INSTRUCTIONS FOR USE

N-Light™ *Salmonella* Risk (REF 00014)

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 24h 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™ swabs, NEMIS dry block incubators, and NEMIS luminometers. NEMIS may make industry-specific application notes available online for other validated use cases.

PERFORMANCE TESTED AOAC RESEARCH INSTITUTE LICENSE NUMBER 072204

Measurement Principle

The method uses AquaSpark®*, a patented ultrasensitive chemiluminescent probe that reacts with an enzyme produced by all *Salmonella* serovars when alive. Some closely related bacteria occupying the same environmental niche also produce this enzyme. With a NEMIS luminometer, the light resulting from this reaction is measured in relative light units (RLU). Test results above the detection threshold indicate an increased risk for the presence of *Salmonella* and live *Salmonella* may be present in the sample, but this should be confirmed by molecular methods.

Specificity and Sensitivity

The N-Light™ *Salmonella* Risk enrichment broth contains a special nutrient mix, supplemented with antibiotics and a proprietary bacteriophage cocktail to provide optimal growth of sub-lethally injured *Salmonella* whilst restricting the growth of competing microorganisms during incubation. **IMPORTANT:** Single strains of *E. coli*, *Klebsiella spp.* or *Citrobacter spp.* may lead to increased RLU readouts as the selective components are not always able to fully inhibit the growth.

Storage and Shelf Life

N-Light™ *Salmonella* Risk antibiotic tablets:

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

N-Light™ *Salmonella* Risk test tubes:

- +2-8°C, **do not freeze**, 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. Shake until the tablet is dissolved.
- Incubate at 37°C for 3 minutes in the NEMIS Dry Block Incubator.
- Test with the NEMIS luminometer 3 minutes after activation.
- Results between 500 and 10'000 RLU are acceptable.

Confirmation

N-Light™ *Salmonella* Risk contains a lysis agent. Presumptive positive results can be confirmed using a recognized confirmatory procedure (e.g., ISO 23418, preferably a validated PCR system or other culture independent method). **CAUTION:** Opening of the N-Light™ 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 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 stored between +1-4°C. Transfer of the swab samples to the N-Light™ test tubes should occur 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 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 (e.g., taking chemotherapy), 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-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.

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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More Info

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

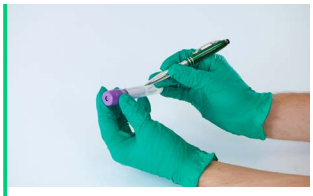
N-LIGHT™ SALMONELLA RISK

PREVENT. DETECT. ACT.

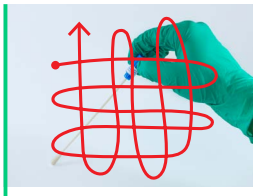
REQUIRED MATERIALS

1. N-Light™ ***Salmonella* Risk** test tubes (incl. dispenser containing antibiotic tablets)
2. N-Light™ sterile dry swabs with breaking point and separate BPW buffer
3. NEMIS Bench-top Luminometer
4. NEMIS Dry Block Heater

1 SAMPLE



Mark according to your test plan



Swab the sampling area

Apply enough pressure and rotate the swab

Open the test tube

Break off the swab in the tube and discard the rest

Add one antibiotic 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 incubator

Incubate the samples for 24 hours (+/- 1 hour)

Incubate samples at 37°C for 24h before activation (tablet release)

3 ACTIVATE

Open the protection lid and firmly push the button to release the AquaSpark™ and Lysis tablets

Verify the tablets have been released into the liquid

Start a timer (3min)

Shake until tablets are dissolved

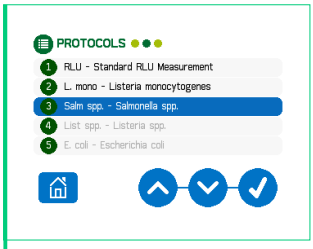
Use vortex if available

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

Measure each sample 3 minutes (+/- 90s) after releasing the tablets

Place the test tube into the luminometer

Indicator organism and/or *Salmonella* may be present

Critical, elevated signal requiring confirmation

No live indicator organism and no live *Salmonella* detected

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