

The CERTUS System

The CERTUS System is a rapid-result, in-house food pathogen detection system designed for food processing plants. The fully bio-contained system provides real-time detection of *Listeria* spp. from environmental samples utilizing immunoassay methodology enhance by Raman detection for swab-to-result in as little as eight hours.

USE CASE

Methodology	Simultaneous Detection During Enrichment - Immunoassay Based System Utilizing Surface Enhanced Raman Spectroscopy
-------------	-------------------------------------------------------------------------------------------------------------------

SWAB-TO-RESULT TIME

Average	10 to 14 hours
Minimum	8 hours
Maximum	24 hours

PERFORMANCE

Environmental Requirements	Between 15-25° Celsius (59 – 77°Fahrenheit). Do not place the unit directly in the air stream of an air conditioning vent or heat outlet. The normal operation of the Detection Unit generates approximately ~60 dB of sound. The instrument should be placed in an area separated from desk and work stations.
Intended Use	Detection of <i>Listeria</i> spp. from environmental surface matrices.
Accuracy	Specificity 98% Sensitivity 98% Analytical Sensitivity 5x10 ⁵ cfu
Data Management	Records of all test data including: site location, zone type, test type, technician ID, frequency, mapping, results and remediation. Enables view of all open cases including those under review, active, and closed. All test data stored on instrument computer.
Remote Diagnostics	Through customer granted Wi-Fi connectivity, basic troubleshooting and software updates are available.
Matrices	Concrete, Stainless Steel, Ceramic, Plastic
Throughput	1-12 samples per run


FACILITY REQUIREMENTS

Size and Weight	Height: 20 inches, Width: 15 inches, Depth: 24 inches, Weight: 40.82 kg (90 lbs)
Power	100-240 VAC - Standard U.S. plug
Network Requirements	Detection Unit connects to facility network via standard Ethernet LAN connection. Control pad connects to Detection Unit via Wi-Fi signal emitted from Detection Unit to Control Pad.
Work Area	Requires standard laboratory tables that provide a flat, rigid, and sturdy surface able to support a minimum of 100 lbs weight and able to withstand vibrations from the detection unit. A minimum surface depth of 24 inches and a width if 15 inches is needed to accommodate the instrument. The Detection Unit is 20 inches tall.
Disposal	Ensure all biohazardous waste is disposed of appropriately. Discard sample and assay waste according to your operating procedures and local safety regulations.

REAGENTS

Components	<ul style="list-style-type: none"> • EL Detection Tube containing dried down conjugates • EL Selective Growth Media, hydrated and ready to use • EL BIO-LOCK™ Sampling Swab • EL Positive and Negative Verification Caps 												
Storage	<table border="1"> <thead> <tr> <th>Kit Component</th> <th>Storage</th> </tr> </thead> <tbody> <tr> <td>Foiled Pouched EL Detection Tube</td> <td>Ambient</td> </tr> <tr> <td>Foiled Pouched EL Verification Caps</td> <td>Ambient</td> </tr> <tr> <td>EL Bio-Lock™ Sampling Swab</td> <td>Ambient</td> </tr> <tr> <td>EL Selective Growth Media</td> <td>2-8°C in dark</td> </tr> </tbody> </table>	Kit Component	Storage	Foiled Pouched EL Detection Tube	Ambient	Foiled Pouched EL Verification Caps	Ambient	EL Bio-Lock™ Sampling Swab	Ambient	EL Selective Growth Media	2-8°C in dark	<i>Note: The expiration date is marked on each of the components.</i>	
Kit Component	Storage												
Foiled Pouched EL Detection Tube	Ambient												
Foiled Pouched EL Verification Caps	Ambient												
EL Bio-Lock™ Sampling Swab	Ambient												
EL Selective Growth Media	2-8°C in dark												

CERTUS SYSTEM

Detection Unit	<p>The Detection Unit is a closed bio-contained enrichment and detection system incorporating both a temperature-controlled incubation chamber and a detection system comprised of a laser and Raman probe. The instrument design allows for real-time detection of the target pathogen during its amplification in the enrichment culture. The design of the system allows for monitoring without the need to open the enrichment culture tube and risking environmental contamination. The system continuously monitors for pathogen amplification during the enrichment process and alerts the appropriate staff as soon as a presumptive positive is detected. The complete bio-containment of the sample from the start of enrichment to test completion along with the simple work flow enable pathogen testing to be conducted with confidence and safety at the food production site.</p>
Principal of the Assay	<p>The CERTUS Environmental <i>Listeria</i> spp. test is a homogeneous no-wash sandwich immunoassay, where antibodies specific to <i>Listeria</i> are covalently bound to magnetic capture microparticles and SERS detection nanoparticles. In the presence of <i>Listeria</i>, the two particles form a complex mediated through simultaneous capture of the <i>Listeria</i> bacteria. This complex is pulled to the side of the detection tube with an external magnet and the complex is excited with a laser resulting in signal generation of the Raman sensitive tag on the SERS nanoparticles. The intensity of the SERS signal is related to the amount of <i>Listeria</i> present in the complex. This process is cycled repeatedly with the raw optical signal automatically interpreted through a proprietary algorithm that flags samples that are presumptive positive.</p>
Control Pad	9.7" iPad equipped with InSite™ facility management software. Wi-Fi connection to the Detection Unit
Instrument Warranty	12 months
Certification	The CERTUS Environmental <i>Listeria</i> spp. has been certified by the AOAC Research Institute as Performance Tested MethodSM 101802
Standards	RoHS compliant to EU Directive RoHS 2002/95/EC
	

SAMPLE WORKFLOW

Technical Skill Required	Minimal
Hands-On Technician Time	3 minutes per sample post sample collection
Workflow Steps	3