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

White Paper

NEMIS Technologies AG
info@nemistech.com

ver. 1.05

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.

As natural prevalence of Listeria monocytogenes is very low, a spiking step with chilled-stressed Listeria was included in the study. For this purpose, Listeria monocytogenes ATCC 19111 was grown in non-selective agar and then chill stressed for 72 h before incubation.

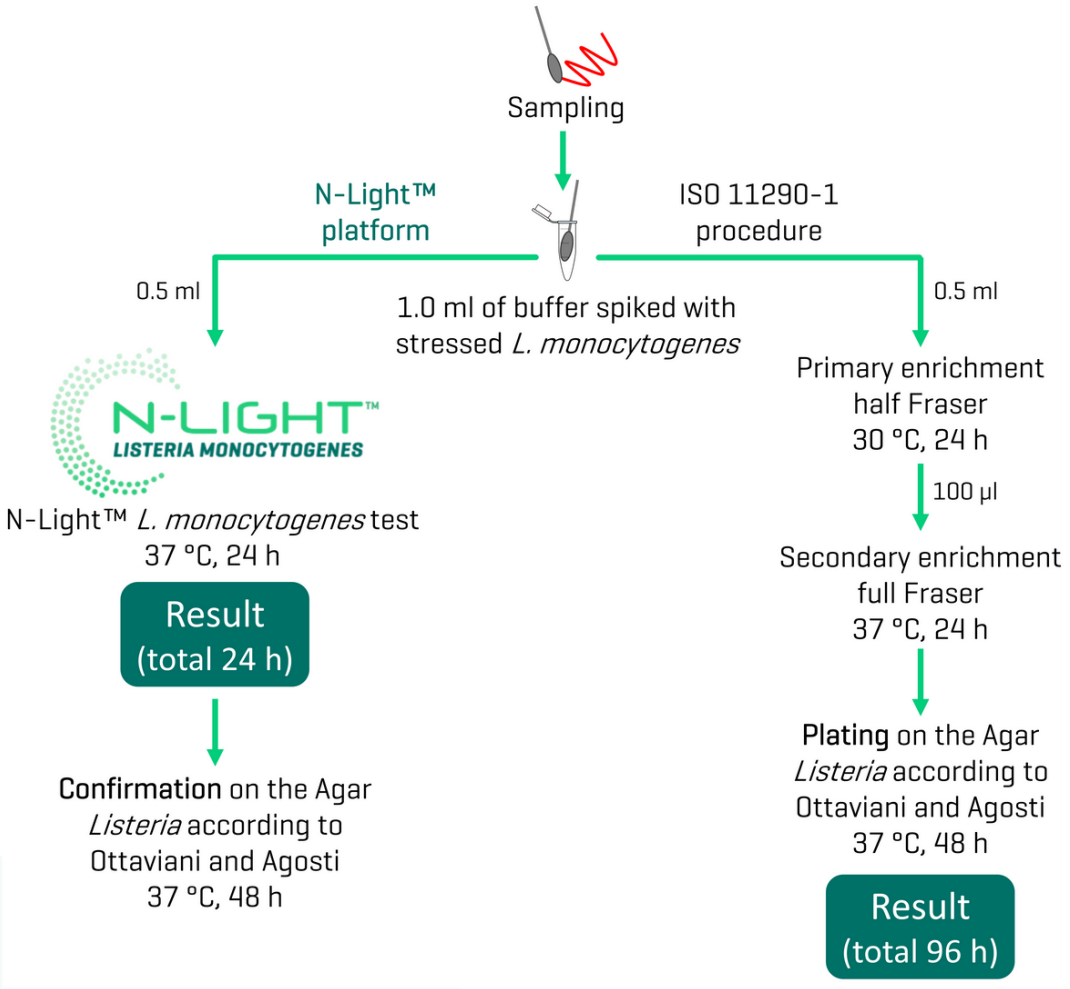
The study incorporated a wide range of samples, including those collected inside and outside the intended use areas. This approach aimed to capture the diversity of the sushi producer's environment and assess the test's performance across different areas within the facility.

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. Many swabs were taken from critical points identified by the producers HACCP study and within all hygiene zones from zone 1 with high risk down to zone 4 with low risk categorization. When the test was utilized within recommended use, it demonstrated exceptional performance with over 93% sensitivity, thus giving performance close to the ISO reference method (see result table below).

Overall impressive sensitivity of 93% can be easily improved in practical application by avoiding most common factors causing decrease in performance:

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

Sample type	N-Light™	ISO 11290-1	N-Light™ vs ISO
door part	3/3	3/3	same performance
food processing equipment	27/27	27/27	same performance
part of production line (before, during, after production)	12/12	12/12	same performance
part of washing line	2/2	2/2	same performance
piping	5/5	5/5	same performance
ventilation	6/6	6/6	same performance
drain	10/10	10/10	same performance
cleaning equipment	4/4	4/4	same performance
food matrix from production line/equipment	11/14	14/14	worse than ISO
old dirt from inaccessible place	2/5	5/5	worse than ISO

	N-Light™	ISO 11290-1
Zone 1	41/45	45/45
Zone 2	21/22	22/22
Zone 3	17/18	18/18
Zone 4	3/3	3/3
Sensitivity	93.2	100.0

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 sensitivity 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% sensitivity (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. The impressive overall test sensitivity 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.