

N-LIGHT

N-Light[™] Salmonella Risk

Intended Use

N-Light™ Salmonella Risk is a qualitative test method for rapid evaluation of the contamination risk for the foodborne bacterial pathogen Salmonella. 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.

Certification

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 *Salmonella* 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 $^{\rm IM}$ swabs, NEMIS Dry Block Heaters, and NEMIS Bench-top Luminometers. The test works also well on most non-clean surfaces. Detailed performance data are available online on our website.

Measurement Principle

The method uses AquaSpark**, a patented ultrasensitive chemiluminescent probe that reacts with alpha-D-galactosidase, an enzyme produced by allSalmonella serovars when alive. Some closely related bacteria occupying the same environmental niche also produce this enzyme. With a NEMIS Bench-top Luminometer, the light resulting from this reaction is measured in relative light units (RLU). Test results above the validated threshold (>20'000 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-LightTM Salmonella Risk enrichment broth contains a special nutrient mix, supplemented with selective agents and a proprietary bacteriophage cocktail to provide optimal growth of sub-lethally injured Salmonella whilst restricting the growth of competing microorganisms during incubation. The N-LightTM Salmonella Risk will also detect certain strains of Klebsiella, Citrobacter and Enterobacter. For more information, please refer to the supporting documents.

Storage and Shelf Life

N-Light™ Salmonella Risk test tubes and starter tablets:

• +2-8 °C, do notfreeze, 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 an N-Light[™] test tube containing only the enrichment broth without sample and without the starter tablet. 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.
- $\bullet\,$ Results up to 10'000 RLU are acceptable.

Confirmation

N-Light Malmonella Risk contains a lysis agent. Presumptive positive results can be confirmed using a recognized confirmatory procedure (preferably a validated PCR system or other culture independent method). In our supporting document "Confirmation protocol", we describe a qPCR and a PCR method compatible with our test. **CAUTION:** Opening of the N-Light test tube and subsequent sample handling must be performed within a safety level II laboratory.

* AquaSpark® is a trademark of Ramot

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 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.

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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:** Salmonella is a gastrointestinal pathogen that normally causes self-limiting diarrhea, lasting around 4-7 days. Infection with a few Salmonella serovars [namely Salmonella Typhi, Salmonella Paratyphoid] can be fatal. Immunocompromised individuals, pregnant women, and elderly are particularly susceptible and should not handle N-Light™ tests after incubation. If you believe that you have been exposed to pathogenic microorganisms like Salmonella, immediately inform your supervisor and seek medical advice.

Disposal

Used N-LightTM tests can be inactivated by autoclaving in an autoclavable bag or by incineration. NEMIS recommends disposal of all N-LightTM tests by a specialized service provider for biohazardous waste. **CAUTION:** Do not dispose of enrichment broth using 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 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 our local representative.



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N-LIGHTTM SALMONELLA RISK

PREVENT. DETECT. ACT.

REQUIRED MATERIALS

- 1. N-Light™ **Salmonella Risk** test tubes [incl. dispenser containing starter tablets]
- 2. NEMIS Bench-top Luminometer
- 3. NEMIS Dry Block Heater
- 4. N-Light™ swabs containing compatible moistening solution:
 - a. N-Light™ sterile dry swabs BP with separate **BPW buffer** [REF 00026]
 - b. N-Light™ sterile dry swabs BP with separate **neutralizer** (REF 00037)

2 3

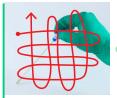
SAMPLE



Mark according to your test plan



 Wet the swab with the moistening solution



Swab the sampling areaApply enough pressure and rotate the swab



Open the test tube

Break off the swab tip in the tube and discard



Add one starter tablet and close the tube by firmly pressing the cap onto the tube until you hear a "click"

Shake until tablet is dissolved

2 INCUBATE



Set the temperature to 37 °C and press <on>

Set a timer to 24 hours



 Make sure each test tube is fully locked



Fully insert the test tubes inside the wells of the Dry Block Heater



Incubate the samples for 24 hours [+/-1 hour] at 37 °C

3 ACTIVATE



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



Verify the tablet is released into the liquid

Start a timer (3 min)



Shake for 20 s, or until tablet is fully dissolved

Use vortex if available



Put activated tubes back at 37 °C Repeat the activation steps consecutively for max. 6 tubes Measure the tubes in order of tablet release

4 MEASURE



Select the Salmonella Risk protocol



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Measure each sample exactly 2-4 minutes after releasing the tablets



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Place the test tube into the luminometer



Presumptive positive.
Indicator organism and/or
Salmonella may be present



No live indicator organism and Salmonella detected

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