viral transport media with swab. Submit as soon as possible, but within five days of collection. **Limitations** This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.
Fungus Culture With Stain	**188243**	**Test Includes** KOH/Calcofluor stain and Fungus (Mycology) Culture [008482]. Calcofluor preparation and culture for fungus; identification (additional charges/CPT code[s] may apply) if culture results warrant. Before results are reported, cultures are held for one to four weeks, based on specimen source: results on sterile body fluids and blood are reported in four weeks; results on hair, skin, and nails are reported in three weeks; results on urine and genital specimens are reported in one week. CPT coding for microbiology and virology procedures often cannot be determined before the culture is performed.
Gabapentin, Serum or Plasma	**716811**	**Methodology** Immunoassay (IA)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus* and Herpes Simplex Virus (HSV) Types 1 and 2, NAA	**198310**	**Volume** ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for ***Chlamydia/Gonococcus***). **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. Specimens collected with the Gen-Probe® Aptima® swab collection kit must arrive intact. **Container** ThinPrep® vial or ThinPrep® vial and Aptima® swab collection kit (for ***Chlamydia/Gonococcus***) **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia* and *Gonococcus:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patients; specimen submitted in a vial that expired according to the manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** liquid-based cytology specimen more than seven days old, Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab or any swab other than the blue-shafted collection swab. **For HSV:** liquid-based cytology specimen more than seven days old.

NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA	**196402**	**Volume** ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for ***Chlamydia/Gonococcus***). **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. Specimens collected with the Gen-Probe® Aptima® swab collection kit must arrive intact. **Container** ThinPrep® vial or ThinPrep® vial and Aptima® swab collection kit (for ***Chlamydia/Gonococcus***) **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia* and *Gonococcus:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patients; specimen submitted in a vial that expired according to the manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** liquid-based cytology specimen more than seven days old, Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab or any swab other than the blue-shafted collection swab.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA and Human Papillomavirus (HPV) (Aptima®)	**193157**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia* and *Gonococcus:*** Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Storage Instructions** Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be done within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for ***Chlamydia/Gonococcus;*** if the Aptima® swab transport is used, it must be tested within 60 days. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the collection swab.

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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA and Human Papillomavirus (HPV) (Aptima®) Detection With Reflex to HPV Genotypes 16 and 18,45 on High-risk Positive Specimens	**199338**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia* and *Gonococcus:*** Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Storage Instructions** Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be done within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for ***Chlamydia/Gonococcus;*** if the Aptima® swab transport is used, it must be tested within 60 days. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the collection swab.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA and Human Papillomavirus (HPV) (Aptima®) With Reflex to HPV Genotypes 16 and 18,45	**199310**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia* and *Gonococcus:*** Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Storage Instructions** Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be done within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for ***Chlamydia/Gonococcus;*** if the Aptima® swab transport is used, it must be tested within 60 days. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the collection swab.

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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U	**199320**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia* and *Gonococcus:*** Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Storage Instructions** Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be done within 21 days of collection. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the collection swab.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U, ASC-H, LSIL, HSIL, AGUS	**199355**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia* and *Gonococcus:*** Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Storage Instructions** Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be done within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for ***Chlamydia/Gonococcus;*** if the Aptima® swab transport is used, it must be tested within 60 days. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the collection swab.

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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas* and Herpes Simplex Virus (HSV) Types 1 and 2, NAA	**198315**	**Volume** ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for C*hlamydia/Gonococcus/Trichomonas*) **Container** ThinPrep® vial or ThinPrep® vial and Aptima® swab collection kit (for ***Chlamydia/Gonococcus/Trichomonas***) **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia, Gonococcus*, and *Trichomonas:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patients; specimen submitted in vial that expired according to the manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For *Chlamydia, Gonococcus*, and *Trichomonas vaginalis:*** liquid-based cytology specimen more than seven days old, Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs; white-shafted cleaning swab or any swab other than the blue-shafted collection swab. **For HSV:** liquid-based cytology specimen more than seven days old.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA	**196502**	**Volume** ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for C*hlamydia/Gonococcus/Trichomonas*) **Container** ThinPrep® vial or ThinPrep® vial and Aptima® swab collection kit (for ***Chlamydia/Gonococcus/Trichomonas***) **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia, Gonococcus*, and *Trichomonas:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patients; specimen submitted in vial that expired according to the manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For *Chlamydia, Gonococcus*, and *Trichomonas vaginalis:*** liquid-based cytology specimen more than seven days old, Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs; white-shafted cleaning swab or any swab other than the blue-shafted collection swab.
NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.		

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA and Human Papillomavirus (HPV) (Aptima®)	**199328**	**Volume** ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for *Chlamydia/Gonococcus/Trichomonas*) **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for *Chlamydia/Gonococcus/Trichomonas*) **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia, Gonococcus,* and *Trichomonas:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Storage Instructions** Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be done within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for *Chlamydia/Gonococcus/Trichomonas;* if the Aptima® swab transport is used, it must be tested within 60 days. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to the manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia, Gonococcus,* and *Trichomonas vaginalis:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the blue-shafted collection swab.
NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.		

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA and Human Papillomavirus (HPV) (Aptima®) Detection With Reflex to HPV Genotypes 16 and 18,45 on High-risk Positive Specimens	**199334**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia, Gonococcus,* and *Trichomonas:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Storage Instructions** Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be done within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for *Chlamydia/Gonococcus/Trichomonas;* if the Aptima® swab transport is used, it must be tested within 60 days. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to the manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia, Gonococcus,* and *Trichomonas vaginalis:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the blue-shafted collection swab.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA and Human Papillomavirus (HPV) (Aptima®) With Reflex to HPV Genotypes 16 and 18,45	**199315**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia, Gonococcus,* and *Trichomonas:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Storage Instructions** Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be done within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for *Chlamydia/Gonococcus/Trichomonas;* if the Aptima® swab transport is used, it must be tested within 60 days. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to the manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia, Gonococcus,* and *Trichomonas vaginalis:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the collection swab.

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Test Updates

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Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U	**199325**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia, Gonococcus,* and *Trichomonas:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Storage Instructions** Maintain specimen at room temperature. Specimens must be processed for testing within 21 days of collection for Pap. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to the manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia, Gonococcus,* and *Trichomonas vaginalis:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the collection swab.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U, ASC-H, LSIL, HSIL, AGUS	**199360**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia, Gonococcus,* and *Trichomonas:*** Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Storage Instructions** Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be done within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for *Chlamydia/Gonococcus/Trichomonas;* if the Aptima® swab transport is used, it must be tested within 60 days.. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to the manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia, Gonococcus,* and *Trichomonas vaginalis:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the collection swab.

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Test Updates

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Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia trachomatis*, NAA	**197676**	**Volume** ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for Chlamydia) **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. Specimens collected with the Gen-Probe® Aptima® swab collection kit must arrive intact. **Container** ThinPrep® vial or ThinPrep® vial and Aptima® swab collection kit (for ***Chlamydia***) **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For *Chlamydia trachomatis:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the blue-shafted collection swab.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Herpes Simplex Virus (HSV) Types 1 and 2, NAA	**198300**	**Volume** ThinPrep® vial **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HSV:** liquid-based cytology specimen more than seven days old.

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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) (Aptima®)	**199330**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Storage Instructions** Maintain liquid-based cytology specimen at room temperature. Pap processing must be performed within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) (Aptima®) Detection With Reflex to HPV Genotypes 16 and 18,45 on High-risk Positive Specimens	**199344**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Storage Instructions** Maintain liquid-based cytology specimen at room temperature. Pap processing must be performed within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial.

