

Intended Use

N-Light™ *Listeria monocytogenes* is a qualitative test method for rapid detection of the foodborne bacterial pathogen *Listeria monocytogenes*. The test method is suitable for use in food processing areas and equipment as part of an environmental monitoring program. Final test results are available 24h after sampling.

Certifications

This method has been evaluated in the AOAC Performance Tested Program. It was found to perform to the manufacturer's specifications for the detection of *Listeria monocytogenes* on clean environmental surfaces (plastic, ceramic, stainless steel) using a wet swab sampling procedure according to the ISO 18593:2018 norm and using N-Light™ swabs, NEMIS dry block incubators, and NEMIS luminometers. NEMIS may make industry-specific application notes available online for other validated use cases.

**Measurement Principle**

The method uses AquaSpark®, a patented ultrasensitive chemiluminescent molecule that reacts with a specific enzyme (PI-PLC) produced by living *Listeria monocytogenes* bacteria. With a NEMIS luminometer, the light resulting from this chemical reaction can be accurately measured in relative light units (RLU). Test results above the validated threshold indicate a presumptive positive result. Further actions (i.e., confirmation) according to site procedures and local regulations may be required.

Specificity and Sensitivity

The N-Light™ *L. monocytogenes* enrichment broth contains a highly selective nutrient mix, supplemented with antibiotics and a mixture of proprietary bacteriophages to provide optimal growth of sub-lethally injured *Listeria monocytogenes* while restricting the growth of competing microorganisms during incubation. For additional information, please refer to our resources available online.

Storage and Shelf Life

+2-8°C, **do not freeze**; check the expiration date on the label.

Functionality check

Users can perform a fit-for-purpose assay to check for any loss of performance due to transport or storage conditions:

- Activate one N-Light™ test tube containing only the enrichment broth without sample. Shake until the tablet is dissolved.
- Incubate at 37°C for 5 minutes in the NEMIS Dry Block Incubator.
- Test with the NEMIS luminometer 5 minutes after activation.
- Results between 500 and 10'000 RLU are acceptable.

Confirmation

Presumptive positive results can be confirmed by streaking the cultivated samples onto commonly used selective agar plates or using any other recognized confirmatory procedure (e.g., ISO 11290-1:2017).

CAUTION: Opening the N-Light™ test tube and subsequent handling of the incubated sample must be performed within a safety level II laboratory.

Precautions

To prevent sample contamination during environmental sample collection, use aseptic techniques and personal protective equipment (PPE) such as plastic gloves. To prevent accidental contamination of the production environment or food products with components of the N-Light™ test, users can perform the sample transfer, incubation, and measurement in a separate area. In this case (as recommended by the ISO 18593:2018 norm), swab samples should be put back to the swab tubes and stored between +1-4°C. Transfer of the swab samples to the N-Light™ test tubes should occur within 4 hours. Any deviation from the recommended storage temperatures, maximal shelf-life, or recommended test procedures will negatively affect the product performance and potentially lead to false results. Due to the permanently closed, liquid-tight test tube, N-Light™ tests are safe for cultivation of environmental microorganisms outside of a laboratory. However, depending on local regulations, product usage may be subject to notification or permission from authorities. It is the responsibility of the user to comply with those obligations.

**Safety**

N-Light™ tests are not hazardous to health when used by qualified personnel in accordance with these instructions. Do not ingest and prevent contact of the enrichment broth with skin and mucosal surfaces. Permanently close the N-Light™ test tube with the biosafety cap before incubation. Always handle cultivated environmental samples as potentially dangerous goods of type UN3373. For additional information, please refer to our Safety Data Sheets (SDS) available online. **CAUTION:** *Listeria monocytogenes* is a disease-causing human pathogen, and infection can be fatal. Immunocompromised individuals, pregnant women, and the elderly are particularly susceptible and should not handle the N-Light™ tests after incubation. **If you believe you have been exposed to pathogenic microorganisms like *Listeria monocytogenes*, immediately inform your supervisor and seek medical advice.**

Disposal

Used N-Light™ tests can be inactivated by autoclaving in an autoclavable bag or by incineration. NEMIS recommends the disposal of all N-Light™ tests by a specialized service provider for biohazardous waste. **CAUTION:** Do not dispose of enrichment broth using the sink, as it contains antibiotics.

Exclusion of warranty and liability

The product is provided on an as-is basis to be used solely in accordance with this instruction of use. NEMIS excludes any guarantee of the quality of food, beverage products, or processes tested with its products. NEMIS excludes all liability for damage to its products. However, should any NEMIS product found to be damaged, NEMIS, at its sole discretion, may choose to either replace or refund such product. To the extent legally possible, NEMIS will not be liable to users or others for any loss or damage, whether direct or indirect, incidental, or consequential, from either proper or improper use of its products.

Contact Information

If you have any questions or require assistance, please refer to the Frequently Asked Questions (FAQ) and other online technical resources or contact our local representative.



NEMIS Technologies AG
Riedhofstrasse 11
8804 Au ZH
Switzerland
www.nemistech.com



REQUIRED MATERIALS

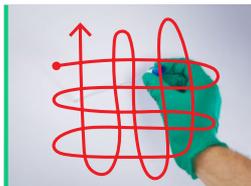
1. N-Light™ *Listeria monocytogenes* Test Tube
2. N-Light™ sterile dry swabs with separate PBS buffer
3. NEMIS Bench-top Luminometer
4. NEMIS Dry Block Heater



1 SAMPLE



Mark according to your test plan



Swab the sampling area
Apply enough pressure and rotate the swab



Open the test tube and swirl the swab inside the liquid for minimum 10s
Discard the swab



Put the cap back on the test tube and press firmly until you hear a "click"

2 INCUBATE



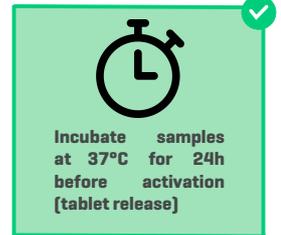
Set the temperature to 37°C and press <on>
Set a timer for 24 hours [+/- 1]



Make sure each test tube is fully locked



Fully insert the test tubes inside the wells of the incubator
Incubate the samples for 24 hours [+/- 1 hour]



Incubate samples at 37°C for 24h before activation (tablet release)

3 ACTIVATE



Hold the tube vertically
Open the lid and firmly push the button to release the AquaSpark™ tablet



Verify the tablet is released into the liquid
Start a timer [5 min]

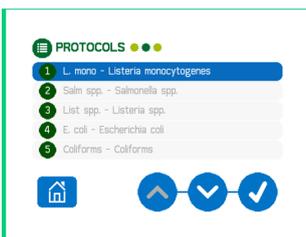


Shake for 20s, until tablet is fully dissolved

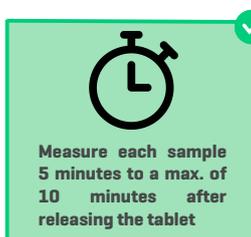


Put activated tubes back at 37°C
Repeat the activation steps consecutively for max 12 tubes. Start immediately to measure the tubes in order of tablet release.

4 MEASURE



Select the *L. mono* protocol



Measure each sample 5 minutes to a max. of 10 minutes after releasing the tablet



Place the test tube into the luminometer
Start the measurement



Presumptive positive. *Listeria monocytogenes* may be present.

No live *Listeria monocytogenes* detected

Results can be downloaded in chronological order after the measurement via the NEMIS data app.