N-LIGHT™ LISTERIA SPP.
INSTRUCTIONS FOR USE

N-LIGHT™
LISTERIA spp.

Intended Use

N-Light™ *Listeria* spp. is a qualitative test method for rapid detection of *Listeria* spp. bacteria, including *L. innocua, L. welshimeri, L. ivanovii, L. seeligeri, L. fleischmannii, L. marthii* and pathogenic *L. monocytogenes*. The test method is suitable for use in food processing areas as part of an environmental monitoring program. Presumptive test results are available 24 hours after sampling. Only trained individuals should perform the N-Light™ test.

Measurement Principle

The method uses patented ultrasensitive chemiluminogenic molecules that react with specific enzymes produced by *Listeria* spp. Using 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 (e.g., confirmation) according to site procedures and local regulations may be required.

Certification

This method has been evaluated in the AOAC Performance Tested Methods Program (License No. 062601). It was found to be equivalent to method ISO 11290-1:2017 for detection of dried *L. mono.*, *L. innocua* and *L. ivanovii* on clean plastic, ceramic and stainless steel surfaces. Please note that the N-Light™ MaxiSampler ist without the scope of the AOAC validation.

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 5 minutes in the NEMIS Dry Block Heater.
- Test with the NEMIS Bench-top Luminometer 4 minutes after activation.

Results up to 3'000 RLU are acceptable.

Confirmation

Method ISO 11290-1:2017, starting with the secondary enrichment step is suitable for confirmation of N-Light™ *Listeria* tests and was used for this purpose in the AOAC validation study. Presumptive positive results can also be confirmed by other culture based or molecular methods if they have been validated by the confirming laboratory for N-Light™ *Listeria* spp. enrichment broth. **CAUTION**: Opening the N-Light™ test tube and subsequent sample handling must be performed within a biosafety level II laboratory. A device for opening of N-Light™ test tubes with sealed biosafety cap is available from NEMIS (NEMIS Tube Cutter, REF 00007).

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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 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. Pregnant women and immunocompromised individuals are 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 should be inactivated by autoclaving in an autoclavable bag, by incineration or by heating to ≥70°C for 20 min. After inactivation, N-Light™ tests can be disposed of with the normal municipal waste. **CAUTION**: Do not dispose of untreated enrichment broth in the sink.

Exclusion of warranty and liability

The product is provided on an as-is basis to be used solely in accordance with this instruction for 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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N-LIGHT™ LISTERIA SPP.

Watch Instruction Video

REQUIRED MATERIALS AND DEVICES

1. N-Light™ *Listeria* spp. test tubes with 2 ml enrichment broth and tablet dispenser cap containing AquaSpark® tablets, box of 50 (REF 00048)
2. NEMIS Bench-top Luminometer (REF 00001)
3. NEMIS Dry Block Heater (REF 00002/00044)
4. Kitchen Timer *(not provided by NEMIS)*
5. Optional: N-Light™ Activation Tool (REF 00008)
6. N-Light™ sampling devices with moistening solution:
   - N-Light™ sterile dry swabs BP with separate neutralizer, box of 50 (REF 00037, kit with 50 test tubes and 50 swabs: REF 00048-NTR)

   or sampling device for large surfaces, not covered by AOAC certificate:
   - N-Light™ sterile MaxiSamplers with separate neutralizer, box of 10 (REF 00064, kit with 50 test tubes and 50 MaxiSamplers: REF 00048-MX-NTR)

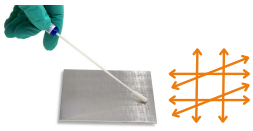
1. PREPARATION

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

Mark/label the swab and N-Light tubes according to your sampling plan. Prewarm tubes for min 20 min at room temperature.

Set temperature of incubator to 37 °C and press <on>.

2. SAMPLING



Swab the sampling area in three directions, turn swab tip in between.
Apply moderate pressure.

3. TRANSFER

Open the test tube.

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

Put the cap back on the test tube. Push the biosafety cap down until you hear a "**click**".

Make sure the tube is fully locked.

Briefly shake the tube.

4. INCUBATE

Incubate the test tubes at 37 °C for 24 (+/-1) h.

5. ACTIVATE

Hold the tube vertically and release the luminescence 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).

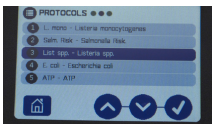
Shake the tube for 5 sec, or until the tablet is fully dissolved.

Put the activated tubes back at 37 °C for 4 (+/-1) minutes.

Tip: 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 luminescence tablet.



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

Place the test tube into the luminometer and start the measurement by pressing green triangle on touch screen.
Remove tube after read.

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

Ordering infomation: www.nemistech.com, sales@nemistech.com