NEOGEN®
ANSR®

Listeria Right Now™

An enrichment-free environmental monitoring tool for *Listeria* detection providing actionable results in less than 60 minutes.

NEOGEN®

Less than an hour? How is this possible?

The ANSR® *Listeria* Right Now system is able to detect very low numbers of *Listeria* spp., including *L. monocytogenes*, from environmental samples without enrichment. The system employs an isothermal, amplified nucleic acid-based reaction to target rRNA. Amplification occurs through a polymerization mechanism by a specific endonuclease. Detection occurs in real-time using a fluorescent, molecular beacon.

Ribosomal RNA is present in much greater numbers in *Listeria* cells than the traditional DNA target (~1000 – 10,000 copies per cell vs. 1 copy per cell for DNA). This can result in a 1,000 – 10,000 fold increase in target analyte concentration.

The isothermal reaction within the instrument produces a constant cycle of molecular replication producing analyte copies much more quickly than traditional PCR reactions which run through a series of heating and cooling cycles.

Summary: significantly more targets with a significantly faster cycle time = significantly faster results.

Less than a 60 Minute Total Time-To-Result Means Everything Has Changed

Now you can:

- Use *Listeria* monitoring as a process control
- Perform corrective actions more quickly — fix the issue before it becomes a serious problem — clean and re-test
- Conduct investigations in near real-time after positives
- Perform vectoring more easily
- Be more flexible and proactive with your environmental testing program

No enrichment with an easy-to-use system means you can conduct *Listeria* environmental testing in your facility without concern for "growing pathogens."

"Culture-independent" method also means no exposure to trace-backs tied to retained cultures.

Neogen Validation Data

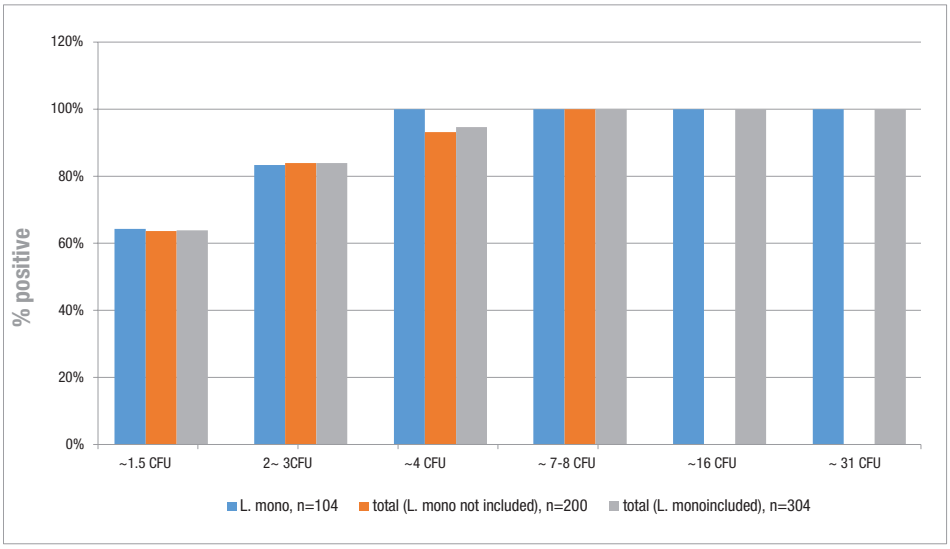
Listeria with and without background organisms on different surfaces:

Surface type	Trial	*Listeria* CFU/swab	N	ANSR *Listeria* Right Now +	Culture +	dPOD (95% CI)
Stainless steel	Lm (4b) only	1	15	3	2	0.07 (-0.21, 0.34)
		2	15	10	7	0.20 (-0.14, 0.48)
		2438	5	5	5	0 (-0.43, 0.43)
		0	5	0	0	0 (-0.43, 0.43)
Stainless steel	Lm (4b) + background	1.8	20	8	7	0.05 (-0.23, 0.32)
		1800	5	5	5	0 (-0.43, 0.43)
		0	5	0	0	0 (-0.43, 0.43)
Plastic	L. innocua + background	2.3	20	9	9	0 (-0.28, 0.28)
		2250	5	5	5	0 (-0.43, 0.43)
		0	5	0	0	0 (-0.43, 0.43)
Sealed concrete	L. welshimeri + background	1.2	20	6	11	-0.25 (-0.5, 0.05)
		1550	5	5	5	0 (-0.43, 0.43)
		0	5	0	0	0 (-0.43, 0.43)
Ceramic tile	Lm (1/2a) + background	1.93	20	14	9	0.25 (-0.05, 0.50)
		1930	5	5	5	0 (-0.43, 0.43)
		0	5	0	0	0 (-0.43, 0.43)

