CERTUS™

Food Pathogen Detection Made Smart

COST SAVINGS

Lower the Cost of your Environmental Monitoring Program with the CERTUS System

Complimentary EMP Software

The CERTUS System includes Empower™ Environmental Monitoring Software with no extra fees or subscription costs. Empower provides automated mapping, scheduling, and FSMA-compliant data management.

Anyone Can Perform

There is no costly certification or training needed to perform the simple 3-step workflow which takes only minutes from sample to test.

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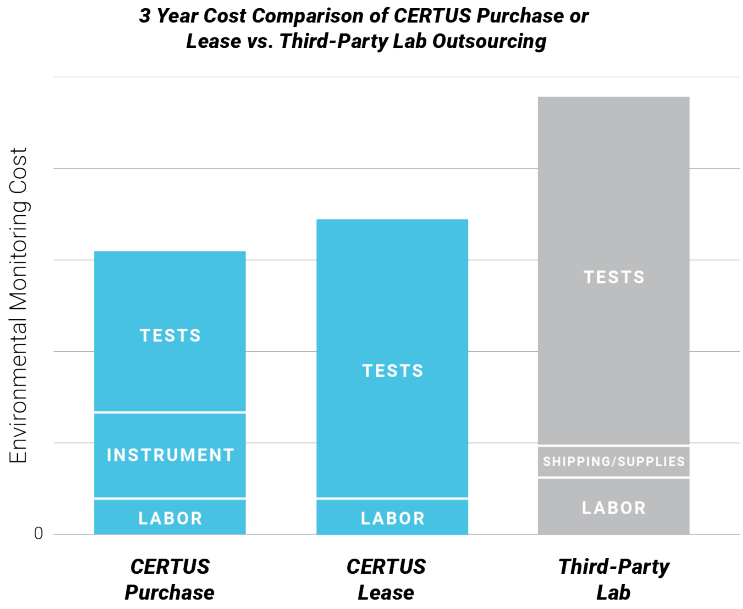
COST SAVINGS

Bring Testing In-House for Substantial Cost Savings with the Bio-Contained CERTUS System

In-House Testing

The CERTUS System is fully bio-contained, allowing you to test for pathogens in-house for dramatically reduced shipping costs and specialty postage fees usually required with third-party testing.



Based on 2,000 samples per year, over the course of 3 years

Flexible Pricing Models

With options to lease, rent or own you're sure to find an option to fit your budget!

Lease

- Low cost per test
- Option to buy the system at the end of the lease

Rent

- No cost barrier to entry
- Minimum monthly test requirement

Own

- Low cost per test
- Substantial cost savings over 3 years
- Own the system

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WORKFLOW

Reduce Labor Costs and Increase Productivity with the CERTUS 3-Step Workflow

Sample, Test, Result.

No specialized training, certification, or experience necessary.

Minimal prep steps means reduced hands-on time per sample.

Automation reduces repetitive manual tasks.

Now anyone in your facility can perform environmental pathogen testing. Simply collect your sample and insert into the Detection Unit following step-by-step directions on your Control Pad.

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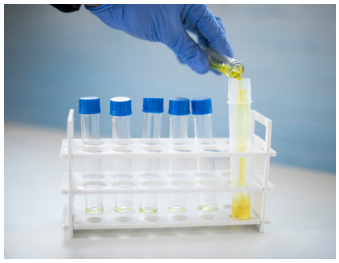
Food Pathogen Detection Made Simple

WORKFLOW

1 Sample

Collect sample using Bio-Lock™ Sampling Swab.



Pour pre-measured selective growth media into Detection Tube.

Insert Bio-Lock Sampling Swab into Detection Tube.

BIO-LOCK™ Once securely closed, Bio-Lock Sampling Swabs form a permanent seal that can't reopen, thus securing the facility from accidental contamination.

2 Test

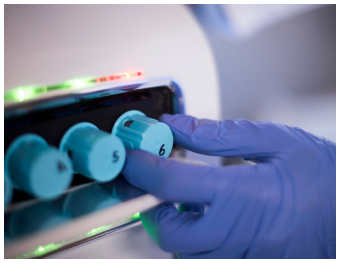
Initiate testing by clicking on "New Test" on Control Pad.

Scan the barcode on the Detection Kit box.

Insert Detection Tube into available slot.

3 Result

Real-time detection begins immediately with results in as little as 8 hours.



Test results on Detection Unit, Control Pad, and via email/SMS alerts.

All testing information is automatically logged and stored for easy traceability.