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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) (Aptima®) With Reflex to HPV Genotypes 16 and 18,45	**199305**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Storage Instructions** Maintain liquid-based cytology specimen at room temperature. Pap processing must be performed within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U	**199300**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U, ASC-H, LSIL, HSIL, AGUS	**199345**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial.

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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U With Reflex to HPV Genotypes 16 and 18,45	**199340**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial.
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA	**192120**	**Volume** ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for ***Chlamydia/Gonococcus***) **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. Specimens collected with the Gen-Probe® Aptima® swab collection kit must arrive intact. **Container** ThinPrep® vial or ThinPrep® vial and Aptima® swab collection kit (for ***Chlamydia/Gonococcus***) **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia* and *Gonococcus:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the blue-shafted collection swab.
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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA	**192520**	**Volume** ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for ***Chlamydia/Gonococcus/Trichomonas***) **Container** ThinPrep® vial or ThinPrep® vial and Aptima® swab collection kit (for ***Chlamydia/Gonococcus/Trichomonas***) **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia, Gonococcus,* and *Trichomonas:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For *Chlamydia, Gonococcus,* and *Trichomonas vaginalis:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the blue-shafted collection swab.
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia trachomatis*, NAA	**192138**	**Volume** ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for ***Chlamydia***) **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. Specimens collected with the Gen-Probe® Aptima® swab collection kit must arrive intact. **Container** ThinPrep® vial or ThinPrep® vial and Aptima® swab collection kit (for ***Chlamydia***) **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Optional Dedicated Specimen for *Chlamydia:*** Use the Gen-Probe® Aptima® swab collection kit. (**Note:** Do **not** use the Gen-Probe® PACE DNA probe collection kit.) Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For *Chlamydia trachomatis:*** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the blue-shafted collection swab.

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Test Updates

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Gynecologic Pap Test–Age-based Guideline for Cervical Cancer (Aptima®)	**193065**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Storage Instructions** Maintain liquid-based cytology specimen at room temperature. Pap processing must be performed within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial.
Gynecologic Pap Test–Age-based Guideline for Cervical Cancer (Aptima®) and STDs	**193060**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Storage Instructions** Maintain liquid-based cytology specimen at room temperature. Pap processing must be performed within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for *Chlamydia/Gonococcus.* **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** liquid-based cytology specimen more than seven days old.

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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Gynecologic Pap Test–Age-based Guideline for Cervical Cancer (Aptima®) Plus *Chlamydia/Gonococcus*	**193070**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Storage Instructions** Maintain liquid-based cytology specimen at room temperature. Pap processing must be performed within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for *Chlamydia/Gonococcus.* **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia trachomatis* and *Neisseria gonorrhoeae:*** liquid-based cytology specimen more than seven days old.
Gynecologic Pap Test–Age-based Guideline for Cervical Cancer (Aptima®) Plus *Chlamydia/ Gonococcus/Trichomonas*	**193075**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Storage Instructions** Maintain liquid-based cytology specimen at room temperature. Pap processing must be performed within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for *Chlamydia/Gonococcus/Trichomonas.* **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For *Chlamydia trachomatis, Neisseria gonorrhoeae,* and *Trichomonas vaginalis:*** liquid-based cytology specimen more than seven days old.
Hepatitis C Virus (HCV) Antibody	**140659**	**Use** Qualitative detection of antibodies to HCV. Per current guidelines, this test should not be used alone to screen for and diagnose HCV infection. HCV antibody positive patients should be tested for HCV RNA to differentiate between previous and active infection. **References** American Association for the Study of Liver Diseases, Infectious Diseases Society of America. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. HCV Guidelines web site. https://www.hcvguidelines.org/evaluate/testing-and-linkage. Accessed December 2020. Workowski KA, Bolan GA, Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recomm Rep.* 2015 Jun 5;64(RR-03):1-137. PubMed 26042815
Heparin Cofactor II	**500187**	**Reference Interval** In healthy adults, heparin cofactor II reference range in plasma is 65% to 145%. Plasma levels of heparin cofactor II are approximately 50% of adult levels at birth and reach adult levels at six months of age.

NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Herpes Simplex Virus (HSV) Types 1/2 Phenotyping for Acyclovir Drug Resistance	**138370**	**Specimen** Actively-growing isolate (preferred) **or** eye, genital, oral, urethral, vesicle, or throat swab (from which HSV isolation will be attempted) **Volume** One cell culture tube **or** one swab in viral transport media **Container** Isolate growing in a permissive cell line (ie MRC-5 or A549) or primary sample in viral transport media (VTM) **Storage Instructions** Maintain isolate at room temperature. Refrigerate viral transport media with swab. Submit as soon as possible, but within five days of collection. **Limitations** This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.
Herpes Simplex Virus (HSV) Types 1 and 2, NAA	**188056**	**Container** Aptima® unisex or Aptima® vaginal swab transport or ThinPrep® liquid cytology vial **Collection Lesion/vesicle swab:** Unroof or scrape the lesion with an Aptima® swab. **Vaginal swab:** ***Care provider specimen:*** Collect vaginal fluid sample using the GenProbe® Aptima® vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. ***Patient self-collection:*** Partially open the package of the GenProbe® Aptima® vaginal swab kit. Do **not** touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima® swab specimen collection kit. Remove the swab. Carefully insert the swab into the vagina about two inches past the vaginal opening and gently rotate the swab for 10 to 30 seconds, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. **Endocervical swab in Aptima®:** Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shafted swab in the package with red printing). **Discard this swab.** Insert the specimen collection swab (blue-shafted swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the scoreline using care to avoid splashing of the contents. Recap the swab specimen transport tube tightly. **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Urine specimen; specimen transported under inappropriate conditions; bacterial swabs; unlabeled specimen or discrepancy between specimen label and test request form; Aptima® COMBO 2 (AC2) swab specimen transport tube with two swabs or swab not supplied by Gen-Probe® or no swab; ProbeTec™ swabs; female urethral swab; SurePath™ vial; Aptima® swab transports >7 days from collection
Human Papillomavirus (HPV) (Aptima®)	**507800**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For HPV:** specimen more than three months old in ThinPrep® vial.
NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.		

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Human Papillomavirus (HPV) (Aptima®) With Reflex to HPV Genotypes 16 and 18,45	**507805**	**Volume** ThinPrep® vial **Minimum Volume** A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For HPV:** specimen more than three months old in ThinPrep® vial.
Human Papillomavirus (HPV) Genotypes 16 and 18,45	**507810**	**Volume** ThinPrep® vial **Minimum Volume** ThinPrep® vial 2 mL (**Note:** This volume does **not** allow for repeat testing.) **Container** ThinPrep® vial **Collection** **ThinPrep® Vial – Broom or Brush/Spatula** ***Broom-like collection technique:*** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial. ***Brush/spatula technique:*** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial. **Causes for Rejection** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For HPV:** specimen more than three months old in ThinPrep® vial.
Microarray-Products of Conception (POC) Reveal® FFPE	**511997**	**Special Instructions** (added) If prior NIPT studies have been performed, include copy of the report.
NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.		

