

MediCheck

Rapid Protein Residue Test
Part Number: MDCK-100

Description/ Intended Use

MediCheck is a ready-to-use, high sensitivity rapid test for detection of protein residues on surfaces. MediCheck will turn from green to purple if protein is present in sample. The more protein collected in sample, the quicker and darker the color change. This test is dependent on sample size, time and temperature; therefore, it is important to let the device reach ambient temperature (15-25°C) before testing. Disregard any color change after specified time.

MediCheck is intended to be used for rapid verification of surface cleanliness in industrial applications. It is not intended to be a microbiological monitoring tool or for precise determination of protein content.

Sanitation is usually a two-step process involving a detergent cleaning and subsequent (optional) disinfecting step. Collecting the sample after detergent cleaning and rinsing, but prior to any terminal disinfection, will ensure best results. Product residues left on a surface after detergent cleaning reduces the effectiveness of the disinfectant. MediCheck will also detect other reducing substances such as simple sugars, tannin and ascorbic acid.

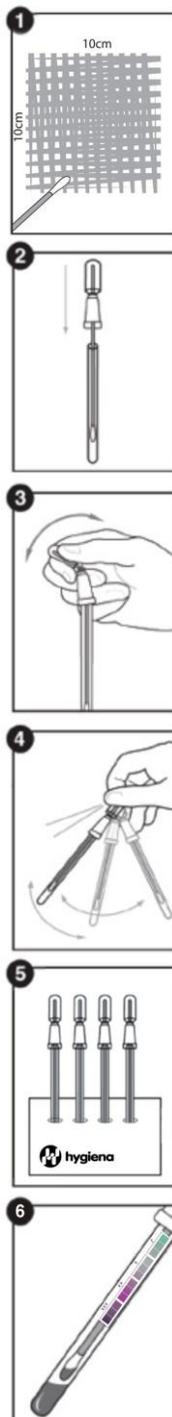
Directions for Use:

1. Ensure that the device is at ambient temperature. Use aseptic technique for sample collection. Do not touch the swab or the inside of the sampling device with fingers. Holding the swab tube, twist and pull the top of the swab out of the swab tube. The swab tip comes pre-moistened with sterile pyrogen-free water. Condensation may be visible on the inside of the swab tube, this is normal. Thoroughly swab a standard 10 x 10 cm (4 x 4 inches) area of interest for a typical flat surface. For irregular surfaces, ensure the swabbing technique remains consistent for each swab and sample a large enough area to collect a good sample. It is important in any sampling program to establish a consistent and easy-to-replicate sampling procedure.
2. After swabbing the area of interest, place swab back in swab tube.
3. To activate device, hold swab tube firmly and use the thumb and forefinger to break the Snap Valve pin by bending the bulb forward and backward. Squeeze the bulb twice, expelling all liquid down the swab shaft.
4. Bathe the swab bud in liquid by gently shaking for 5-10 seconds
5. Incubate at 37°C for 30 minutes or at 55°C for 15 minutes.
6. There is no need to continue timing if color changes to purple before 15 minutes. Compare color of reagent against MediCheck color chart on tube label and record result.

Interpretation of Results

The color of the solution and the time in which the color change occurs will indicate the level of protein residue on surface. By comparing the color of the solution against the MediCheck label, an estimate of surface cleanliness can be made.

- Green ► Pass result = Clean, no further action required
- Grey ► Caution, small amount of residue present = Retest, re-rinse or re-clean, depending on your protocol and procedures.
- Pink/ Purple ► Fail result = Re-clean and re-test.
- **Caution:** At very low levels of protein, 1 micro gram (µg) or 1ppm, when the color intensity is weak (grey) care needs to be taken when interpreting results. Green-grey or any green color should be regarded as a negative for protein, therefore, Pass result. Comparison with a negative control (activated without protein, incubated exactly like the test) should also be conducted.



Sensitivity

The limit of detection of the test is dependent on both temperature and time i.e. Incubation at

- 37°C for 15 minutes will detect 2-3 µg (2 -3 ppm) protein.
- 37°C for 30 minutes will detect 1 µg (1 ppm) protein.
- 55°C for 15 minutes will detect 1 µg (1 ppm) protein.

The background color of the test develops more rapidly at 55°C which could be misinterpreted as a positive test for protein and careful interpretation is required. Comparison with a negative control (activated without protein, incubated exactly like the test) should also be conducted.

Storage

18 months at room or refrigerated temperatures (2° - 25°C)

Sanitizer Information

Common sanitizers at normal concentrations do not cause interference or false positives. High concentrations of alkaline sanitizers may cause false-negative results in some cases. Peroxide based disinfectants can cause a false-positive color change reaction. It is best practice to wait for the appropriate time after sanitizing before testing the surface.

Safety Information

The components of MediCheck do not pose any health risk when used in accordance with standard laboratory practices and procedures in this insert.

For further safety instruction, refer to the MediCheck Material Safety Data Sheet (MSDS).

Contact

If more information is required, please visit us at www.hygiena.com

or contact us at:

Hygiena — Americas

941 Avenida Acaso
Camarillo, CA 93012

Phone: 001.805.388.8007
Fax: 001.805.388.5531
email: enquiries@hygiena.com

Hygiena — International

Unit 11 Wenta Business Centre
Colne Way Watford
Hertfordshire WD24 7ND UK

Phone: ++44 (0)1923 818821
Fax: ++44 (0)1923 818825
email: enquiries@hygiena.com