CERTUS™

Simple, Safe, Smart Food Pathogen Detection

RESEARCH & DEVELOPMENT

CERTUS is on a Mission to Make the World a Safer Place to Eat

March 2016

Technology License From BD

December 2016

Environmental *Listeria* Assay Research and Development Begins with Solus Scientific

February 2017

Prototype Detection Unit Become Available and Assay R&D Moves Forward

June 2017

CERTUS Brand Launched at IAFP

May 2018

CERTUS System Debuts at Food Safety Summit

July 2018

External Validation Studies Initiated

October 2018

CERTUS Detection System Gains AOAC Certification

March 2019

Debut of Empower™ Software

Future Direction

Build out Environmental Menu with *Salmonella, E. Coli O157:H7*

Apply CERTUS Technology Platform to the Direct Testing of Food Products

Increase Functionality to the Empower™ Software

Increase Throughput

Assess the Potential to Run a Multi-plex Targeted Assay using Unique SERS Reported Groups

CERTUS

Simple, Safe, Smart Food Pathogen Detection

RESEARCH & DEVELOPMENT

Revolutionary Technologies and Strategic Partnerships Make CERTUS an Innovative Leader in Food Safety

The CERTUS System featured core SERS technology and instrument design based on innovative technology exclusively licensed from BD (Becton, Dickinson and Company), a leading global medical technology company, for applications in the food safety market.

This revolutionary technology enables CERTUS to provide easy and cost effective ways to detect environmental *Listeria* in food processing environments.

Assay development is conducted in collaboration with UK-based Solus Scientific. With a strong technical team at Solus' Research and Development laboratory, CERTUS developed a robust assay with high sensitivity and specificity for detection of *Listeria* spp. on a variety of environmental surfaces and is currently developing an environmental assay based on the same technology.

Solus has scientific expertise in the development of immunoassay-based tests specific for the food pathogen testing market.

PERFORMANCE TESTED AOAC RESEARCH INSTITUTE LICENSE NUMBER 101802

CERTUS™

Simple, Safe, Smart Food Pathogen Detection

SPECIFICATIONS

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 enhanced 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 by 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 *Listeria* 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.

CERTUS™

Simple, Safe, Smart Food Pathogen Detection

SPECIFICATIONS

REAGENTS

Components	• *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

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

Note: The expiration date is marked on each of the components.

CERTUS SYSTEM

Detection Unit	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.
Principal of the Assay	The CERTUS Environmental *Listeria* spp. test is a homogeneous no-wash sandwich immunoassay, where antibodies specific to *Listeria* are covalently bound to magnetic capture microparticles and SERS detection nanoparticles. In the presence of *Listeria*, the two particles form a complex mediated through simultaneous capture of the *Listeria* 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 *Listeria* 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.
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 *Listeria* 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

CERTUS™

Food Pathogen Detection Made Safe

FAST AND ACCURATE

Get Results in as Little as 8 Hours with the CERTUS System

Combining real-time monitoring, selective enrichment, and sensitive and specific detection in a single tube gives food producers a simple, safe and smart method for detecting environmental pathogens on-site.

PERFORMANCE TESTED
AOAC
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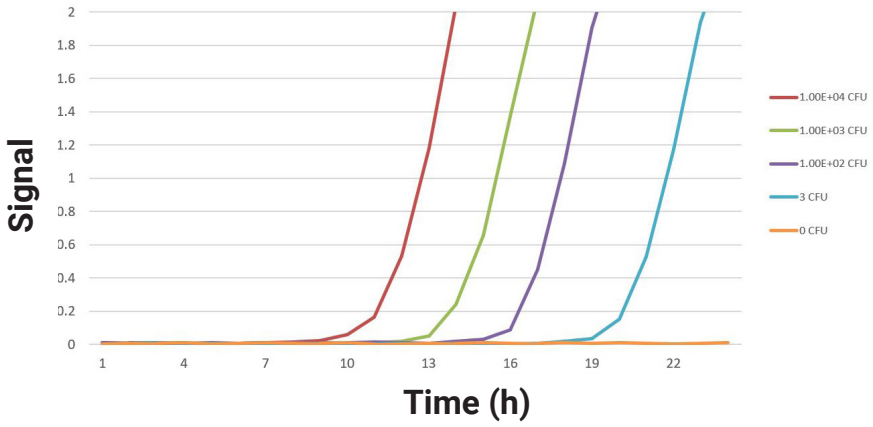
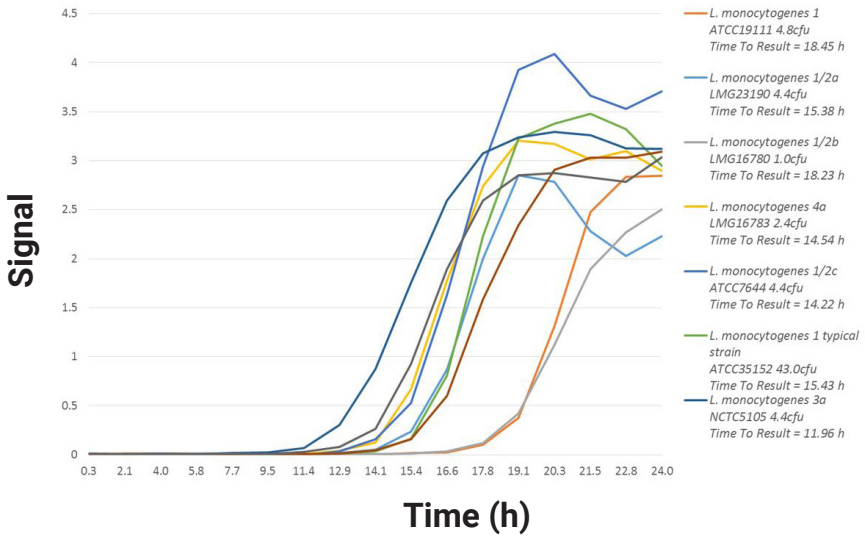
Growth profile curves of *Listeria monocytogenes* 4b ATCC19115 from varying inoculation levels on the CERTUS EL Assay Detection system