dPOD (95% CI) = difference between the candidate method and reference method calculated as a Probability of Detection with a 95% confidence interval. The ANSR *Listeria* Right Now kit is designed using swabs, not sponges for sampling in order to get the proper sample concentration into the assay. ANSR *Listeria* Right Now has been tested on surfaces with residual cleaning agents. The residual cleaning agents had no effect on the assay. ANSR *Listeria* Right Now is an environmental test and due to sample homogeneity, matrix effects, and representative sample volume, it is not intended for use with food products.

Limit of Detection:

4 CFU per swab with 95% confidence



Method: Inoculated directly onto swab

Organisms Tested:

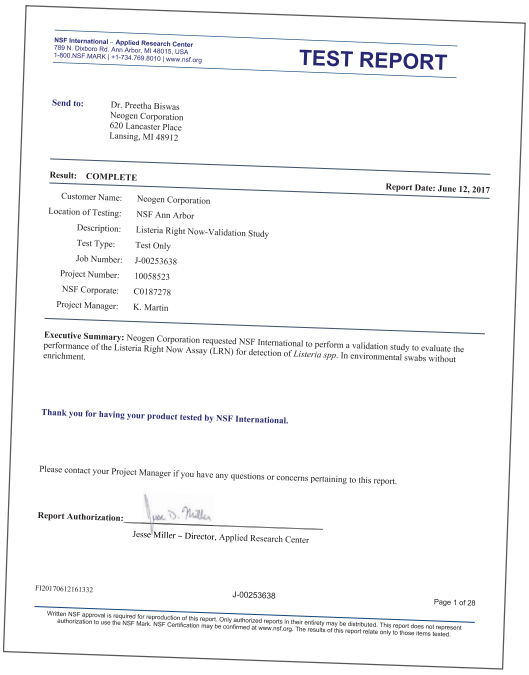
L. monocytogenes
L. innocua
L. welshimeri
L. grayi
L. ivanovii
L. seeligeri

NSF International Study—Applied Research Center

Environmental surface study results for *Listeria monocytogenes* and background organisms on stainless steel.

Level	Theoretical Inoculum (CFU/swab)	Sample Number	LRN Positive	% LRN Positive	Culture Positive	% Culture Positive
Negative	0	5	0	0%	0	0%
Positive	2.4E+4	5	5	100%	5	100%
L1	3	15	14	93%	9	60%
L2	9	15	15	100%	15	100%
L3	22.5	15	15	100%	15	100%

Note: The table presents the results for the environmental surface study using a challenge inoculum of *L. monocytogenes* plus a consortium of competing organisms. Three different inoculation levels were evaluated on the stainless steel carriers: Level 1 = 3 CFU, Level 2 = 9 CFU and Level 3 = 22.5 CFU (theoretical CFU/swab). At Level 1, the detection rates for LRN and the reference enrichment-based culture method were 93% and 60%, respectively. At Levels 2 and 3, the detection rates for ANSR *Listeria* Right Now and the reference enrichment-based culture method were 100%. No false negatives, false positives or invalids were observed during this study. The data illustrates that under the conditions employed in this study ANSR *Listeria* Right Now is as sensitive as the enrichment-based culture reference method for detection of *L. monocytogenes* on a stainless steel surface.



NSF International - Applied Research Center
789 N. Dixboro Rd, Ann Arbor, MI 48105, USA
1-800.NSF.MARK | +1-734.769.8010 | www.nsf.org

TEST REPORT

Send to: Dr. Preetha Biswas
Neogen Corporation
620 Lancaster Place
Lansing, MI 48912

Result: COMPLETE — **Report Date: June 12, 2017**

Customer Name: Neogen Corporation
Location of Testing: NSF Ann Arbor
Description: Listeria Right Now-Validation Study
Test Type: Test Only
Job Number: J-00253638
Project Number: 10058523
NSF Corporate: C0187278
Project Manager: K. Martin

Executive Summary: Neogen Corporation requested NSF International to perform a validation study to evaluate the performance of the Listeria Right Now Assay (LRN) for detection of *Listeria spp.* in environmental swabs without enrichment.