Test Updates

<table>
<tr><th>Test Name</th><th>Test No.</th><th>Field/Change (Only fields that change are included here.)</th></tr>
<tr><td>Neisseria gonorrhoeae, NAA</td><td>188086</td><td>
Container Gen-Probe® Aptima® swab or Aptima® urine specimen transport; ThinPrep® liquid cytology vial
Collection
Option 1: Gen-Probe® Aptima® Endocervical, Male Urethral, or Vaginal Swab
Endocervical swab: Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shaft swab in the package with red printing). Discard this swab. Insert the specimen collection swab (blue-shaft swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of the contents. Recap the swab specimen transport tube tightly.
Male urethral swab: The patient should not have urinated for at least one hour prior to specimen collection. Insert the specimen collection swab (blue-shaft swab in the package with the green printing) 2 to 4 cm into the urethra. Gently rotate the swab clockwise for two to three seconds in the urethra to ensure adequate sampling. Withdraw the swab carefully. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of contents. Recap the swab specimen transport tube tightly.
Vaginal swab: Care provider specimen: Collect vaginal fluid sample using the Gen-Probe® Aptima® vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap.
Patient self-collection: Partially open the package of the Gen-Probe® Aptima® vaginal swab kit. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima® swab specimen collection kit. Remove the swab. Carefully insert the swab into the vagina about two inches past the introitus and gently rotate the swab for 10 to 30 seconds, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap.
Option 2: Urine Specimen: The patient should not have urinated for at least one hour prior to specimen collection. Direct patient to provide a first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity; lesser volumes may not adequately rinse organisms into the specimen. Female patients should not cleanse the labial area prior to providing the specimen. Add urine to the Aptima® Combo 2 urine collection device. The final volume must be between the two black lines on the device (about 2 mL).
Option 3: Liquid-based Cytology Specimen
ThinPrep® Vial – Broom or Brush/Spatula
Broom-like collection technique: Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.
Brush/spatula technique: Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do not over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.
Causes for Rejection Specimen with incorrect patient identification; unlabeled specimen; inappropriate specimen transport conditions; specimen leaked in transit; specimen in expired transport or incorrect transport device; specimens with inappropriate source for test requested; specimen with fixative or additives; APTIMA® urine transport >30 days from collection; APTIMA® urine transport with incorrect specimen volume; <15 mL urine submitted in sterile container; receipt of urine in sterile container >72 hours from collection; APTIMA® swab transport >60 days from collection; APTIMA® swab specimens with incorrect specimen volume; APTIMA® swab specimen without a swab; cleaning swab (white-shaft swab) in APTIMA® swab transport; any non-Gen-Probe® swab submitted in APTIMA® transport device; wooden-shafted swab in transport device; transport device with multiple swabs; female urethral swab; bloody or grossly mucoid specimens; bacterial swabs; specimen in ProbeTec™ UPT transport; ProbeTec™ Q-swabs; BD ProbeTec™ ET male urethral swab; swab specimen in universal transport media or viral transport media; SurePath™ vial
</td></tr>
<tr><td>Neuron-specific Enolase (NSE)</td><td>140624</td><td>
Volume 0.5 mL
Stability
<table>
<tr><th>Temperature</th><th>Period</th></tr>
<tr><td>Room temperature</td><td>7 days</td></tr>
<tr><td>Refrigerated</td><td>7 days</td></tr>
<tr><td>Frozen</td><td>14 days</td></tr>
<tr><td>Freeze/thaw cycles</td><td>Stable x3</td></tr>
</table>
Causes for Rejection Hemolysis; gross icterus; plasma specimen
Use An aid in the detection and monitoring of neuroendocrine tumors (NETs), particularly those associated with small-cell lung cancer (SCLC)
</td></tr>
<tr><td colspan="3">NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.</td></tr>
</table>

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Neuron-specific Enolase (NSE) (continued)	**140624**	**Limitations** Results of this test are labeled for research purposes only by the assay's manufacturer. The performance characteristics of this assay have not been established by the manufacturer. The result should not be used for treatment or for diagnostic purposes without confirmation of the diagnosis by another medically established diagnostic product or procedure. The performance characteristics were determined by Labcorp. Because erythrocytes a contain large amount of NSE, hemolysis can cause falsely elevated levels.[1] **Methodology** The ThermoFisher/BRAHMS KRYPTOR® assay employs Time-Resolved Amplified Cryptate Emission (TRACE) technology based on a non-radioactive energy transfer between a donor (europium cryptate) and an acceptor (XL665) in a sandwich immunofluorescent format using two mouse monoclonal antibodies. **Reference Interval** 0.0–17.6 ng/mL **Additional Information** Neuron-specific enolase (NSE) is an enzyme that is found in the cytoplasm of neurons and neuroendocrine cells.[2,3] The production of NSE occurs late in neural differentiation, thus making NSE an index of neural maturation.[2] Increased serum levels of NSE may occur in patients with of neuroendocrine tumors (NETs).