Growth profile curves of multiple *Listeria monocytogenes* serotypes ranging from 3 to 19 cfu on the CERTUS EL Assay Detection system



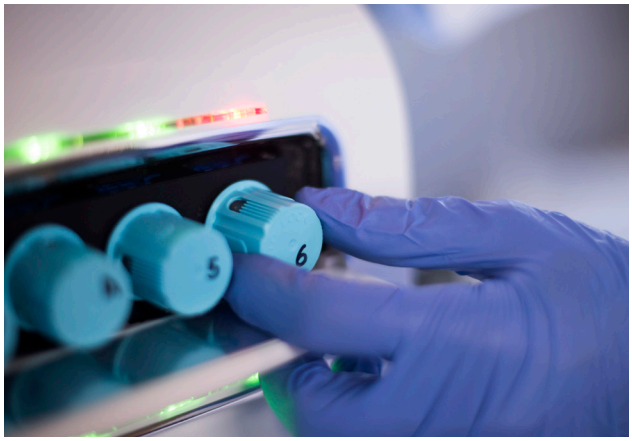
CERTUS™

Food Pathogen Detection Made Safe

FAST AND ACCURATE

The CERTUS System Provides In-House Environmental Monitoring with AOAC-Certified Performance Benefits

Swab-to-Result Time



Minimum
8 hours

Average
10-14 hours

Maximum
24 hours

Accuracy

Specificity
98%

Sensitivity
98%

Analytical Sensitivity
5×10^5 cfu

The CERTUS E*L* assay has the capability of detecting *L. grayi, L. innocua, L. ivanovii, L. marthii, L. seeligeri,* and *L. welshimeri* and multiple serotypes of *Listeria monocytogenes* in a time dependent manner that inversely correlates with the relative starting levels of *Listeria* – the higher the starting *Listeria* cell level the earlier the inflection point of the curve occurs and Time to Result.

The CERTUS E*L* assay successfully recovers *Listeria* species from multiple environmental surfaces (stainless steel, plastic, ceramic, and sealed concrete) analyzed either in the presence or absence of competing bacterial microflora at varying bio-burden levels within a 24 h timeframe.

The results of the inclusivity and exclusivity evaluation confirms the high specificity and sensitivity of the CERTUS E*L* assay to *Listeria* spp. with an overall 98% accuracy.

For more information on performance, visit www.CertusFoodSafety.com.

CERTUS™

Simple, Safe, Smart Food Pathogen Detection

THE CERTUS SYSTEM

Strengthen Quality Control

Take Control of Your Environmental Monitoring Program with the All-In-One, All-In-House CERTUS System

- **Make Informed Decisions with Fast Results**
- **Streamline FSMA Compliance Protocol**
- **Take Control with Bio-Contained In-House System**
- **Start a New Test Within Minutes**
- **24/7 Access to All Records and Reports**
- **Reduce Human Errors**
- **Run Additional Samples Easily and Quickly**

Increase Sales Opportunities and Strengthen Brand with Improved Quality Control

Enhance Your Reputation as a Trusted Supplier by Controlling Your Sampling Program Each Step of the Way