Thank you for having your product tested by NSF International.

Please contact your Project Manager if you have any questions or concerns pertaining to this report.

Report Authorization:
Jesse Miller – Director, Applied Research Center

FI20170612161332 — J-00253638 — Page 1 of 28

Written NSF approval is required for reproduction of this report. Only authorized reports in their entirety may be distributed. This report does not represent authorization to use the NSF Mark. NSF Certification may be confirmed at www.nsf.org. The results of this report relate only to those items tested.

Summary/Conclusion

The purpose of this study was to evaluate the performance of the ANSR *Listeria* Right Now (LRN) assay for the detection of *Listeria* spp. in environmental swabs without a prior enrichment process.

After allowing the inoculum to partially dry (50%), surface samples were collected using semi-paired swabs. One swab was tested by the ANSR *Listeria* Right Now assay and the other swab was enriched by the culture method. The swab for the culture method was enriched overnight at 37°C in growth medium and an aliquot plated on to agar plates for detection on the following day. In the ANSR *Listeria* Right Now test, the entire collected contents of the swab were subjected to sample processing and testing on the same day.

No false negatives, false positives or invalids were observed during this study. The evaluation determined that under the conditions employed in this study, **the enrichment-free *Listeria* Right Now method is as sensitive as the enrichment-based culture reference method** for detection of *L. monocytogenes* on a stainless steel surface.

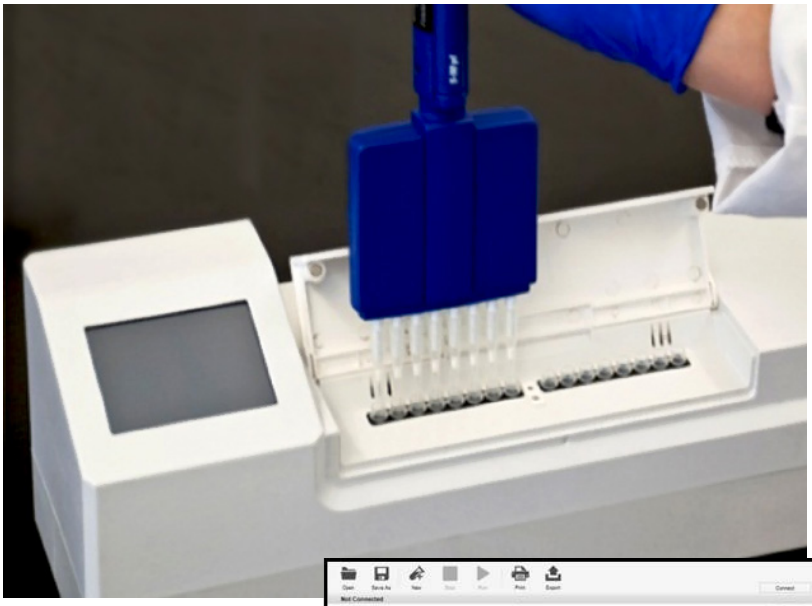
ANSR *Listeria* Right Now is a Complete System

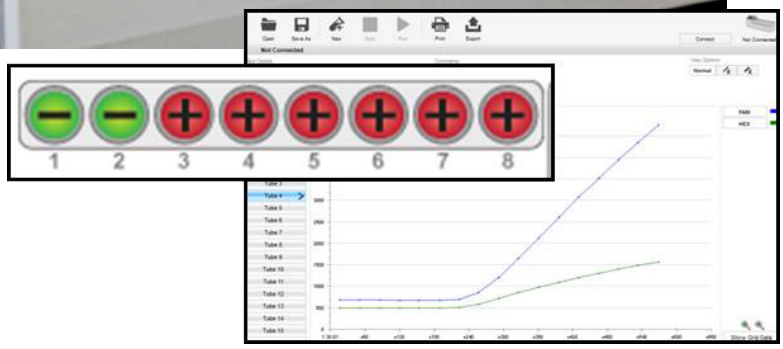
System components: Item No. 9837

16-well, isothermal polymerization instrument
ANSR *Listeria* Right Now detection software
Two (2) heater blocks

