

Micro-Snap™ *Enterobacteriaceae* Detection Device
Catalog No. MS-EN-100 / For use with Hygiena Luminometers
For Investigational Use only



This is used along with the following:

Cat No. ES-EE-100: Enrichment Swab
 Cat No. EB-EE-100: Enrichment Broth 2ml
 Cat No. MS-EC-100: Detection device for E. Coli.
 Each device (Enrichment and Detection) is sold separately in packages containing 100 devices.

Description and Intended use

Description and intended use:
 The Micro-Snap assay is a rapid bioluminescent method for estimation of members of the *Enterobacteriaceae* in less than 8 hours from surface samples, food samples and filterable liquids, eliminating the need for confirmation.

Principle

The assay requires 2 self-contained tube devices that are used in a 2 step procedure. Device 1 is the Enrichment device (same device is used for *Enterobacteriaceae*, Coliforms and E. Coli test). Device 2 is the Detection device.

MS-EN is used for *Enterobacteriaceae*

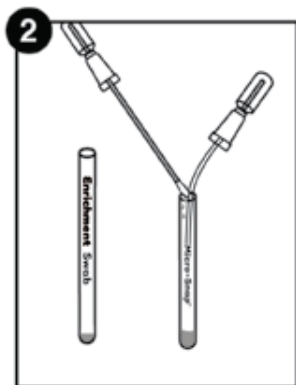
MS-EC is used for E. coli test

STEP 1: The culture media in Device 1 (ENRICHMENT DEVICE) is inoculated with the sample to be tested and incubated at 37°± 1°C for up to 8 hours.
STEP 2: An aliquot of the incubated sample is manually transferred to Device 2 (DETECTION DEVICE) and the enzymatic action on the substrates is measured via bioluminescence on the Hygiena ENSURE luminometer. 1 bacterium per mL will create sufficient enzymatic activity if grown for 7 hours at 37°± 1°C. A threshold level of activity has been set at 10 RLUs (Relative Light Units). If 7 hours incubation cannot be achieved prior to the DETECTION Step 2, then samples can be left to incubate for a longer period of time or overnight without impairment of result.

Test Procedure:

1

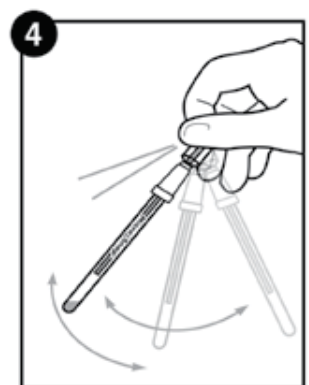
Refer to **Enrichment Swab ES-EE** insert for sample preparation or Enrichment Broth **EB-EE** insert for filterable sample preparation.



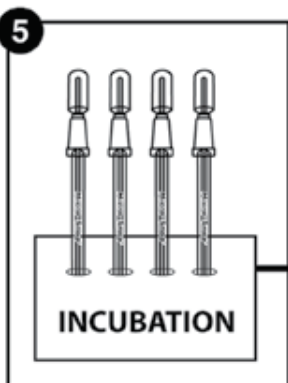
2. Transfer 0.1mL (2 to 3 drops) of enriched sample to detection device from Enrichment Swab or petri dish containing filter.



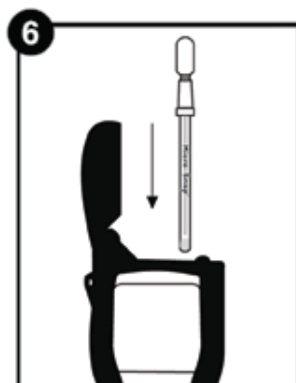
3. Activate device by breaking the snap valve with a snap and squeeze action.



4. Shake the tube gently to mix sample in the liquid.



5. Incubate for a minimum of 10 minutes at 37°± 1°C . Longer incubation times of 20 minutes or up to 60 minutes are possible and offer more sensitivity.



6. Read in Hygiena Luminometer.

Test Procedure Text

Note: Refer to insert for Enrichment device for sample collection and incubation for enrichment.

