Enviro X-F

Executive Summary

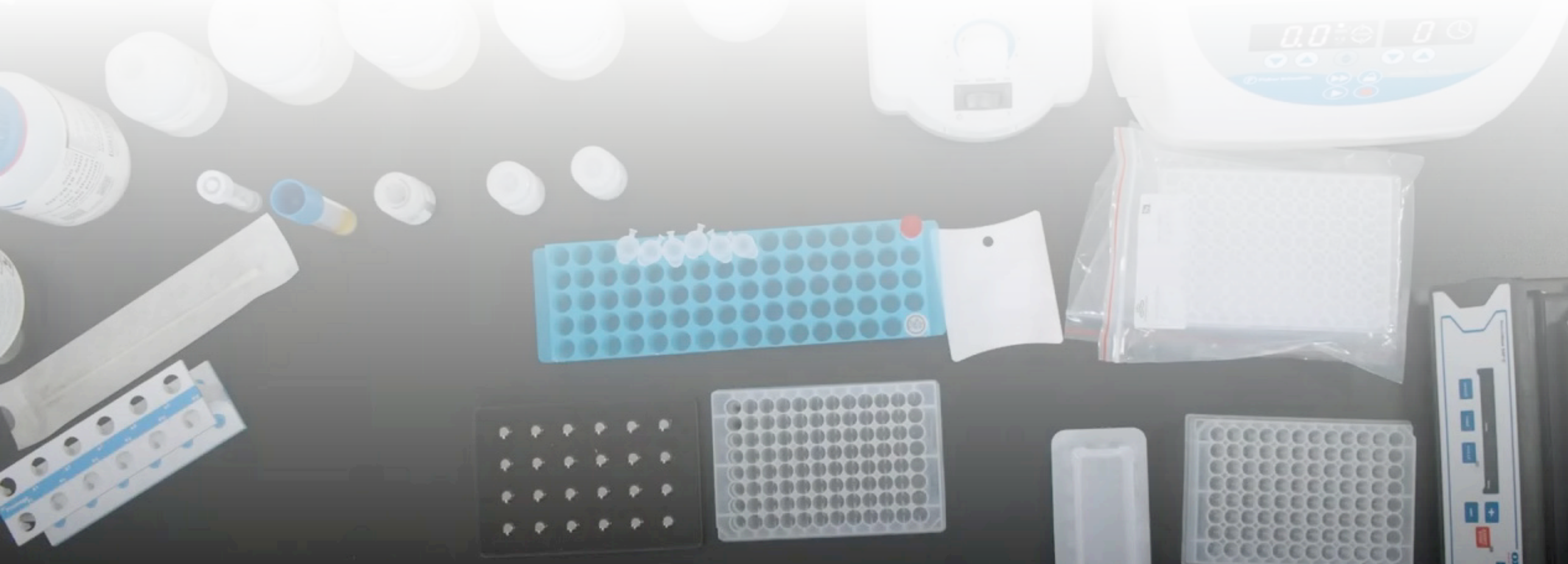
Fast. Multiplexed. Flexible.

PathogenDx

Setting the standard in DNA testing

EXECUTIVE SUMMARY

The Food Safety Industry has many different types of test systems and kits for professionals to identify pathogens in their food processing plants and analyze in their labs. One main component to consider when evaluating prospective solutions is their performance under a 3rd-party evaluation. The AOAC Performance Tested Method (PTM) evaluation for Enviro$^{X\text{-}F}$ is summarized in this document.



CERTIFICATION

AOAC® *Performance Tested*℠

Certificate No.

092001

The AOAC Research Institute hereby certifies the test kit known as:

Enviro[X-F]

manufactured by

PathogenDx
9375 E. Shea Blvd., Ste. 100
Scottsdale, Arizona 85260
USA

This method has been evaluated in the AOAC® *Performance Tested Methods*℠ Program and found to perform as stated by the manufacturer contingent to the comments contained in the manuscript. This certificate means that an AOAC® Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC *Performance Tested*℠ certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER'S SPECIFICATIONS" - on the above mentioned method for a period of one calendar year from the date of this certificate (September 24, 2020 – December 31, 2021). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Scott Coates

Scott Coates, Senior Director
Signature for AOAC Research Institute

October 08, 2020
Date

2275 Research Blvd., Ste. 300, Rockville, Maryland, USA Telephone: +1-301-924-7077 Fax: +1-301-924-7089
Internet e-mail: aoacri@aoac.org * World Wide Web Site: http://www.aoac.org

AOAC Performance Tested Method: Certificate No: 092001

In October 2020, the PathogenDx Enviro$^{X\text{-}F}$ Assay was granted Performance Tested Method Status by the AOAC Research Institute for the **multiplex detection of Salmonella spp., Listeria spp., and L. monocytogenes without an enrichment step**. The study was conducted by an independent, third-party lab and consisted of 30 replicates at varied inoculum levels across a variety of common food manufacturing surfaces. The results indicated that PathogenDx Enviro$^{X\text{-}F}$ is an effective method for the qualitative detection of the three targets on four processing surfaces.

