N-LIGHT™ SALMONELLA RISK
INSTRUCTIONS FOR USE

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. Only trained individuals should perform the N-Light™ test.

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 Heaters, and NEMIS Bench-top Luminometers. Please note that the N-Light™ MaxiSampler is outside the scope of the AOAC PTM Validation. Performance data for this sampling device are available online on our website.

PERFORMANCE TESTED AOAC RESEARCH INSTITUTE LICENSE NUMBER 072204

Measurement Principle

The method uses AquaSpark®*, a patented ultrasensitive chemiluminescent probe that reacts with alpha-D-galactosidase, 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 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-Light™ *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-Light™ *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

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 and without the starter tablet. Shake until the tablet is dissolved.
- Incubate at 37°C for 2 minutes in the NEMIS Dry Block Heater.
- Test with the NEMIS Bench-top Luminometer 2 minutes after activation.

Results up to 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 (preferably a validated PCR system or other culture independent method). In our supporting document "Conformation protocol", we describe a qPCR and PCR method compatible with our test. **CAUTION**: Opening the N-Light™ test tube and subsequent sample handling must be performed in a safety level II laboratory.

* AquaSpark® is a trademark of Ramot

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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 standard), samples should be transferred 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**: *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. 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 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 in the sink.

Exclusion of warranty and liability

The product is provided on an as-is basis to be used solely in accordance with following this instruction ofor 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™ SALMONELLA RISK

Watch Instruction Video

REQUIRED MATERIALS AND DEVICES:

1. N-Light™ *Salmonella* Risk test tubes, incl. dispenser with starter tablets (REF 00014)
2. NEMIS Bench-top Luminometer (REF 00001)
3. NEMIS Dry Block Heater (REF 00002/00044)
4. Optional: N-Light™ Tablet Dispenser Tool (REF 00018)
5. Kitchen Timer *(not provided by NEMIS)*
6. Optional: N-Light™ Activation Tool (REF 00008)
7. 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 00014-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 00014-MX-NTR)

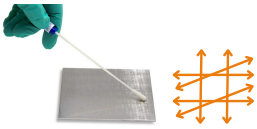
1. PREPARATION

Wet the swabs in the vial with neutralizer solution and put them back in the swab tube.

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

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

2. SAMPLING



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

3. ADDITION OF STARTER TABLET AND SWAB TRANSFER

Open the test tube.

Add one starter tablet to each 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 (3 minutes).

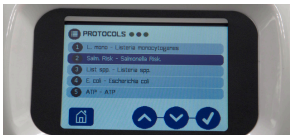
Shake the tube for 5 seconds, or until the tablet is fully dissolved.

Put the activated tubes back at 37 °C for 3 minutes (+/- 1 minutes).

Tip: Repeat the activation steps consecutively for max. 6 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 2-4 minutes after releasing the Aquaspark® tablet.



Switch on the luminometer and select the *Salmonella* Risk protocol.

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

Presumptive positive.
Live indicator organism and/or *Salmonella* spp. may be present

No live indicator organism and *Salmonella* spp. detected

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

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