InSite *L. mono* Glo

Environmental Surface Screening Test for *Listeria* spp. and *Listeria monocytogenes*

Part No: ILMG050 (50 tests)

PERFORMANCE TESTED AOAC RESEARCH INSTITUTE LICENSE NUMBER 061802

Performance Tested AOAC Research Institute License # 061802
This test kit's performance was reviewed by AOAC Research Institute and was found to perform to the manufacturer's specifications for detecting *Listeria* spp. and *Listeria monocytogenes* on environmental surfaces (plastic, ceramic, stainless steel).

Description:
InSite *L. mono* Glo is a screening test for *Listeria* species and *Listeria monocytogenes* (*L. mono)*, intended to be used for environmental monitoring in food processing environments after cleaning. A color change of the media from yellow/amber to grey/black is considered presumptive positive for *Listeria* species. Samples presumptive for *Listeria* species which exhibit green fluorescence under ultraviolet (UV 395 -400nm) light indicate sample is presumptive positive for *L. mono*.

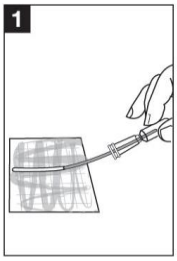
Principle:
InSite *L. mono* Glo contains a proprietary formula of antibiotics, growth enhancers and color-changing compounds. Antibiotics inhibit most non-*Listeria* microorganisms while growth enhancers provide recovery nutrients to support growth of sub-lethally injured *Listeria*. Indicator compounds turn broth from yellow to black by utilizing β-glucosidase enzyme produced by *Listeria* species. Verification of *L. mono* is shown by green fluorescence under UV light due to presence of diagnostic enzyme phospholipase C.

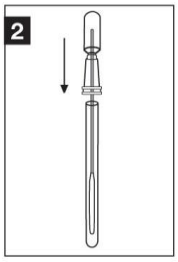
Intended User:
Laboratory personnel trained in standard microbiological practices are qualified to use InSite *L. mono* Glo.

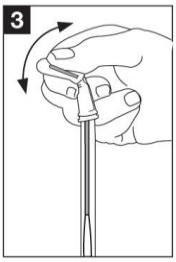
Required Materials (Not Included):
- Incubator set to 37 ± 1 °C, available from Hygiena™
- Longwave (395 -400nm) ultraviolet inspection lamp
- Self-sealing adhesive tape, plastic wrap, or paraffin film
- UV safety glasses

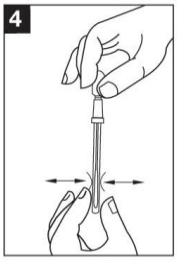
Directions:
1. When collecting sample, make sure to use aseptic technique. Do not touch swab or inside of sampling device. Holding swab tube firmly, twist and pull top of swab out of swab tube. Foam tip swab is pre-moistened; condensation may be visible on inside of swab tube - this is normal. Thoroughly swab a standard 10 x 10 cm (4 x 4 inch) area of interest for a typical flat surface. Rotate swab as sample is being collected to ensure maximum sample pickup and apply sufficient pressure to create flex in swab shaft. For irregular surfaces, ensure swabbing technique remains consistent for each test and swab a large enough area to collect a representative sample.
2. After swabbing desired test area, place swab back in swab tube and close device firmly. *Tip: Seal device to avoid accidental spillage by wrapping joint of swab tube and bulb with adhesive tape or self-sealing wrap.*
3. To activate InSite, hold swab tube firmly and use thumb and forefinger to break Snap-Valve by bending bulb forward and backward. Squeeze bulb 3 – 4 times, expelling all liquid down into tube.
4. Gently massage bottom of tube by squeezing tube 3 times, then shake for 3 seconds. This will help release cells from swab and displace air bubbles.
5. Incubate for 24 – 48 hours at 37 ± 1 °C. Observe media color change and refer to Interpretation of Results below. Results cannot be considered negative until sample has been incubated for 48 hours.

