

# **Evaluating the test performance of N-Light™ *L. monocytogenes* in the field**

**White Paper**



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## Introduction

NEMIS conducted an in-depth field study at a ready-to-eat sushi production site to assess the real performance of the N-Light™ *Listeria monocytogenes* test. While many competitors typically conduct performance tests in controlled laboratory settings, the objective was to take a more bold and honest approach by evaluating the test's performance directly in the field.

The decision to conduct the performance test in an actual food production environment reflects a commitment to real-world accuracy and reliability. By eschewing the controlled conditions of a laboratory, NEMIS sought to evaluate the test's reliability in a setting that mirrors the complex and dynamic nature of food processing facilities. This approach enables a more comprehensive assessment of the test's performance and its ability to deliver reliable results in a practical context.

In the following sections, we will delve into the details of the field study, examining the methodology employed, the results obtained, and the implications for food safety practices. This study showcases the commitment to innovation and rigorous evaluation, ultimately contributing to enhanced consumer protection and the continuous improvement of food safety standards.

## Study Design

The study collected a total of 90 samples over the course of two days, using N-Light™ Neutralizer for sample collection. Swabs with collected bacteria were analyzed within 2 h after taking the samples.

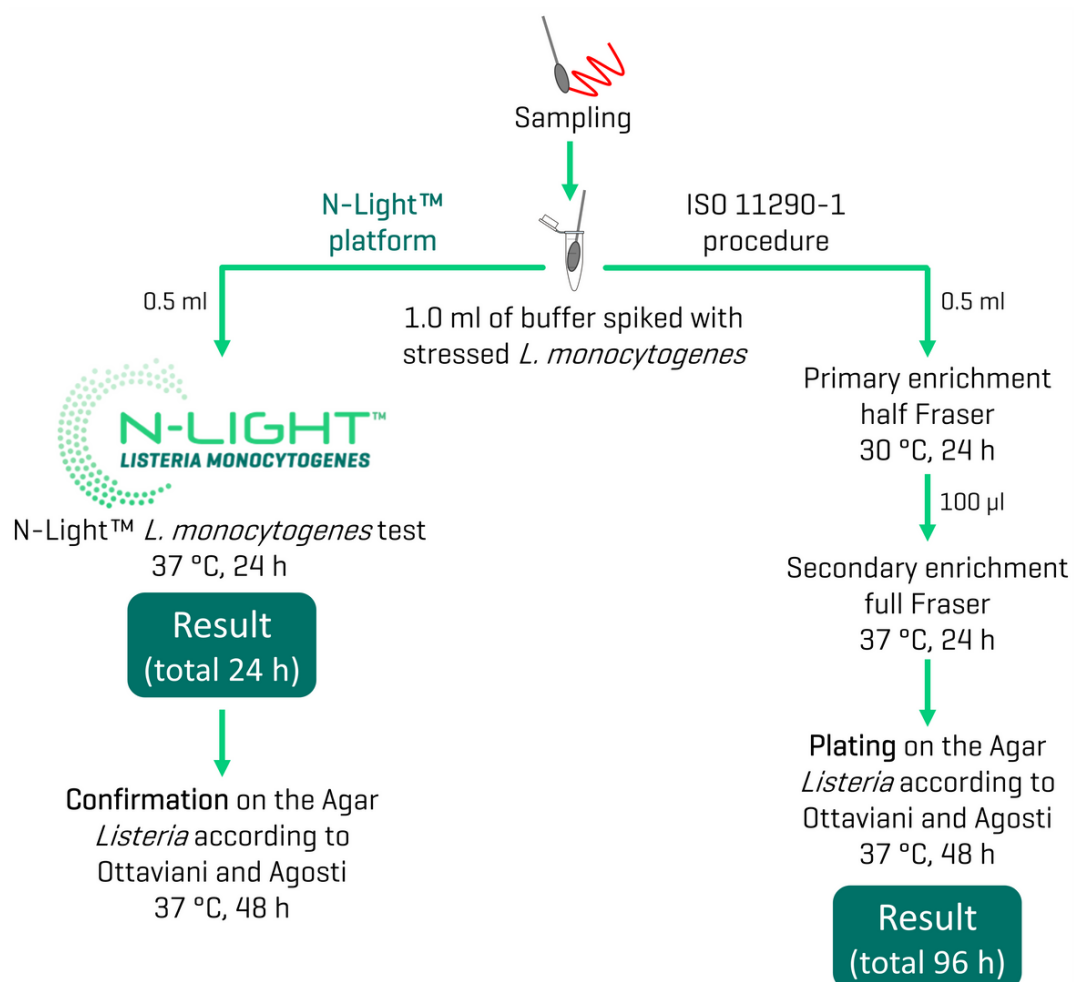
The study incorporated a wide range of samples, including those collected inside and outside the intended use areas. This approach aimed to capture the diversity of the sushi producer's environment and assess the test's performance across different areas within the facility.

