

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 probe that reacts with specific enzymes produced by living *L. 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 a 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 proprietary bacteriophage cocktail to provide optimal growth of sub-lethally injured *L. monocytogenes*, whilst 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.

N-Light™ *L. monocytogenes* Broth Tubes:

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

N-Light™ *L. monocytogenes* Biosafety Caps:

- below -20°C or +2-8°C: check expiration dates on 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 a N-Light™ tube containing only enrichment broth w/o sample. Shake until the tablet is dissolved.
- Test with the luminometer 10 minutes after activation.
- Results up to 6000 RLU are acceptable. Contact your supplier in case of larger values for further guidance.

Confirmation

Presumptive positive results can be confirmed by streaking the cultivated samples onto commonly used selective agar plates or by using any other recognized confirmatory procedure (e.g. ISO 11290-1:2017). **CAUTION:** Opening of the test tube and subsequent sample handling 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 test tube, NEMIS considers the 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 to 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 test tube with the N-Light™ 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:** *L. 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 that you have been exposed to pathogenic microorganisms like *L. 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 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 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 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 technical resources available online, or contact your local distributor.



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

REQUIRED MATERIALS



N-Light™ Swab



NEMIS Dry Block Incubator



NEMIS Bench-top Luminometer



Test Tube [contains the enrichment broth]



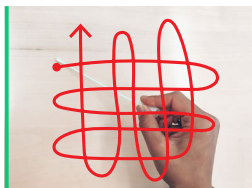
Biosafety Cap [contains the AquaSpark™ tablet]

N-Light™ *Listeria monocytogenes* Test Kit

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 enrichment broth for min. 5s.
Discard the swab.

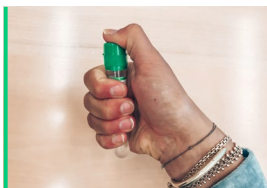
2 INCUBATE



Set the temperature to 37°C and press <on>.
Set the timer to 1440 minutes [24h].



Remove the outer foil from the Biosafety Cap.



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



Fully insert the test tubes inside the wells of the incubator.

3 ACTIVATE

↓ INCUBATION TIME IS EXACTLY 24 HOURS (+/- 1 HOUR)



Open the protection lid and firmly push the button to release the AquaSpark™ tablet.



Verify the tablet is released into the liquid.
Start a timer.



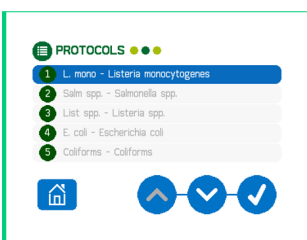
Shake until tablet is dissolved.



Put the test tube back into the incubator.

4 MEASURE

↓ MEASURE EACH SAMPLE EXACTLY 10MIN (+/- 1MIN) AFTER RELEASING THE TABLET



Select the L. mono protocol.



Place the test tube into the luminometer.



Presumptive positive.
Listeria monocytogenes may be present.



No live *Listeria monocytogenes* detected.