

RapiScreen™ Dairy Kit for Autosampler

Product No. KIT4015 (25,000 tests)



Introduction

Description and Intended Use

The RapiScreen™ Dairy kit, together with the Innovate™ Rapid Microbial Screening System (luminometer and software), provides a rapid method to confirm the absence of microbial contamination in long-life dairy and dairy-alternative products. After first enriching samples by incubation in their original packaging, the Innovate System uses ATP bioluminescence to rapidly determine the presence/absence of microorganisms in the sample.

Kit Components of the RapiScreen Dairy Kit (25,000 tests)

Kit Configuration	Quantity
Sensilux	50 x 500 test vials
Dilutor DS	5 x 575 mL bottles
Cellsolver DE	4 x 325 mL bottles
ATX	50 x 500 test vials
Dilutor DA	3 x 230 mL bottles
Microwash	2 x 400 mL bottles
PP vials – 150 mL	20 each
PP vials – 50 mL Blue	10 each
PP vials – 50 mL Red	10 each
Microplates, 96 well	280 each

Required Materials (Not Provided)

- Innovate System (Product No. MCH4000)
- Autosampler III System (Product No. MCH4003)
- ATP Positive Control Kit (Product No. KIT4014)
- Pipette and tips

Important Tips and Notes Before Starting the Test

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



Test Procedure

Getting Started

1. Remove one vial of each reagent from storage at 2 to 8 °C.
2. Unscrew the Microwash cap and transfer 50 mL of Microwash to both 50 mL blue-capped PP vials on-board the Innovate System.
3. Carefully open a vial of Sensilux (yellow cap) and dispense the first 25.5 mL Dilutor DS into the vial, swirl gently to mix and pour it into the 150 mL PP vial. Do not shake. Dispense the second 25.5 mL Dilutor DS directly into the same 150 mL PP vial.
Note: This is enough Sensilux for 500 samples.
4. Carefully open a vial of ATX (red cap) and dispense 13.2 mL of Dilutor DA into the vial, swirl gently to mix and pour the total contents into the 50 mL red-capped PP vial.
Note: This is enough ATX for 500 samples.
5. Place the reagents, including the Cellsolver DE bottle, in the Innovate System reagent holder and leave for 15 minutes before use.
Note: This is enough Cellsolver DE for 6,250 samples.
6. Prime the Innovate System 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.*
2. Shake the sample to ensure any contamination is well-mixed.
3. Pipette 50 µL of the sample into a well.
4. Place the microtiter plate in the luminometer and run the appropriate protocol.

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

Additional Information

Interpretation of Results

Compare the RLU values of the samples and determine the pass/fail status of each sample. Refer to the *Innovate System Implementation Guide* or contact your Hygiena Technical Support Representative to determine how the RLU readings should be interpreted.

Controls

Hygiena® recommends running an instrument blank, reagent control and ATP positive control on each day before using the instrument to ensure the system is functioning properly.

* Refer to parameters that may need to be set for individual users or applications. Contact your local Technical Support Representative for further information.

AOAC RI Performance Tested MethodsSM Certification

The detection of mesophilic microorganisms using the Innovate System luminometer and the RapiScreen Dairy Kits have earned AOAC RI *PTM* Certification (License #092301) from the AOAC Research Institute.



The AOAC validation studies included the following matrices:

Matrix
Ultra-high temperature (UHT) bovine milk
UHT plant-based drink (almond drink)
Half and half (10% fat)
Protein-based drink (casein)
Extended shelf life (ESL) plant-based drink (oat drink)

Storage and Shelf Life

- Store at 2 to 8 °C (36 to 46 °F) upon receipt.
- Once reconstituted, the reagents will remain stable for 5 days when stored in the Innovate System reagent cooling unit.
- The performance of this kit and its components cannot be guaranteed beyond the expiration date stated on the kit box.

Safety and Precautions

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

The Innovate System method includes procedures that could result in the growth of potential pathogens to detectable levels. Because pathogens can cause human illness, appropriate safety precautions must be taken and personal protective equipment must be worn when handling samples, media, reagents, glassware, equipment and other supplies that could be contaminated with potentially pathogenic bacteria.

- Reagents used with the Innovate System assays should pose no hazards when used as directed. Before using this assay, please review the Safety Data Sheet (SDS) available at www.hygiena.com/documents.

Hygiena Liability

Hygiena will not be liable to the user or others for any loss or damage, whether direct or indirect, incidental or consequential from use of these devices. If this product is proven to be defective, Hygiena’s sole obligation will be to replace the product, or at its discretion, refund the purchase price. Promptly notify Hygiena within 5 days of discovery of any suspected defect and return the product to Hygiena; contact Customer Service for a Returned Goods Authorization Number.

Contact Information

For more information, visit www.hygiena.com/contact. For technical support, visit www.hygiena.com/support.

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