[2,4-13] A number of NETs are considered to be "nonfunctioning" in that they do not produce elevated serum concentrations of substances that cause endocrine symptoms. NSE is similar to chromogranin A (CgA) in that it can serve as a general neuroendocrine tumor marker that can be of clinical value in in the assessment of non-functioning tumors.[4,14] NSE can be particularly useful in the assessment of patients with high-grade, poorly differentiated tumors.[4,14] Serum NSE levels are often elevated in patients with small-cell lung cancer (SCLC) and NSE levels are applied as a biomarker for disease staging and monitoring.[3,11,13-27] NSE levels have been shown to correlate with tumor burden, number of metastatic sites and response to treatment in SCLC.[6,28,29] A meta-analysis of 11 studies determined that SCLC patients with higher levels of NSE had a poorer prognosis than those with lower levels of NSE.[30] Increased levels of NSE have been also reported in non-small cell lung cancer (NSCLC).[2,31,32] Differentiation between SCLC and NSCLC can have prognostic and therapeutic value, due to the dissimilar behavior of these malignancies.[2,33] In a comparative analysis of the performance of several NSE assays, Stern and coworkers found that the Brahms Kryptor assay had a 22% sensitivityfor distinguishing cancer patients (SCLC and NSCLS) from benign lung disease with a specificity of 95% using a cut-off concentration of 20 ug/L.[34] In the same study, the Brahms assay had a 55% sensitivity for distinguishing SCLC form NSCLS at 95% specificity,[34] employing an NSE cut-off of 21ug/L. This was the highest sensitivity of the seven NSE methods evaluated. Raised serum levels of NSE have been found in patients with neuroblastoma, especially in widespread and metastatic disease, with high serum levels correlated with significantly worse outcome in terms of disease-free survival.[35-37] Increased serum NSE levels have also been observed in patients with diverse conditions including: melanoma, seminoma, renal cell carcinoma, Merkel cell tumor, carcinoid tumors, dysgerminomas and immature teratomas, malignant pheochromocytoma, Guillain-Barrésyndrome and Creutzfeldt-Jakob disease.[2] Measurement of serum NSE has been applied to the assessment of neuronal injury[37] and the estimation of brain damage in conditions including: ischemic stroke,38 intracerebral hemorrhage,[39,40] seizure,[41] after cardiopulmonary resuscitation for cardiac arrest[42] and in traumatic brain injury.[43] **Footnotes** 1. Ramont L, Thoannes H, Volondat A, Chastang F, Millet MC, Marquart MF. Effects of hemolysis and storage condition on neuron-specific enolase (NSE) in cerebrospinal fluid and serum: implications in clinical practice. *Clin Chem Lab Med.* 2005;43(11):1215-1217. 2. Isgrò MA, Bottoni P, Scatena R. Neuron-Specific Enolase as a Biomarker: Biochemical and Clinical Aspects. *Adv Exp Med Biol.* 2015;867:125-143. PubMed 26530364 3. Hofland J, Zandee WT, de Herder WW. Role of biomarker tests for diagnosis of neuroendocrine tumors. *Nat Rev Endocrinol.* 2018 Nov;14(11):656-669. PubMed 30158549 4. Oberg K, Jelic S; ESMO Guidelines Working Group. Neuroendocrine gastroenteropancreatic tumors: ESMO clinical recommendation for diagnosis, treatment and follow-up. *Ann Oncol.* 2009 May;20 Suppl 4:150-153. PubMed 19454440 5. Korse CM, Taal BG, Vincent A, et al. Choice of tumour markers in patients with neuroendocrine tumors is dependent on the histological grade. A marker study of Chromogranin A, Neuron specific enolase, Progastrin-releasing peptide and cytokeratin fragments. *Eur J Cancer.* 2012 Mar;48(5):662-671. PubMed 21945100 6. Yao JC, Pavel M, Phan AT, et al. Chromogranin A and neuron-specific enolase as prognostic markers in patients with advanced pNET treated with everolimus. *J Clin Endocrinol Metab.* 2011 Dec;96(12):3741-3749. PubMed 21994954 7. O'Toole D, Grossman A, Gross D, et al. ENETS Consensus Guidelines for the Standards of Care in Neuroendocrine Tumors: biochemical markers. *Neuroendocrinology.* 2009;90(2):194-202. PubMed 19713711 8. de Herder WW. Biochemistry of neuroendocrine tumors. *Best Pract Res Clin Endocrinol Metab.* 2007 Mar;21(1):33-41. PubMed 17382264 9. Eriksson B, Oberg K, Stridsberg M. Tumor markers in neuroendocrine tumors. *Digestion.* 2000;62 Suppl 1:33-38. PubMed 10940685 10. Bajetta E, Ferrari L, Martinetti A, et al. Chromogranin A, neuron specific enolase, carcinoembryonic antigen, and hydroxyindole acetic acid evaluation in patients with neuroendocrine tumors. *Cancer.* 1999 Sep 1;86(5):858-865. PubMed 10463986 11. Baudin E, Gigliotti A, Ducreux M, et al. Neuron-specific enolase and chromogranin A as markers of neuroendocrine tumors. *Br J Cancer.* 1998 Oct;78(8):1102-1107. PubMed 9792158 12. Jiang SX, Kameya T, Shoji M, Dobashi Y, Shinada J, Yoshimura H. Large cell neuroendocrine carcinoma of the lung: a histologic and immunohistochemical study of 22 cases. *Am J Surg Pathol.* 1998 May;22(5):526-537. PubMed 9591721 13. Nobels FR, Kwekkeboom DJ, Coopmans W, et al. Chromogranin A as serum marker for neuroendocrine neoplasia: comparison with neuron-specific enolase and the alpha-subunit of glycoprotein hormones. *J Clin Endocrinol Metab.* 1997 Aug;82(8):2622-2628. PubMed 9253344 14. Oberg K, Couvelard A, Delle Fave G, et al. ENETS Consensus Guidelines for Standard of Care in Neuroendocrine Tumours: Biochemical Markers. *Neuroendocrinology.* 2017;105(3):201-211. PubMed 28391265 15. Petrović M, Bukumirić Z, Zdravković V, Mitrović S, Atkinson HD, Jurišić V. The prognostic significance of the circulating neuroendocrine markers chromogranin A, pro-gastrin-releasing peptide, and neuron-specific enolase in patients with small-cell lung cancer. *Med Oncol.* 2014 Feb;31(2):823. PubMed 24375395