Each Assay Kit contains: Item No. 9873

96 reaction tubes with internal positive control
96 environmental sampling swabs
All necessary components



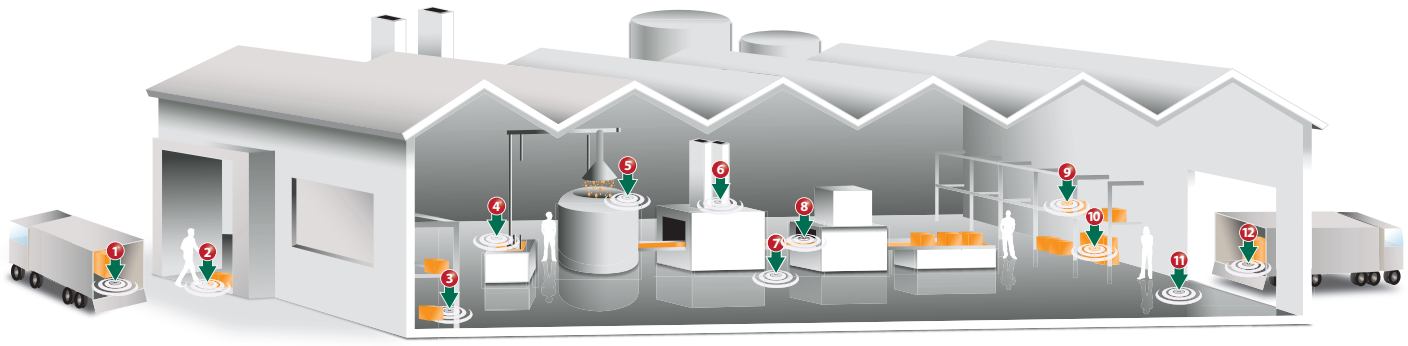


Simple and Easy To Use

1. Swab surface
2. Express swab in Eppendorf tube with lysis buffer
3. Transfer solution to cluster tube and place in first heater block
4. Transfer tubes to second heater block
5. Transfer solution to reagent tubes, cap and place in reader. Hit “start”

Vectoring

The process of identifying the sources and flow of environmental pathogens is often called “vectoring.” This process typically involves a physical examination of an identified source and its surrounding area as well as specific processes such as the food production and sanitation efforts involved in the area. Through a structured series of microbiological samples, sources and vectors of contamination can be identified and corrective actions implemented. Because of the quick time to result of ANSR *Listeria* Right Now and its relative low cost, vectoring is easier without the need for external resources.



Neogen's Food Safety Division

From easy-to-use lateral flow tests for numerous contaminants, to DNA-definitive assays for pathogens, Neogen offers testing products, expertise, service and support for the food industry.

Food safety testing solutions

- Natural toxins
- Food allergens
- Sanitation verification
- Spoilage organisms
- Pathogens/foodborne bacteria
- Residues
- Dehydrated culture media

Online ordering

Experience the convenience and efficiency of our online ordering system at: **http://order.neogen.com/LAN.** *(Available in the USA and Canada)*

Training and support

Neogen provides continual support and follow-up training, utilizing a combination of virtual and on-site training. Our dedicated technical service and field application specialists provide around-the-clock professional technical support should questions arise about any of our products.

NeoCare™/LabLive

We offer a variety of service programs designed to optimize your results when using Neogen products. LabLive is a unique lab-to-lab experience connecting our technical support experts and your lab.

NeoCare

LabLive

NEOGEN®

Neogen is a leader in developing and marketing food safety solutions. Contact us today to put our products and expertise to work for you.

Global Headquarters:
800/234-5333 or 517/372-9200
foodsafety@neogen.com
foodsafety.neogen.com

Europe:
+44 1292 525 628
contact_uk@neogeneurope.com

Europe, Middle East and Africa Division:
+44 1292 526 093
contact_emea@neogeneurope.com
www.neogeneurope.com

Brazil:
+55 19 3935 3727
info@neogendobrasil.com.br
www.neogendobrasil.com.br

Latin America:
+52 55 5254 8235
informacion@neogenlac.com
www.neogenlac.com

China:
+86 21 6271 7013
info@neogenchina.com.cn
www.neogenchina.com.cn

India:
+91 484 230 6598
info@neogenindia.com
www.neogenindia.com

FD1050-0617