Swab Multiple Testing Locations

Reduce Probability of Human Error and Enable FSMA Compliance with Empower™ Environmental Monitoring Software

Get Results Days Sooner than Shipping to Third Party Lab

CERTUS™ | Simple, Safe, Smart Food Pathogen Detection

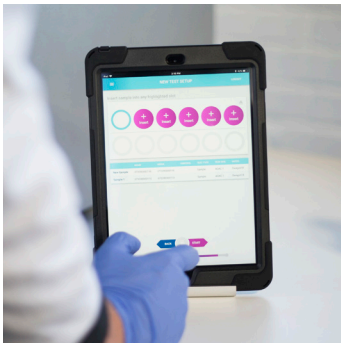
Save Time & Money

The CERTUS System is Your Simple, Safe, Smart Solution for Environmental Monitoring

- Minimum Hands-On Time
- Reduce Labor Costs
- No Ancillary Equipment Needed
- Mapping and Scheduling
- Subscription-Free Data Management
- Flexible Pricing Models
- Reduced Shipping Fees
- No Specialized Training Needed

Reduce the Time and Budget You Commit to Environmental Monitoring with the CERTUS System

Streamline Food Pathogen Testing with a Truly Simple Workflow, Fast Results and Environmental Monitoring Software



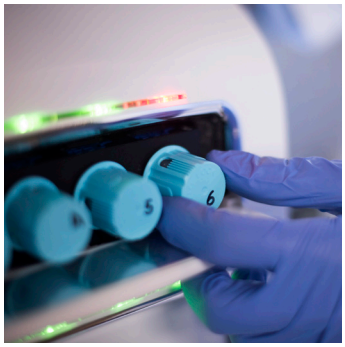
Empower™ Environmental Monitoring Software Included with No Subscription Cost

SAMPLE
3 Minute Hands-On Technician Time Per Sample

TEST
Immunoassay with Real-Time SERS Detection Methodology

RESULT
Instant Notifications of Presumptive Positive Result

Simple 3-Step Workflow Anyone Can Perform with Minimal Training



Swab-to-Result in as Little as 8 Hours

CERTUS™

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EMPOWER SOFTWARE

Strengthen and Streamline Your Environmental Monitoring Program with Empower™ EMP SOFTWARE

Guide

Simplify day-to-day environmental monitoring protocol

Every CERTUS System includes the Control Pad (9.7" iPad) equipped with intuitive Empower Environmental Monitoring Software. Empower guides technicians through the day's testing protocol, including sample locations and step-by-step workflow directions. Empower communicates directly with the Detection Unit to initiate and monitor testing.

Automate

Reduce labor-intensive, repetitive tasks and reduce errors

Set up your testing schedule - including locations, frequency, and dates with the touch of a button. Empower integrates your schedule with a map of your facility so everyone knows when and where to perform the day's environmental monitoring tasks. Adjusting the schedule or adding extra monitoring of trouble-zones is just as easy!

Report

Collect and manage performance, risk and remediation data

Empower provides access to testing records and corrective actions taken at all times making it easy to create custom reports for internal, client and regulatory audits. With Empower real time and historical facility overview, stakeholders gain insight into problem areas that may require proactive correction and receive instant notification of positive test results.

www.CertusFoodSafety.com | 872-810-4123 | 4809 N Ravenswood Ave #113, Chicago, IL 60640

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EMPOWER SOFTWARE

Reduce Risk and Save Money

Generate schedules, corrective action plans, notifications and alerts to ensure that every step of your EMP is followed every time.

MAPPING

Develop detail-rich facility maps including risk level, zone, environmental matrices and real-life photography of actual surface to be swabbed for easy site identification.

SCHEDULING

Create testing schedules that ensure every hotspot within your facility is tested on a regular basis, according to your EMP.