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Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Neuron-specific Enolase (NSE) (continued)	**140624**	**Footnotes (continued)** 16. Kanakis G, Kaltsas G. Biochemical markers for gastroenteropancreatic neuroendocrine tumors (GEP-NETs). *Best Pract Res Clin Gastroenterol.* 2012 Dec;26(6):791-802. PubMed 23582919 17. Franjević A, Pavićević R, Bubanović G. Differences in initial NSE levels in malignant and benign diseases of the thoracic wall. *Clin Lab.* 2012;58(3-4):245-252. PubMed 22582497 18. Kulpa J, Wójcik E, Reinfuss M, Kołodziejski L. Carcinoembryonic antigen, squamous cell carcinoma antigen, CYFRA 21-1, and neuron-specific enolase in squamous cell lung cancer patients. *Clin Chem.* 2002 Nov;48(11):1931-1937. PubMed 12406978 19. Giovanella L, Ceriani L, Bandera M, Garancini S. Immunoradiometric assay of chromogranin A in the diagnosis of small cell lung cancer: comparative evaluation with neuron-specific enolase. *Int J Biol Markers.* Jan-Mar 2001;16(1):50-55. PubMed 11288956 20. 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The North American Neuroendocrine Tumor Society Consensus Guidelines for Surveillance and Medical Management of Midgut Neuroendocrine Tumors. *Pancreas.* 2017 Jul;46(6):707-714. PubMed 28609356 29. Yao JC, Lombard-Bohas C, Baudin E, et al. Daily oral everolimus activity in patients with metastatic pancreatic neuroendocrine tumors after failure of cytotoxic chemotherapy: a phase II trial. *J Clin Oncol.* 2010 Jan 1;28(1):69-76 PubMed 19933912 30. Zhao WX, Luo JF. Serum neuron-specific enolase levels were associated with the prognosis of small cell lung cancer: a meta-analysis. *Tumour Biol.* 2013 Oct;34(5):3245-3248. PubMed 23775010 31. Molina R, Auge JM, Filella X, et al. Pro-gastrin-releasing peptide (proGRP) in patients with benign and malignant diseases: comparison with CEA, SCC, CYFRA 21-1 and NSE in patients with lung cancer. *Anticancer Res.* May-June 2005;25(3A):1773-1778. PubMed 16033098 32. Giovanella L, Piantanida R, Ceriani, L et al. Immunoassay of neuron-specific enolase (NSE) and serum fragments of cytokeratin 19 (CYFRA 21.1) as tumor markers in small cell lung cancer: clinical evaluation and biological hypothesis. *Int J Biol Markers.* Jan-Mar 1997;12(1):22-26. PubMed 9176714 33. Paone G, De Angelis G, Munno R, et al. Discriminant analysis on small cell lung cancer and non-small cell lung cancer by means of NSE and CYFRA-21.1. *Eur Respir J.* 1995 Jul;8(7):1136-1140. PubMed 7589398 34. Stern P, Bartos V, Uhrova J, et al. Performance characteristics of seven neuron-specific enolase assays. *Tumour Biol.* 2007;28(2):84-92. PubMed 17259755 35. Riley RD, Heney D, Jones DR, et al. A systematic review of molecular and biological tumor markers in neuroblastoma. *Clin Cancer Res.* 2004 Jan 1;10(1 Pt 1):4-12. PubMed 14734444 36. Zeltzer PM, Marangos PJ, Evans AE, Schneider SL. Serum neuron-specific enolase in children with neuroblastoma. Relationship to stage and disease course. *Cancer.* 1986 Mar 15;57(6):1230-1234. 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NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
2019 Novel Coronavirus (COVID-19), NAA	**139900**	**Special Instructions** (added) We have been regularly tracking mutations of the virus throughout the pandemic to determine the impact it would have on our test sensitivity. To date, we have not seen any impact.
2019 Novel Coronavirus (COVID-19), NAA using Saliva Collection	**139945**	**Container** Oragene saliva collection tube
2019 Novel Coronavirus (COVID-19) with Influenza A and Influenza B	**140147**	**Special Instructions** (added) We have been regularly tracking mutations of the virus throughout the pandemic to determine the impact it would have on our test sensitivity. To date, we have not seen any impact.
2019 Novel Coronavirus (COVID-19) with Influenza A, Influenza B and Respiratory Syncytial Virus, NAA	**140140**	**Special Instructions** (added) We have been regularly tracking mutations of the virus throughout the pandemic to determine the impact it would have on our test sensitivity. To date, we have not seen any impact.
2019 Novel Coronavirus (COVID-19) with Respiratory Syncytial Virus, NAA	**140172**	**Special Instructions** (added) We have been regularly tracking mutations of the virus throughout the pandemic to determine the impact it would have on our test sensitivity. To date, we have not seen any impact.
Organism Identification by Matrix-assisted Laser Desorption/Ionization Time-of-Flight MS With Reflex to Sequence-based Identification	**183402**	**Special Instructions** Susceptibility testing may be requested for an additional charge. The client submitting the isolate for testing should provide Labcorp with clinical and testing information regarding test procedures already performed at the submitting laboratory in order to expedite testing on receipt. Broth medium containing a pure culture may be submitted for testing; however, additional time will be required in order to perform subculture to solid media prior to initiation of MALDI testing. Testing will reflex to sequencing when ID cannot be determined by MALDI-TOF. **Specimen** Pure culture isolate of bacteria, yeast, filamentous fungi, AFB, *Nocardia,* or aerobic *Actinomycetes* **Causes for Rejection** Isolate nonviable; unlabeled specimen or name discrepancy between the specimen and the name in the computer or on the test request form; isolate transported under inappropriate conditions; broken tube or plate; mixed culture; single specimen identifier **Limitations** Broth medium containing a pure culture may be submitted for testing; however, additional time will be required in order to perform subculture to solid media prior to initiation of MALDI testing. The technology is limited to what is claimed in the spectral database. If organism is not obtained, the test will reflex to identification by ITS gene sequencing.
Rheumatoid Factor by Turbidimetry, Synovial Fluid (RDL)	**520164**	**Name** Changed from "Rheumatoid Factor by Turbidimetry, Body Fluid (RDL)" **Specimen** Synovial fluid **only** **Container** Transport tube or other container **Collection** Collect synovial fluid aseptically into tube or other container. **Causes for Rejection** Grossly hemolyzed; bacterial contamination; lipemic, icteric, non-synovial body fluids
SARS-CoV-2 Antibodies, Nucleocapsid	**164068**	**Name** Changed from "SARS-CoV-2 Antibodies" **Use** Qualitative detection of high affinity antibodies to SARS-CoV-2 nucleocapsid (N) protein, the virus that causes COVID-19, to aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. This assay enriches detection of higher affinity antibodies which are more likely to be specific for SARS-CoV-2 N protein. While this assay in principle can detect high affinity antibodies of all isotypes (i.e., IgG, IgA, IgM), it preferentially detects IgG antibodies since these are more likely to evolve to become high affinity. Serologic results should not be used as the sole basis to diagnosis or exclude recent SARS-CoV-2 infection. This test is recommended for individuals at greater than or equal to 14 days post-symptom onset or following exposure to individuals with confirmed COVID-19.The incubation period for COVID-19 ranges from 5 to 7 days.
SARS-CoV-2 Antibody, IgG, Spike	**164055**	**Name** Changed from "SARS-CoV-2 Antibody, IgG" **Synonyms** COVID-19; S protein; Severe Acute Respiratory Syndrome (SARS); Spike **Stability** Temperature / Period: Room temperature / 14 days; Refrigerated / 14 days; Frozen / 14 days; Freeze/thaw cycles / Stable x3 **Use** Qualitative detection of IgG antibodies to SARS-CoV-2, the virus that causes COVID-19, to help identify individuals who have been exposed to the virus. Serologic results should not be used as the sole basis to diagnose or exclude recent SARS-CoV-2 infection. This test is recommended in individuals at least 10 days post symptom onset or following exposure to individuals with confirmed COVID-19. The incubation period for COVID-19 ranges from 5 to 7 days. Current literature suggests that detectable IgG-class antibodies against SARS-CoV-2 develop approximately 8 to 11 days following onset of symptoms. Correlation with epidemiologic risk factors and other clinical and laboratory findings is recommended. A positive serological result is not diagnostic but indicates that an individual has likely been infected with SARS-CoV-2 and produced an immune response to the virus. It is not known at this time whether detectable antibody correlates with immunity. A negative serologic result indicates that an individual has not developed detectable antibodies at the time of testing. While contingent on a variety of factors, this could be due to testing too early in the course of infection, the absence of exposure to the virus, or the lack of adequate immune response, which can be due to conditions or treatments that suppress immune function.
SARS-CoV-2 Semi-Quantitative Total Antibody, Spike	**164090**	**Name** Changed from "SARS-CoV-2 Semi-Quantitative Total Antibody"

NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.

Test Updates

<table>
<tr><th>Test Name</th><th>Test No.</th><th>Field/Change (Only fields that change are included here.)</th></tr>
<tr><td>Selenium, Serum or Plasma</td><td>716910</td><td>Reference Interval
<table>
<tr><th>Age</th><th>Male</th><th>Female</th></tr>
<tr><td>0 to 4 m</td><td>25–111</td><td>25–111</td></tr>
<tr><td>5 to 10 m</td><td>23–131</td><td>23–131</td></tr>
<tr><td>11 m to 1 y</td><td>38–150</td><td>38–150</td></tr>
<tr><td>2 to 5 y</td><td>59–168</td><td>59–168</td></tr>
<tr><td>6 to 12 y</td><td>73–177</td><td>73–177</td></tr>
<tr><td>13 to 18 y</td><td>81–188</td><td>81–188</td></tr>
<tr><td>>18 y</td><td>93–198</td><td>93–198</td></tr>
<tr><td colspan="3">Environmental exposure: 79–326 µg/L</td></tr>
</table></td></tr>
<tr><td>SNP Microarray (Direct)–Prenatal (Reveal®)</td><td>510200</td><td>Special Instructions For current chromosome analysis, please order Chromosome Analysis, Amniotic Fluid With Reflex to SNP Microarray (Reveal®) [052104]. Chromosome studies are recommended to detect balanced rearrangements that will not be detected by the array.
Pertinent medical findings must accompany the test request form. A complete Informed Consent and Prenatal Chromosome SNP Microarray Questionnaire should accompany specimens. Call 800-345-4363 to request the Informed Consent and Questionnaire form. If a chromosome study has been performed, it's recommended that it be included with sample submission. If prior NIPT studies have been performed, include copy of the report. If specimens from a twin pregnancy are submitted by request it can be reported if these are DZ or MZ twins. Concurrent maternal cell contamination (MCC) studies (Maternal Cell Contamination [511402]) are recommended. If the specimen does not meet minimum DNA quality and quantity requirements, array testing will be performed on cultured material and test code will be updated to 510100 Prenatal Chromosome Microarray. If cultures are needed and performed by Labcorp, additional days will be required to complete testing. A delay notification will be sent to the client if cultures are necessary. If cultured flasks are submitted under this test code, test code will be changed to 510100.
Specimen A minimum of 10 mL plus additional of amniotic fluid for direct array only and GA is >18+ weeks. Minimum 15 mL plus additional for backup for amniotic fluid for direct array only and GA is 15-17 weeks.
If ordered concurrently for chromosomes, a minimum of 25 mL of amniotic fluid is required. Gender by ultrasound is required. Please submit maternal blood (sodium heparin or EDTA) for maternal cell contamination (MCC) studies. CVS: 15 mg or greater.
Volume 10-15 mL amniotic fluid for direct depending on GA and 25 mL for concurrent array and chromosomes.
Minimum Volume 10 mL plus additional for backup for amniotic fluid if direct only and GA is > 18+ weeks. Minimum 15 mL plus additional for backup for amniotic fluid if direct only and GA is 15-17 weeks.
Causes for Rejection Quantity not sufficient for analysis (less than 10 mL of amniotic fluid or DNA quantity <20 ng/µL); bloody sample</td></tr>
<tr><td>SNP Microarray–Prenatal (Reveal®)</td><td>510100</td><td>Synonyms aCGH; Amniotic Fluid Cultures; CGH; CVS Cultures; Prenatal; Reveal; SNP; SNP Microarray
Special Instructions A completed Informed Consent and Prenatal Chromosome SNP Microarray Questionnaire should accompany specimens. Call 800-345-4363 to request the Informed Consent and Questionnaire form. If a chromosome study has been performed, it's recommended that it be included with sample submission.
If prior NIPT studies have been performed, include copy of the report.
If specimens from a twin pregnancy are submitted by request, it can be reported if these are DZ or MZ twins. Concurrent maternal contamination (MCC) Studies (Maternal Cell Contamination [511402]) are recommended. If Direct Amniotic fluid or chorionic villus sample (CVS) submitted, test code will auto change to 510200 Direct Prenatal Microarray test code. If Direct submitted under test code 510200 doesn't meet requirements for Microarray testing, test code will be changed to 510100 and cultures will be needed.
If cultures are needed and performed by Labcorp, additional days will be required to complete testing. A delay notification will be sent to the client if cultures are necessary.
Specimen Cultured amniotic fluid sample or Chorionic villus sample (CVS) cells. Maternal cell contamination studies are recommended, submit maternal blood (EDTA) using Maternal Cell Contamination [511402].
Volume Two T-25 flasks of cultured cells
Minimum Volume One T-25 flask
Container T-25 flask</td></tr>
<tr><td>SNP Microarray–Products of Conception (POC)/Tissue (Reveal®)</td><td>510110</td><td>Special Instructions Pertinent medical findings must accompany test request form. For formalin fixed paraffin embedded blocks or slides, please use Microarray-Products of Conception (POC) Reveal® FFPE [511997].
If prior NIPT studies have been performed, include copy of the report.</td></tr>
<tr><td>Thyroid Antibodies</td><td>006684</td><td>Test Includes Thyroid Peroxidase (TPO) Ab; Thyroglobulin Antibody</td></tr>
<tr><td>Trichomonas vaginalis, NAA</td><td>188052</td><td>Container Gen-Probe® Aptima® swab or Aptima® urine specimen transport; ThinPrep® liquid cytology vial
Causes for Rejection Specimen with incorrect patient identification; unlabeled specimen; inappropriate specimen transport conditions; specimens received after prolonged delay (usually >72 hours); specimen leaked in transit; specimen in expired transport or incorrect transport device; specimens with inappropriate source for test requested; specimen with fixative or additives; Aptima® urine transport >30 days from collection; Aptima® urine transport with incorrect specimen volume; <15 mL urine submitted in sterile container; receipt of urine in sterile container >24 hours from collection; Aptima® swab transport >60 days from collection; Aptima® swab specimens with incorrect specimen volume; Aptima® swab specimen without a swab; cleaning swab (white-shaft swab) in Aptima® swab transport; any non–Gen-Probe® swab submitted in Aptima® transport device; wooden-shaft swab in transport device; transport device with multiple swabs; female urethral swab; bloody or grossly mucoid specimens; bacterial swabs; specimen in ProbeTec™ UPT transport; ProbeTec™ Q-swabs; UTM-RT; SurePath™ vial</td></tr>
<tr><td colspan="3">NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.</td></tr>
</table>

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Triglycerides	**001172**	**Limitations** If triglyceride is >800 mg/dL, LDL cannot be calculated accurately by the NIH formula. Some women on estrogens and high estrogen oral contraceptives have an increase of triglyceride. Increases occur with pregnancy, similar to those with oral contraceptives. The most common cause of triglyceride increase is inadequate patient fasting. Hypertriglyceridemia is associated with use of thiazide diuretics and β-adrenergic blocking agents. **Additional Information** Triglycerides commonly increase with obesity and may increase with chronic renal or liver disease. A positive association exists between diabetes mellitus and hypertriglyceridemia. Extremely high triglyceride levels suggest the possibility of pancreatitis. **Chylomicronemia,** although associated with pancreatitis, is not accompanied by increased atherogenesis. Chylomicrons are not seen in normal fasting serum, but are found in the sera of normal subjects following a fatty meal as exogenous triglycerides. Left refrigerated, chylomicrons float to the surface of a sample overnight; VLDL remain in suspension. Triglyceride physiologically is carried mostly as very low-density lipoproteins (VLDL). The triglyceride in VLDL is endogenous from hepatic synthesis. When turbidity of blood, serum, or plasma is seen, triglyceride is often >350 mg/dL. **Fasting chylomicronemia** occurs with but is not limited to deficiency of apo-CII (apolipoprotein work-up). It occurs also with deficiency of **lipoprotein lipase,** an enzyme. A positive association exists between gout and hypertriglyceridemia. Drug effects have been summarized.[4] **Footnotes** 1. Rifkind BM, Segal P. Lipid Research Clinics Program reference values for hyperlipidemia and hypolipidemia. *JAMA.* 1983 Oct 14; 250(14):1869-1872. PubMed 6578354 2. Brunzell JD, Austin MA. Plasma triglyceride levels and coronary disease. *N Engl J Med.* 1989 May 11; 320(19):1273-1275. PubMed 2710207 3. Faulkner WR. Triglycerides–What do they mean? *Lab Report for Physicians.* 1987; 9:49-52. 4. Steinmetz J, Jouanel P, Thuillier Y. Triglycerides. In Siest G, Galteau MM, eds. *Drug Effects on Laboratory Test Results Analytical Interferences and Pharmacological Effects.* Littleton, Mass: PSG Publishing Co Inc; 1988:405-422.
Uric Acid	**001057**	**Reference Interval** • Male:[1] – 0 to 30 days: 3.9–7.8 mg/dL – 1 to 6 months: 1.9–8.1 mg/dL – 7 to 11 months: 2.0–6.5 mg/dL – 1 to 11 years: 2.2–5.5 mg/dL – 12 years: 2.9–7.0 mg/dL – 13 to 17 years: 3.9–7.7 mg/dL – 18 years and older: 3.8–8.4 mg/dL • Female: – 0 to 30 days: 2.7–6.5 mg/dL – 1 to 6 months: 2.0–6.6 mg/dL – 7 to 11 months: 2.1–5.7 mg/dL – 1 to 5 years: 2.0–5.0 mg/dL – 6 to 11 years: 2.4–5.6 mg/dL – 12 to 17 years: 2.9–6.1 mg/dL – 18 to 50 years: 2.6–6.2 mg/dL – 51 to 70 years: 3.0–7.2 mg/dL – 71 years and older: 3.1–7.9 mg/dL ***Therapeutic*** target for gout patients: <6.0[2]
Vitamin A and Carotene	**001750**	**Limitations** This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.
NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.		