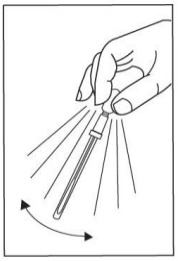
Interpretation of Results:
- No change in media color after 48 hours indicates sample is negative for *Listeria* species. **UV light should not be applied when media remains amber/yellow after 48 hours.**
- Grey/black color change is indicative of *Listeria* species. To verify the presence of *Listeria monocytogenes,* shine UV light directly into side of bottom portion of tube. If green fluorescence is visible, sample is presumptive positive for *L. mono.* .
- Tips:
  - Reduced ambient light improves visibility of fluorescence.
  - If fluorescence is unclear, invert test device. Since fluorescent compounds bind to tube material, interpretation of results is improved when no media is present in viewing area at the bottom of the tube.
- Both grey/black media change and the presence of green fluorescence indicates sample is presumptive positive for *L. mono.*

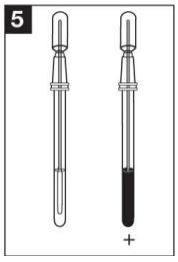












***Listeria*-like Organisms:**
Certain bacteria in high numbers such as *Enterococcus spp*. can produce blackening of the media. Detection of these "*Listeria*-like" organisms in the environment can indicate that improvements in cleaning and sanitation are needed and that conditions at the sample site may be conducive to the growth of *Listeria*. A higher rate of presumptive positives can be expected when testing highly contaminated surfaces such as floors and drains. To verify the presence of *Listeria* in a presumptive positive sample Hygiena recommends testing the incubated media from the Insite device with a more specific method e.g. PCR, ELISA, or lateral flow.

Confirmation:
Presumptive positive samples can be confirmed by an appropriate reference method such as:
- U.S. FDA Bacteriological Analytical Manual (BAM)
- USDA FSIS Microbiology Laboratory Guidebook (MLG)
- Health Canada Compendium of Analytical Methods
- International Organization for Standardization (ISO)

Presumptive positive samples can also be verified with Hygiena's BAX® System PCR Assays for Genus *Listeria* or *Listeria monocytogenes*. For a list of BAX® System PCR service labs visit hygiena.com/service-lab.html.

Any confirmatory results should be handled according to appropriate regulations.

Storage & Shelf Life:
- Store devices at 2 – 8 °C (35 – 46 °F)
- Devices have a 12-month shelf life.
- Check expiration date on label.

Disposal:
Disinfect before disposal. InSite devices can be disinfected by autoclaving, incinerating, or by soaking unsealed devices in 20% bleach for 1 hour. Then, they can be placed in the trash. Alternatively, InSite devices may be discarded at a biohazard waste disposal facility.

Safety & Precautions:
Components of InSite devices do not pose any health risk when used correctly. Used devices should be considered a biohazard and should be disposed of safely in compliance with Good Laboratory Practice and Health and Safety Regulations.
- InSite is intended to be used on production and environmental surfaces after cleaning.
- *Listeria monocytogenes* (*L. mono*) is a human pathogen. When handling samples that possibly contain *L. mono*, extreme care should be taken to contain incubated samples of InSite devices. Immuno-compromised individuals and pregnant women are particularly susceptible to exposure of *L. mono* and should not be allowed near testing.
- Wear appropriate protective eyewear when using UV lamp or flashlight.

Hygiena Liability:
As with any culture medium, InSite results do not constitute a guarantee of quality of food, beverage products or processes that are tested with these devices. Hygiena will not be liable to 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 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 Number**.**

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

Hygiena
Phone: 805.388.8007
Fax: 805.388.5531
Email: info@hygiena.com

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

InSite *L. mono* Glo

Environmental Surface Screening Test for *Listeria* spp. and *Listeria monocytogenes*

Part No: ILMG050 (50 tests)