REPORTS

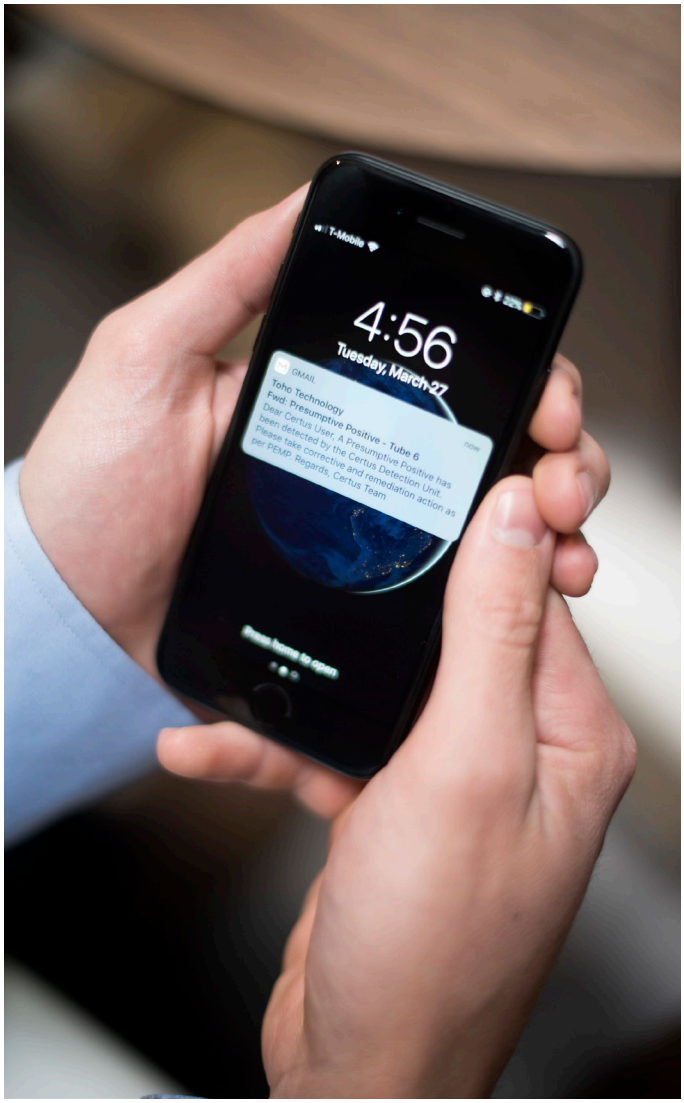
Generate custom digital and printed reports to comply with FDA, FSMA, USDA, CFIA and internal policies and audits. Sort by date, zone, technician and more. Export to CSV or PDF and send from the Control Pad by email.

DATA MANAGEMENT

Keep meticulous records of tests, results and corrective actions for easy, streamlined FSMA-compliance. View all open cases including those under review, active, and closed.

REMEDIATION

Upon positive test result, Empower™ Software guides and logs corrective actions according to predetermined remediation protocol - including instant alerts sent to stakeholders via text and email.



CERTUS™

Food Pathogen Detection Made Simple

SYSTEM COMPONENTS

The CERTUS System Includes Everything You Need for Safe, In-House Food Pathogen Detection

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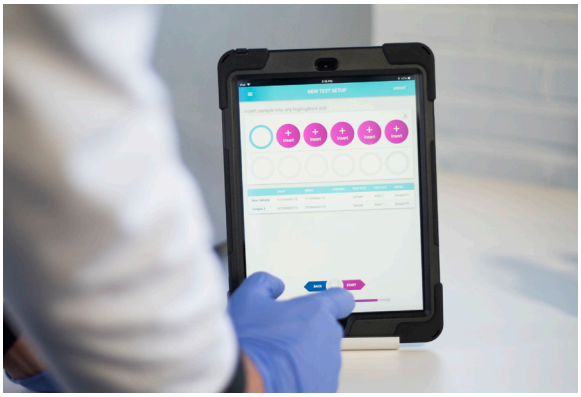
SYSTEM COMPONENTS

Detection Unit

The CERTUS Detection Unit utilizes immunoassay with Surface Enhanced Raman detection technology for real-time detection. This revolutionary instrument provides quick, accurate, in-house pathogen detection capabilities with results in as little as 8 hours.

Footprint: 14"W X 17.7"H X 22"D



Control Pad

The Control Pad is a 9.7" generation 6 iPad equipped with robust Empower™ Environmental Monitoring Software. The Control Pad leads technicians through each step of the workflow with mapping, automated scheduling, FSMA-compliant reports and more, allowing plant managers to strengthen and streamline their pathogen environmental monitoring program.

Detection Kit

The consumable Detection Kits are pathogen specific and eliminate the need for purchasing separate swabs, stomacher bags, media, controls, pipettes, centrifuge, incubators, or other ancillary equipment.

Detection Kits include Bio-Lock™ Sampling Swabs, Detection Tubes, Pre-Measured Selective Growth Media, and Positive / Negative Verification Caps.

Storage: 60 ct dry box 14"W X 17.7"H X 22"D, 120 ct dry box 14"W X 17.7"H X 22"D (Store in ambient temperature). 60 ct media box 14"W X 17.7"H X 22"D, 120 ct media box 14"W X 17.7"H X 22"D (Store at 2-8°C in the dark).