Test Updates

Test Name	Test No.	Field/Change (Only fields that change are included here.)
Vitamin B2, Whole Blood	**123220**	**Volume** 0.5 mL **Minimum Volume** 0.2 mL (**Note:** This volume does **not** allow for repeat testing.) **Container** EDTA (lavender top) whole blood, preferred. Also acceptable are lithium heparin (green-top) whole blood and sodium heparin (light green-top) whole blood. **Collection** The blood is to be collected by venipuncture into a lavender-top tube containing EDTA and mixed immediately by gentle inversion at least six times to ensure adequate mixing. Do not separate. Transfer whole blood to a labeled amber plastic transport tube with amber stopper and **freeze.** For amber plastic transport tube and amber stopper, order Labcorp No. 23598. If amber tubes are unavailable, cover standard transport tube completely, top and bottom, with aluminum foil. Identify specimen with patient's name directly on the container and the outside of the aluminum foil. Secure with tape. To avoid delays in turnaround time when requesting multiple test on frozen samples, **please submit separate frozen specimens for each test requested.** **Storage Instructions** Specimens should be light-protected, stored **frozen** immediately, and maintained frozen during shipping. **Causes for Rejection** Receipt of non-frozen sample; receipt of plasma or serum specimen; receipt of specimen not protected from light **Reference Interval** 137–370 µg/L. (**Note:** Reference interval reflects Flavin Adenine Dinucleotide (FAD), which accounts for approximately 90% of the total riboflavin in whole blood.) **Use** Detect vitamin B2 deficiency **Limitations** This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration. **Methodology** Liquid chromatography/tandem mass spectrometry (LC/MS-MS) **Additional Information** Vitamin B2 refers to a family of water-soluble flavin vitamins that are critical for metabolism and energy generations in the aerobic cell, through oxidative phosphorylation.[1-4] These compounds are synthesized in plants and microorganisms and occur naturally in three forms: the physiologically inactive riboflavin, and the physiologically active coenzymes flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD). FAD accounts for about 90% of the total riboflavin in tissues. Because of their capacity to transfer electrons, FAD and FMN are essential for proton transfer in the respiratory chain, for the dehydration of fatty acids, the oxidative deamination of amino acids, and for other redox processes.[1-4] The effects of riboflavin deficiency on growth and development have generally been explained in terms of these functions. Flavin derivatives ingested with the diet (FAD, FMN) are dissociated by gastric acid from their protein binding, transformed by phosphatases to riboflavin, and absorbed in the small intestines.[1,2] The reconversion of riboflavin to the coenzymes FMN and FAD occurs in the cytoplasm in many different tissues. Vitamin B2 deficiency is common in many parts of the world, particularly in developing countries.[1,5,6] Several studies have indicated that vitamin B2 deficiency may be widespread in industrialized countries as well, both in the elderly[7,8] and in young adults.[9] Dietary deficiency of riboflavin is characterized by lesions on the lips and the angles of the mouth, fissured and magenta-colored tongue, corneal vascularization and normocytic, normochromic anemia.[1-4] Skin lesions include red scaly, greasy patches on the nose, eyelids, scrotum, and labia and seborrheic dermatitis.[1-4] These symptoms are a consequence of oxidation stress due to the accumulation of lipid peroxides. Vitamin B2 deficiency leads to reduced activity of the flavin-containing enzymes (glutathione reductase and glutathione peroxidase) which, in turn, allows these peroxidase to express their deleterious effects. Vitamin B2 is involved in the metabolism of folate, vitamin B12, vitamin B6, and other vitamins.[10] Plasma vitamin B2 is a determinant of plasma homocysteine level, which is associated with cardiovascular disease, pregnancy complications, and cognitive impairment.[10] Recent studies have suggested that riboflavin may play and important role in the determination of cell fate, which would have implications for growth and development.[3] Specifically, riboflavin deficiency impairs the normal progression of the cell cycle, probably through effects on the expression of regulatory genes, exerted at both the transcriptional and proteomic level.[3] No case of riboflavin toxicity in humans has been reported. **Footnotes** 1. Ball GFM. *Vitamins: their role in the human body.* Oxford: Blackwell Publishing; 2004:289-299. 2. Rivlin RS, Pinto JT. Riboflavin (vitamin B2). In: Rucker RB, Suttie JW, McCormick DB, Machlin LJ, eds. *Handbook of Vitamins.* 3rd ed. New York, NY: Marcel Dekker; 2001:255-273. 3. Powers HJ. Riboflavin (vitamin B-2) and health. *Am J Clin Nutr.* 2003 Jun;77(6):1352-1360. PubMed 12791609 4. Powers HJ, Corfe BM, Nakano E. Riboflavin in development and cell fate. *Subcell Biochem.* 2012;56:229-245. PubMed 22116702 5. Bamji MS, Sarma KV, Radhaiah G. Relationship between biochemical and clinical indices of B-vitamin deficiency. A study in rural school boys. *Br J Nutr.* 1979 May;41(3):431-441. PubMed 465434 6. Boisvert WA, Castañeda C, Mendoza I, et al. Prevalence of riboflavin deficiency among Guatemalan elderly people and its relationship to milk intake. *Am J Clin Nutr.* 1993 Jul;58(1):85-90. PubMed 8317395 7. Bailey AL, Maisey S, Southon S, Wright AJ, Finglas PM, Fulcher RA. Relationships between micronutrient intake and biochemical indicators of nutrient adequacy in a 'free-living' elderly UK population. *Br J Nutr.* 1997 Feb;77(2):225-242. PubMed 9135369 8. Madigan SM, Tracey F, McNulty H, et al. Riboflavin and vitamin B-6 intakes and status and biochemical response to riboflavin supplementation in free-living elderly people. *Am J Clin Nutr.* 1998 Aug;68(2):389-395. PubMed 9701198 9. Benton D, Haller J, Fordy J. The vitamin status of young British adults. *Int J Vitam Nutr Res.* 1997;67(1):34-40. PubMed 9119611 10. Hustad S, Ueland PM, Vollset SE, Zhang Y, Bjørke-Monsen AL, Schneede J. Riboflavin as a determinant of plasma total homocysteine: effect modification by the methylenetetrahydrofolate reductase C677T polymorphism. *Clin Chem.* 2000 Aug;46(8 Pt 1):1065-1071. PubMed 10926884

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Test Updates

<table>
<tr><th>Test Name</th><th>Test No.</th><th>Field/Change (Only fields that change are included here.)</th></tr>
<tr><td>Vitamin B2, Whole Blood (continued)</td><td>123220</td><td>References
Capo-chichi CD, Guéant JL, Lefebvre E, et al. Riboflavin and riboflavin-derived cofactors in adolescent girls with anorexia nervosa. Am J Clin Nutr. 1999 Apr;69(4):672-678. PubMed 10197568
Hautem JY, Morel C, Couderc R, Moussa F. Liquid chromatographic determination of B(2) vitamers in human plasma and whole blood. Clin Chem. 2006 May;52(5):907-908. PubMed 16638966
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<tr><td>Zinc, Serum or Plasma</td><td>001800</td><td>Reference Interval
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<tr><th>Age</th><th>Male</th><th>Female</th></tr>
<tr><td>0 to 2 m</td><td>50–123</td><td>50–123</td></tr>
<tr><td>3 to 4 m</td><td>44–133</td><td>51–124</td></tr>
<tr><td>5 to 10 m</td><td>49–134</td><td>49–134</td></tr>
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<tr><td colspan="3">NOTE: Please consult the online Test Menu at https://www.labcorp.com/tests for the most current test information.</td></tr>
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CPT Code Updates

