RapiScreen™ Beverage Kit

For Hygiena's Innovate™ Rapid Microbial Screening System

Product No. KIT4010 (1,000 tests)

PERFORMANCE TESTED AOAC RESEARCH INSTITUTE LICENSE NUMBER 052301

Introduction

Description and Intended Use

Hygiena's RapiScreen™ Beverage kit, along with the Innovate™ System luminometer and Innovate™ software, provides a rapid screening method to confirm the absence of microbial contamination in beverages. The presence/absence of microorganisms is determined by using ATP bioluminescence technology.

The system is intended for use by trained operators.

Kit Components of the RapiScreen Beverage Kit (1,000 tests)

Kit Configuration	1,000-Test Kit
Hygiena LuminATE™	10 x 100 test vials
Hygiena LuminATE™ Buffer	10 x 14 mL vials
Hygiena LuminEX™	1 x 136 mL bottle
Hygiena LuminASE™	10 x 100 test vials
Hygiena LuminASE™ Buffer	10 x 10 mL vials
Microwash	1 x 400 mL bottle
Polypropylene (PP) vials	4 x 50 mL vials
Microplates, 96-well	12 plates

Test Procedure

Getting Started

1. Remove one bottle of each reagent from storage at 2 to 8 °C, and allow reagents to warm to room temperature before reconstitution.

   Note: To avoid contamination, wear gloves when opening glass vials.

2. Carefully open a bottle of Hygiena LuminATE (yellow cap) and a bottle of Hygiena LuminATE Buffer (yellow cap). Pour the contents of the Hygiena LuminATE Buffer into the Hygiena LuminATE, replace the lid and swirl gently to mix. Then pour the total contents into a 50 mL PP vial.
3. Carefully open a bottle of Hygiena LuminASE (red cap) and a bottle of Hygiena LuminASE Buffer (red cap). Pour the contents of the Hygiena LuminASE Buffer into the Hygiena LuminASE, replace the lid and swirl gently to mix. Pour the total contents into a second 50 mL PP vial.
4. The Hygiena LuminEX and Microwash are ready for use.
5. Place the reagents in the Innovate System reagent holder cooling unit and leave for 15 minutes before use.
6. Prime the Innovate System luminometer with the prepared reagents ready for use.

Protocol

1. Incubate the sample in its original packaging (or separate container) at 30 °C (or other validated temperature) per the product's SOP.
2. Following incubation, shake the sample to ensure any contamination is well-mixed.
3. Pipette 50 µL of the sample into a well in the microtiter plate.
4. Place the microplate in the luminometer and run the appropriate protocol.

   The light emitted is then measured and recorded in Relative Light Units (RLUs).

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

Additional Information

Controls

It is recommended to run an instrument blank, reagent blank and ATP positive control daily in ensure the system is functioning properly.

Interpretation of Results

Compare the RLU values 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.

Positive results should be further confirmed and identified according to the user-defined microbiology methods for contamination investigations.

AOAC RI *Performance Tested Methods*℠ Certification

The detection of mesophilic microorganisms using the Innovate System luminometer and the RapiScreen Beverage Kit has earned AOAC RI *PTM* Certification (License #052301) from the AOAC Research Institute.

The AOAC validation studies included the following matrices:

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

Kit Storage and Shelf Life

1. The RapiScreen Beverage kit for the Innovate System must be stored refrigerated at 2 to 8 °C when not in use.
2. The reconstituted Hygiena LuminATE and LuminASE are stable for up to 5 days when stored in the Innovate reagent holder cooling unit.
3. At the end of the day, the Hygiena LuminEX can be stored within the unit at room temperature.
4. Do not mix reagents from different kit lots.
5. 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.