1. Transfer enriched sample to detection device:
 Aseptically remove an aliquot of the sample (optimum volume is 0.1ml, 2-3 drops) from the Enrichment Device and transfer it to the Detection Device for general *Enterobacteriaceae*, MS-EN. The Enrichment Device can be used as a Pasteur pipette for convenience. Squeeze and release the bulb to mix and withdraw the sample into the bulb. Remove the swab from the tube and carefully dispense 2-3 drops into the Detection Device. The remaining enrichment broth can be returned to the Enrichment device for extended incubation or storage. Continue incubation of the sample if required and take further aliquots for detection if required. If using a filterable sample, refer to EB-EE insert. From the 47mm petri-dish the aliquot of 0.1ml can be removed by standard pipette into the Detection Device.

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Micro-Snap™ *Enterobacteriaceae* Detection Device MS-EN

2. Activate Detection device. Incubate for 10 minutes:

Bend the bulb, to break the snap valve. Squeeze bulb 3 times to release the reagent, and incubate at 37°± 1°C for a minimum of 10 minutes. Longer incubation times of 20 minutes or up to 60 minutes are possible and offer more sensitivity. The same Detection Device can be read at 10, 20, 30 minutes if required.

3. Read in Hygiena Luminometer:

Follow the operating instructions for the luminometer and switch it on. Place the detection device in the Hygiena Luminometer and press “OK” button. Results will appear in 15 seconds.

Further Testing

If a positive result is found using the MS-EN device then the convention would be to confirm the absence of *Escherichia coli* from the sample. This can easily be done by re-testing the same enrichment broth using the specific E.coli Detection Device available from Hygiena. Follow the insert from the MS-EC-100 device.

Interpretation of Results:

Results are displayed in Relative Light Units (RLU). The threshold for positive samples has been set at 10 RLU on the ENSURE luminometer. Negative samples will have RLU results of 0 – 9 RLU. Thresholds for other Hygiena instruments SystemSure Plus, SystemSure II and Hygiena Pi-102 are available on request.

These threshold levels and the Inoculum Time Table are used for qualitative assays only to provide an approximate level of bacteria present in the original inoculum. The Inoculum Time Table 1 is based upon 10 minutes incubation time for detection devices.

Inoculum Time Table 1

Initial Inoculum range	Minimum Incubation time required at 37°C In hours
1-5	7
10	6
100	5
1000	4
10000	3
100000	2
500000	1

Quantitative Determinations:

To run a quantitative assay multiple Micro-Snap Detection Devices are required to be run from the same Enrichment Device sample at different incubation times.

An algorithm can be applied to the RLU results at the specific time to determine starting inoculums. For more information visit www.hygiena.net and read the document “Extended Applications for Hygiena Micro-Snap using Kinetic Analysis.”

Controls:

Run positive and negative controls according to Good Laboratory Practice.

Safety Precautions:

Components of Micro-Snap Detection devices do not pose any health risk when used correctly. Used devices should be treated as a biohazard and should be disposed off safely in compliance with Good Laboratory Practice and Health and Safety regulations.

1. Devices are designed for a single use. Do not reuse.
2. Do not use devices after Expiration date.
3. Sampling should be done aseptically, to avoid cross contamination.
4. Ensure proper incubation temperature and time for your application.
5. When activating devices, ensure that the liquid in the bulb is transferred to the tube below.

Material and Reagents Required But Not Provided

Sample preparation equipment and diluents.

Recommended Diluents for product samples:

- Buffered Peptone Water
- Butterfields
- Maximum Recovery Diluent
- Other validated diluents of users choice

Storage & Shelf Life:

Store bags of devices at 2-8°C

Devices have a shelf life of 12 months. Check expiration date on label.

Caution and User Responsibility:

1. Micro-Snap devices have not been tested with all possible food products, food processes, testing protocols or with all possible strains of the Enterobacteriaceae family.
2. Do not use this test in the diagnosis of conditions in humans and animals.
3. No single culture medium will always recover the exact same strains or enumerate a particular strain exactly as another medium. Other external factors such as sampling method, testing protocol and handling may influence recovery.
4. It is the user's responsibility in selecting a test method to evaluate a sufficient number of samples of particular foods and microbial challenges to satisfy the user that the chosen method meets the user's criteria.
5. As with any culture medium, Micro-Snap results do not constitute a guarantee of quality of food, beverage products or processes that are tested with these devices.
6. The user must train personnel in proper testing techniques.

Hygiena Liability:

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

Contact Information:

If more information is required, please visit us at www.hygiena.net or contact us at:



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.net