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Manufactured in Germany for Hygiena.

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RapiScreen™ Dairy 1000 kit

Catalog Number: KIT4000 (82010) • 1,000 assays

Intended Use

The RapiScreen™ Dairy kit together with the Innovate system provide a rapid method to confirm the absence of microbial contamination in long-life dairy, soy and similar products.

Summary of the Test

RapiScreen is a primary screening assay that utilizes the efficient light-producing enzyme system of ATP bioluminescence to detect the absence or presence of microbiological contamination in samples.

The Innovate luminometer controls the addition of reagents, the timing of the reaction, and the recording of any generated light signal, which it reports in relative light units (RLUs). An enrichment step is included in the protocol, prior to performing the screening assay. This enrichment step involves incubation of the product in growth medium for a defined period of time to allow any present microbes to multiply. Often, the product itself is used as a growth medium, allowing the original packaging to be used during incubation.

Kit Configuration	Quantity
Sensilux	10 x 100 assay vials
Dilutor DS	10 x 9.8 ml vials
Cellsolver DE	1 x 101 ml vial
ATX	10 x 100 assay vials
Dilutor DA	10 x 9.8 ml vial
Microwash	1 x 290 ml bottle
PP-vials	4
Microplates, 96 well	11

General Safety Precautions

- Use universal lab safety precautions when performing this assay and when handling samples and materials.
- Intended for *in vitro* use only.
- Dispose of all assay material according to your standard laboratory operating procedure and appropriate prescribed local regulations.

Storage Instructions

- The RapiScreen Dairy kit must be stored at 2-8°C when not in use.
- Do not use kits beyond the stated expiration date.
- Once reconstituted, the reagents will remain stable for up to 5 days when stored in the Innovate reagent cooling unit.

Handling Precautions

- Gloves should be worn when running the test to prevent contamination.
- Do not mix reagents from different kit lots.
- Observe standard aseptic procedures when handling or transferring samples and reagents.

Additional Materials Required

- Innovate system
- ATP Positive Control kit
- Pipette and tips

Preparation

- 1) Remove one vial of each reagent from storage at 2-8°C. In order to avoid contamination from hands, wear gloves when opening the glass vial.
- 2) Carefully open a vial of **Sensilux** (yellow cap) and a vial of **Dilutor DS** (yellow cap). Pour the contents of the **Dilutor DS** into the **Sensilux**, swirl gently to mix and pour the total contents into the 50 ml PP-vial. **DO NOT SHAKE**
- 3) Carefully open a vial of **ATX** (red cap) and a vial of **Dilutor DA** (red cap). Pour the contents of the **Dilutor DA** into the **ATX**, swirl gently to mix and pour the total contents into the 50 ml PP-vial.
- 4) The **Cellsolver DE** is ready for use.
- 5) Place the reagents in the Innovate Reagent holder and leave for 15 minutes before use.
- 6) Prime the Innovate luminometer with the prepared reagents.

Protocol

- 1) Incubate the sample in its original packaging at 30°C (or other validated temperature) for a minimum of 48 hours.
Note: typical incubation time for UHT dairy products is 48-72 hours. All users should determine the most appropriate sample preparation, incubation times and temperatures based on their product types and microorganisms of interest.
- 2) Following incubation, shake the sample to ensure any contamination is well mixed.
- 3) Pipette 50 µl of the sample into a well of the microtiter plate.
- 4) Place the microtiter plate in the luminometer and perform the appropriate protocol.

Refer to the Innovate Operator Manual for full instructions on the programming and operation of your instrument.

Controls

Hygiena recommends running an Instrument Blank, Reagent Blank and ATP Positive Control on each day before using the instrument to ensure the system is functioning properly.

Interpretation of Results

Compare the RLU values and determine the pass/fail status of each sample. Please refer to the Validation Guide or your Hygiena Technical Support Representative for more information on how the RLU readings should be interpreted.

Technical Support

Contact your local Technical Support Representative for further information.

Precautions and Disclaimers

SDS are available upon request. Customers are also invited to visit the Hygiena website for anytime access to product and software manuals, troubleshooting tips and SDS.