N-LIGHT™ LISTERIA spp. INSTRUCTIONS FOR USE

Intended Use

N-Light™ *Listeria* spp. is a qualitative test method for rapid detection of the *Listeria* spp. bacteria, including *Listeria innocua, Listeria welshimeri* and the pathogenic species *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 24 h after sampling. Only trained individuals should perform the N-Light™ test.

Measurement Principle

The method uses AquaSpark®*, a patented ultrasensitive chemiluminescent molecule that reacts with a specific enzyme produced by living *Listeria* spp. bacteria. With a NEMIS Bench-top Luminometer, the light resulting from this reaction can be accurately measured in relative light units (RLU). Test results above the validated threshold (>4'000 RLU) 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™ *Listeria* spp. enrichment broth contains a unique nutrient mix, supplemented with selective agents and a mixture of bacteriophages, to promote the optimal growth of sub-lethally injured *Listeria* spp. while restricting the growth of competing microorganisms during incubation. For more information, please refer to the supporting documents.

Storage and Shelf Life

Storage conditions: +2-8 °C / 36-46 °F, **DO NOT FREEZE**
Transport conditions: Ambient (for essential durations)

Shelf life: Guaranteed efficacy up to the expiration date stated on the product 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 an N-Light™ test tube containing only the enrichment broth without sample. Shake until the tablet is dissolved.
- Incubate at 37 °C for 3 minutes in the NEMIS Dry Block Heater.
- Test with the NEMIS Bench-top Luminometer 3 minutes after activation.
- Results up to 3'000 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 such as ISO 11290- 1:2017 and real-time PCR. **CAUTION:** Opening the N-Light™ test tube and subsequent sample handling must be performed within a biosafety level II laboratory.

Precautions

To prevent sample contamination during environmental sample collection, use aseptic techniques and personal protective equipment (PPE) such as 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 transferred to the N-Light™ test tubes 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 trained personnel following 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. Young, old, pregnant, and immunocompromised (YOPI) people are groups most vulnerable to foodborne illnesses and should not handle 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 disposal of all N-Light™ tests by a specialized service provider for biohazardous waste. **CAUTION:** Do not dispose of enrichment broth in the sink.

Exclusion of warranty and liability

The product is provided on an as-is basis to be used solely following 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 technical resources available online or contact **techsupport@nemistech.com**

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more info

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N-LIGHT™ LISTERIA spp.

Watch Instruction Video

REQUIRED MATERIALS

1. N-Light™ *Listeria* spp. test tubes
2. NEMIS Bench-top Luminometer
3. NEMIS Dry Block Heater
4. Kitchen Timer
5. Optional: N-Light™ Activation Tool [REF 00008]
6. N-Light™ sampling devices containing compatible moistening solution:
   a. N-Light™ sterile dry swab BP with separate **PBS buffer** [REF 00039]
   b. N-Light™ sterile dry swab BP with separate **neutralizer** [REF 00037]
   c. N-Light™ sterile MaxiSampler with separate **PBS buffer** [REF 00060]
   d. N-Light™ sterile MaxiSampler with separate **neutralizer** [REF 00064]

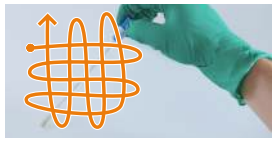
1. PREPARATION

Wet the swabs in the moistening solution and put them back in their swab tube.

Mark/label the swab tubes and the test tubes according to your test plan.

Heat the incubator: set the temperature to 37 °C and press <on>.

2. SAMPLING



Swab the sampling area.

Apply enough pressure and rotate the swab.

3. TRANSFER

Open the test tube.

Break off the swab tip in the test tube and discard the rest.

Put the cap back on the test tube. Push the cap down until you hear a “click”.

Make sure the tube is fully locked.

Briefly shake the tube.

4. INCUBATE

Incubate the samples at 37 °C for 24 hours (+/- 1 hour).

5. ACTIVATE

Hold the tube vertically and release the AquaSpark® tablet (open the lid and firmly push the button with the thumb or use the Activation Tool with the lid closed).

Verify the tablet is released into the liquid.

Start a timer (4 minutes).

Shake the tube for 5 seconds, or until the tablet is fully dissolved.

Use a vortex mixer if available.

Put the activated tubes back at 37 °C for 4 minutes.

Tipp: *Repeat the activation steps consecutively for max. 8 tests (1 test every 30 seconds) and measure then each test in the order of tablet release (1 test every 30 seconds).*

6. MEASURE

IMPORTANT: *Measure each test exactly 3-5 minutes after releasing the AquaSpark® tablet.*

Switch on the luminometer and select the *Listeria* spp. protocol.

Place the test tube into the luminometer and start the measurement.

Presumptive positive.
Listeria spp. and/or *Listeria monocytogenes* may be present

No live *Listeria* spp. or *Listeria monocytogenes* detected

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