Test Name	Test No.	CPT (s)
Acetyl Fentanyl, Screen and Confirmation, Urine	**791350**	80307
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA and Human Papillomavirus (HPV) (Aptima®)	**193157**	87491; 87591; 87624; 88175
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA and Human Papillomavirus (HPV) (Aptima®)	**199328**	87491; 87591; 87624; 87661; 88175
Human Immunodeficiency Virus 1 (HIV-1) PhenoSense® (Monogram® Phenotype)	**551800**	87903; 87904(x12)
Human Immunodeficiency Virus 1 (HIV-1) PhenoSense GT® (Monogram® Phenotype/Genotype)	**551690**	87900; 87901; 87903; 87904(x12)

Deleted Tests

Deleted Tests	Test No.	Labcorp Offers	Test No.
Cysticercosis (*Taenia solium*)	**138347**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus* and Herpes Simplex Virus (HSV) Types 1 and 2, NAA and Human Papillomavirus (HPV) High-risk DNA Detection With Reflex to HPV Genotypes 16 and 18	**198320**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus* and Herpes Simplex Virus (HSV) Types 1 and 2, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U	**198345**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus* and Herpes Simplex Virus (HSV) Types 1 and 2, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	**198340**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA and Human Papillomavirus (HPV) DNA With Reflex to Genotypes 16 and 18 and HPV E6/E7 (QuantaSURE®)	**199420**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA and Human Papillomavirus (HPV) DNA With Reflex to HPV E6/E7 (QuantaSURE®)	**199435**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA and Human Papillomavirus (HPV) High-risk DNA Detection	**192153**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA and Human Papillomavirus (HPV) High-risk DNA Detection With Reflex to HPV Genotypes 16 and 18	**197124**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA With Reflex to Human Papillomavirus (HPV) DNA When ASC-U or LSIL and Reflex to HPV E06/E07 (QuantaSURE®)	**199405**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U	**194027**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	**196565**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS With Reflex to HPV Genotypes 16 and 18	**197102**	Please contact your Labcorp representative for testing options.	

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Deleted Tests	Test No.	Labcorp Offers	Test No.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U With Reflex to HPV Genotypes 16 and 18	**197117**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas* and Herpes Simplex Virus (HSV) Types 1 and 2, NAA and Human Papillomavirus (HPV) High-risk DNA Detection With Reflex to HPV Genotypes 16 and 18	**198305**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas* and Herpes Simplex Virus (HSV) Types 1 and 2, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U	**198335**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas* and Herpes Simplex Virus (HSV) Types 1 and 2, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	**198330**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas* and Herpes Simplex Virus (HSV) Types 1 and 2, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U With Reflex to HPV Genotypes 16 and 18	**198385**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA and Human Papillomavirus (HPV) DNA With Reflex to Genotypes 16 and 18 and HPV E6/E7 (QuantaSURE®)	**199425**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA and Human Papillomavirus (HPV) DNA With Reflex to HPV E6/E7 (QuantaSURE®)	**199440**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA and Human Papillomavirus (HPV) High-risk DNA Detection	**196553**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA and Human Papillomavirus (HPV) High-risk DNA Detection With Reflex to Genotypes 16 and 18	**196599**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA With Reflex to Human Papillomavirus (HPV) DNA When ASC-U or LSIL and Reflex to HPV E6/E7 (QuantaSURE®)	**199410**	Please contact your Labcorp representative for testing options.	

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Deleted Tests	Test No.	Labcorp Offers	Test No.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U	**196527**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	**196595**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia trachomatis*, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U	**195677**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia trachomatis*, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	**198888**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Herpes Simplex Virus (HSV) Types 1 and 2, NAA and Human Papillomavirus (HPV) High-risk DNA Detection With Reflex to HPV Genotypes 16 and 18	**198325**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Herpes Simplex Virus (HSV) Types 1 and 2, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U	**198355**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Herpes Simplex Virus (HSV) Types 1 and 2, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	**198350**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) DNA With Reflex to Genotypes 16 and 18 and HPV E6/E7 (QuantaSURE®)	**199415**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) High- and Low-risk DNA Detection	**198190**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) High-risk DNA Detection	**199123**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) High-risk DNA Detection With Reflex to HPV Genotypes 16 and 18	**197146**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U	**194074**	Please contact your Labcorp representative for testing options.	

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Deleted Tests	Test No.	Labcorp Offers	Test No.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	**196250**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS With Reflex to HPV Genotypes 16 and 18	**197116**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U With Reflex to HPV Genotypes 16 and 18	**197132**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus,* NAA and Human Papillomavirus (HPV) High-risk DNA Detection	**192146**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus,* NAA and Human Papillomavirus (HPV) High-risk DNA Detection With Reflex to HPV Genotypes 16 and 18	**197017**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus,* NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U	**192112**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus,* NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	**192104**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus,* NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS With Reflex to HPV Genotypes 16 and 18	**197014**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus,* NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U With Reflex to HPV Genotypes 16 and 18	**197012**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas,* NAA and Human Papillomavirus (HPV) High-risk DNA Detection	**192546**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas,* NAA and Human Papillomavirus (HPV) High-risk DNA Detection With Reflex to HPV Genotypes 16 and 18	**192560**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas,* NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U	**192512**	Please contact your Labcorp representative for testing options.	

Deleted Tests

Deleted Tests	Test No.	Labcorp Offers	Test No.
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	**192504**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia trachomatis*, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U	**193130**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and *Chlamydia trachomatis*, NAA With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	**193148**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and Human Papillomavirus (HPV) High- and Low-risk DNA Detection	**197070**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and Human Papillomavirus (HPV) High-risk DNA Detection	**195050**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation and Human Papillomavirus (HPV) High-risk DNA Detection With Reflex to HPV Genotypes 16 and 18	**192197**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U	**192047**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test, Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	**192630**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test–Age-based Guideline for Cervical Cancer and STDs	**193030**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test–Age-based Guideline for Cervical Cancer Plus *Chlamydia/Gonococcus*	**193035**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test–Age-based Guideline for Cervical Cancer Plus *Chlamydia/Gonococcus/Trichomonas*	**193045**	Please contact your Labcorp representative for testing options.	
Gynecologic Pap Test–Age-based Guideline for Cervical Cancer Screening	**193025**	Please contact your Labcorp representative for testing options.	
Human Papillomavirus (HPV) DNA Detection With Reflex to HPV Genotypes 16 and 18,45	**507815**	Please contact your Labcorp representative for testing options.	
Human Papillomavirus (HPV) High- and Low-risk DNA Detection	**500306**	Please contact your Labcorp representative for testing options.	
Human Papillomavirus (HPV) High-risk DNA Detection	**507301**	Please contact your Labcorp representative for testing options.	
Influenza A and B, Real-time RT-PCR	**186221**	Influenza A and Influenza B, NAA	140165
Insulin, Bovine	**602651**	Please contact your Labcorp representative for testing options.	
Insulin, Porcine	**602650**	Please contact your Labcorp representative for testing options.	
Prostate Cancer Gene 3 (PCA3)	**489160**	Please contact your Labcorp representative for testing options.	
Rheumatoid Arthritis (RA), Quantitative, Fluid, Hemagglutination	**161463**	Please contact your Labcorp representative for testing options.	

The CPT codes listed are in accordance with the current edition of Current Procedural Terminology, a publication of the American Medical Association. CPT codes are provided for the convenience of our clients; however, correct coding often varies from one carrier to another. Consequently, the codes presented here are intended as general guidelines and should not be used without confirming with the applicable payer that their use is appropriate in each case.

LOINC® Map. The Logical Observation Identifiers Names and Codes (LOINC®) corresponding to individual Labcorp published assays is updated on a regular basis at www.labcorp.com.

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