

N-Light™ *L. monocytogenes* - Instructions for use



Intended Use

N-Light™ *L. 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 the N-Light™ swabs, incubators, and 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

Store the product outside the reach of children.
+2-8°C, **do not freeze**; check the expiration date on the label.

Functionality Test

Customers 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 containing only the enrichment broth without sample. Shake until the tablet is dissolved.
- Incubate at 37°C for 10 minutes (NEMIS Incubator).
- Test with the luminometer 10 minutes after activation.
- Results up to 10.000 RLU are acceptable. In case of larger values, contact your supplier for further guidance.

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™ 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 a good aseptic technique 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), samples should be stored between +1-4°C and transferred to the enrichment broth within 4 hours. Any deviation from the recommended storage temperatures, shelf-life, or procedures will negatively affect the product performance and potentially lead to false-positive or false-negative results. Due to the permanently closed, liquid-tight N-Light™ tube, NEMIS considers N-Light™ tests safe to cultivate environmental microorganisms for the intended use outside of a laboratory environment. 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. Prevent contact of the enrichment broth with the skin and mucosal surfaces, and do not ingest. Permanently close the N-Light™ 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 N-Light™ product be 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 your local distributor.

(*) AquaSpark® is a trademark of Ramot at Tel Aviv University



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More Info

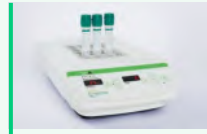
REQUIRED MATERIALS



N-Light™ *Listeria monocytogenes* Test



N-Light™ Swab



NEMIS Dry Block Incubator



NEMIS Bench-top Luminometer

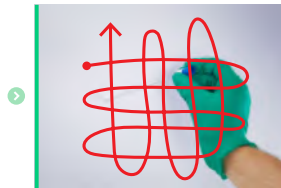


Training

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 5s



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

Discard the swab

2 INCUBATE



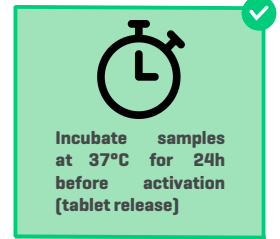
Set the temperature to 37°C and press <on>
 Set a timer for 24 hours [+/- 1]



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]



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 (10min)

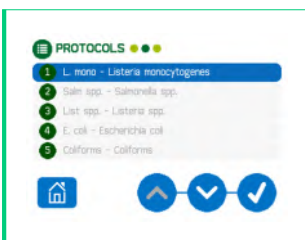


Shake until tablet is fully dissolved

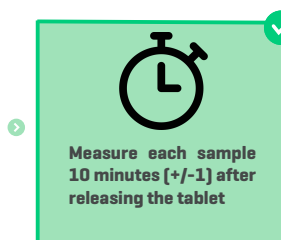


Put activated tubes back at 37°C
 Shake tubes again after 5 minutes to ensure good distribution of AquaSpark™

4 MEASURE



Select the *L. mono* protocol



Place the test tube into the luminometer
 Start the measurement

