

N-Light™ *E. coli*

Intended Use

N-Light™ *E. coli* is a qualitative test method for rapid detection of the bacterial hygiene indicator *Escherichia coli*. *E. coli* is present in the digestive tract of most warm-blooded animals and is a well-known indicator for fecal contamination and the presence of enteric pathogens in food, water and beverages. Certain *E. coli* strains are pathogenic themselves. The test method is suitable for use in food processing areas and equipment as part of an environmental monitoring program and can also be used for testing process water and other liquid samples. Final test results are available 16 h after sampling.

Measurement Principle

The method uses AquaSpark®*, a patented ultrasensitive chemiluminescent molecule that reacts with a specific enzyme (beta-glucuronidase) produced by living *E. coli*. With a NEMIS Bench-top Luminometer, the light resulting from this chemical reaction can be accurately measured in relative light units (RLU). Test results above the validated threshold (>10'000 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™ *E. coli* enrichment broth contains a nutrient mix that provides for optimal growth of sub-lethally injured *E. coli*. Competing microorganisms are inhibited due to an elevated incubation temperature of 44 °C. For additional information, please refer to our resources available online.

Storage and Shelf Life

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

Functionality Test

Customers can perform a fit-for-purpose assay to check for any loss of performance due to transport or storage conditions:

- Activate one N-Light™ test containing only the enrichment broth without sample. Shake until the tablet is dissolved.
- Incubate at 44 °C for 3 minutes in the NEMIS Dry Block Heater.
- Test with the NEMIS Bench-top Luminometer 3 minutes after activation.
- Results up to 5'000 RLU are acceptable.

Confirmation

N-Light™ *E. coli* contains a lysis agent. Presumptive positive results can be confirmed using the NEMIS PCR protocol or another recognized confirmatory procedure (*e.g.*, a validated qPCR 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 a good aseptic technique 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.

* AquaSpark® is a trademark of Ramot

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, shelf-life, or procedures will negatively affect the product performance and potentially lead to false-positive or false-negative results. Due to the permanently closed and liquid-tight N-Light™ tube, NEMIS considers N-Light™ tests safe to cultivate environmental microorganisms for the intended use outside of a laboratory environment. However, depending on local regulations, such cultivation 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™ 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:** Some *E. coli* strains are disease-causing human pathogens, and infection can be fatal. Immunocompromised individuals, pregnant women, and the elderly are particularly susceptible and should not handle the N-Light™ tests after incubation. **If you believe you have been exposed to pathogenic microorganisms, 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 the disposal of all N-Light™ tests by a specialized service provider for biohazardous waste. **CAUTION:** Do not dispose of enrichment broth using the sink, as it contains antibiotics.

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 be 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 online technical resources or contact our local representative.



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More Info

REQUIRED MATERIALS

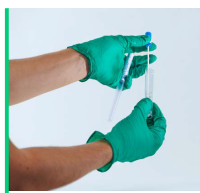
1. N-Light™ *E. coli* test tubes
2. NEMIS Bench-top Luminometer
3. NEMIS Dry Block Heater
4. N-Light™ swabs containing compatible moistening solution:
 - a. N-Light™ sterile dry swabs BP with separate **BPW buffer** [REF 00026]
 - b. N-Light™ sterile dry swabs BP with separate **neutralizer** [REF 00037]



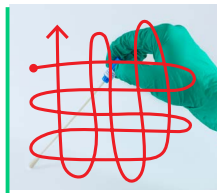
1 SAMPLE



Mark according to your test plan



Wet the swab with the moistening solution



Swab the sampling area
Apply enough pressure and rotate the swab



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



Put the cap back on the test tube and press firmly until you hear a "click"

2 INCUBATE



Set the temperature to 44°C and press <on>
Set the timer to 16 hours



Make sure each test tube is fully locked



Fully insert the test tubes inside the Dry Block Heater



Incubate the samples at 44 °C for 16 hours (possible up to 72 hours)

3 ACTIVATE



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



Verify the tablet have been released into the liquid
Start a timer (3 min)

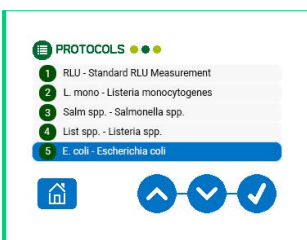


Shake for 20 s, or until tablet is fully dissolved
Use vortex if available

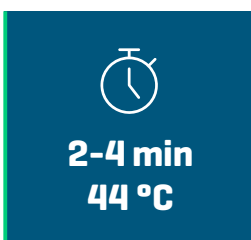


Put activated tubes back at 44 °C
Repeat the activation steps consecutively for max. 6 tubes
Measure the tubes in order of tablet release

4 MEASURE



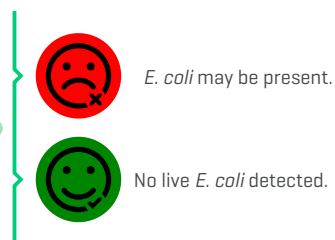
Select the *E. coli* protocol



Measure each sample exactly 2-4 minutes after releasing the tablet.



Place the test tube into the luminometer



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