Separately, the bacterial inoculum was prepared by growing *Listeria monocytogenes* ATCC 19111 on non-selective agar and incubated at 37 °C for 18-24 h. A single colony from that plate was inoculated into BHI broth and incubated at 37 °C for 18-24 h. The culture was then stored at 4 °C for 72 h to chill stress the bacteria before incubation. The culture was then plated out and diluted to achieve the required concentration for the spiking step.

Before incubation, all samples were resuspended in 1 ml of buffer and spiked with 200 cfu/ml of chill-stressed *Listeria monocytogenes* ATCC 19111, ensuring all samples were considered positive for the *L. monocytogenes* bacterium.

Each sample underwent testing using two different methods: the N-Light™ *L. monocytogenes* test and the ISO 11290-1 method. This dual-testing approach thoroughly compared the evaluated rapid test and the established ISO method commonly used for *Listeria monocytogenes* detection. By comparing the results of both methods, the study could assess the performance of the rapid test in relation to the industry-standard ISO method.

The last step was a confirmation procedure from the N-Light™ *L. monocytogenes* test. After the measurement, the content of the tube was directly inoculated on the Agar *Listeria* according to Ottaviani and Agosti and incubated at 37 °C for 48 h.



## Results

The samples were collected both in locations designated within the recommended use of the test and also outside the scope. Several swabs were taken from HACCPs defined in the producer's sampling plan. As presented below, when the test was utilized within recommended use, it demonstrated exceptional performance with 100% accuracy, thus giving performance equivalent to the ISO reference method.

Sample type	Recommended use	N-Light™	ISO 11290-1	N-Light™ vs ISO
door part	yes	3/3	3/3	same performance
food processing equipment	yes	27/27	27/27	same performance
part of production line (before, during, after production)	yes	12/12	12/12	same performance
part of washing line	yes	2/2	2/2	same performance
pipng	yes	5/5	5/5	same performance
ventilation	yes	6/6	6/6	same performance
drain	no	10/10	10/10	same performance
cleaning equipment	no	4/4	4/4	same performance
food matrix from production line/equipment	no	11/14	14/14	worse than ISO
old dirt from inaccessible place	no	2/5	5/5	worse than ISO

	N-Light™		ISO 11290-1	
	Recommended use	Outside of recommended use	Recommended use	Outside of recommended use
Zone 1	29/29	12/16	29/29	16/16
Zone 2	17/17	4/5	17/17	5/5
Zone 3	6/6	11/12	6/6	12/12
Zone 4	3/3	n/a	3/3	n/a
Accuracy	100.0	81.8	100.0	100.0
Total accuracy	<b>93.2</b>		<b>100.0</b>	

It is important to notice that even when used outside its intended purpose, the test still exhibits commendable performance, achieving 82% accuracy. The observed decrease in performance was present due to two main factors:

- Overloading the sample with food matrix residues collected from the production line or equipment.
- Old dirt collected from inaccessible places.

Overall accuracy lies at an impressive 93%, and it can be easily improved in practical application by avoiding loading the sample with food residues or old accumulated dirt.

An important finding from the study was that no correlation was observed between the test performance and the zone where the test was conducted. This result suggests that the test maintained consistent accuracy regardless of the specific location within the sushi producer's facility.

Lastly, utilizing confirmation directly from the tube on the ALOA plate proves highly effective, yielding 100% accuracy [data not shown]. These results confirm that simple ALOA plating offers a reliable and rapid confirmation solution without a need for a long and costly full ISO cultural method.

## Conclusions

In conclusion, the field study conducted in the RTE factory by NEMIS on the N-Light™ *Listeria monocytogenes* test demonstrated exceptional performance within the recommended use, achieving 100% accuracy, a result comparable with the golden standard ISO 11290-1 method. Even when used outside its intended purpose, the test still exhibited commendable performance, with 82% accuracy.

The impressive overall test accuracy of 93% can be easily improved by avoiding overloading the sample with food residues or old accumulated dirt. Together with its other advantages, such as being a user-friendly, lab-free method and generating actionable results within only 24 h, the N-Light™ *L. monocytogenes* test is invaluable for mitigating risks and reestablishing control in every ready-to-eat food facility.