Key Findings

- No False Positives for 3 targets across 4 matrices
- Minimum False Negatives
- No Significant Statistical Differences

Study Element	Result
Time to Result	6 hours
Enrichment	No
Sensitivity	> 98%
Specificity	100%
False Negative	< 2%
False Positives	0%

Enviro$^{X\text{-}F}$

Contents of the Enviro$^{X\text{-}F}$ Kit

- Live Dead Reagents
- Sample Prep & Digestion Buffers
- PCR Master Mix
- Primer Sets
- Positive Controls
- Negative Controls
- 8 Enviro$^{X\text{-}F}$ Microarray Slides

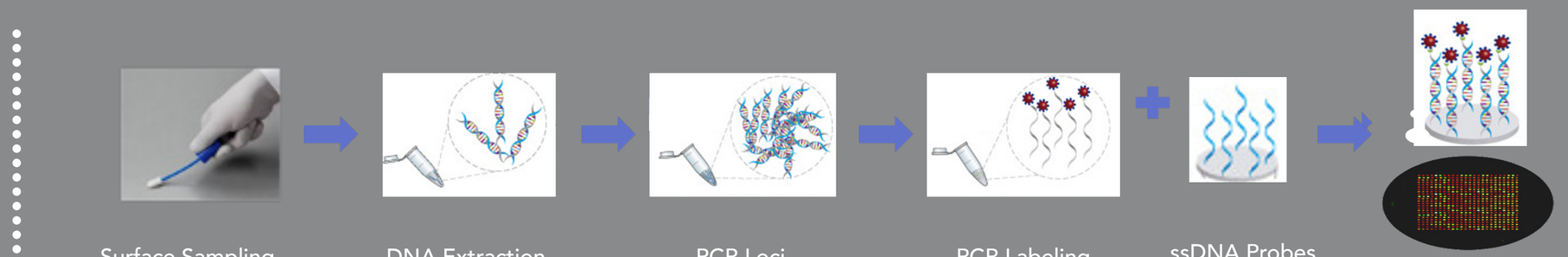
Principle of the Method

The Cy3-labeled PCR product does not require amplicon clean-up, quantitation, or normalization.

It is diluted in hybridization buffer, which is then hybridized to the microarray, and then washed and imaged to yield a pattern distributed among the probe spots.

The PathogenDx software analysis tool, Augury©, automatically finds the spots in the image and then calculates the median Cy3 intensity of each hybridized spot.

Assay Process



AOAC PTM Method Study Summary Table

Matrix	Strain	CFU[a]/ Test Area	N[b]	Enviro[X-F]				Reference		dPOD$_C$[f]	95% CI[g]
				Presumptive	Confirmed	Specificity	X	POD$_R$[e]	95% CI		
Stainless Steel (4" x 4")	*Salmonella* Typhimurium ATCC 14028	-	5	0	0	-	0	0	0.00, 0.43	0	-0.43, 0.43
	&	48 &110	20	7	7	100	8	0.4	0.22, 0.61	-0.05	-0.32, 0.23
	Citrobacter freundii ATCC 8090	& 1200	5	5	5	100	5	1	0.57,1.00	0	-0.43, 0.43
	L. monocytogenes 4b ATCC 13932		5	0	0	-	0	0	0.00, 0.43	0	-0.43, 0.43
	&	58 & 191	20	9	9	100	6	0.3	0.15, 0.52	0.15	-0.14, 0.41
	Enterococcus faecalis ATCC 29212	450 & 1100	5	5	5	100	5	1	0.57,1.00	0	-0.43, 0.43
Plastic (4" x 4")	*Salmonella* Heidelberg ATCC 8326	-	5	0	0	-	0	0	0.00, 0.43	0	-0.43, 0.43
		63	20	9	9	100	8	0.4	0.22, 0.61	0.05	-0.24, 0.33
		160	5	5	5	100	5	1	0.57,1.00	0	-0.43, 0.43
	L. innocua ATCC 33091	-	5	0	0		0	0	0.00, 0.43	0	-0.43, 0.43
		46	20	8	8	100	8	0.4	0.22, 0.61	0	-0.28, 0.28
		130	5	5	5	100	5	1	0.57,1.00	0	-0.43, 0.43
	L. monocytogenes 4b ATCC 51780	-	5	0	0	-	0	0	0.00, 0.43	0	-0.43, 0.43
		52	20	9	0.45	100	6	0.3	0.15, 0.52	0.15	-0.14, 0.41
		170	5	5	1	100	5	1	0.57,1.00	0	-0.43, 0.43
Rubber (4" x 4")	*Salmonella* Enteritidis ATCC 13076	-	5	0	0	-	0	0	0.00, 0.43	0	-0.43, 0.43
		61	20	9	9	100	8	0.4	0.22, 0.61	0.05	-0.24, 0.33
		130	5	5	5	100	5	1	0.57,1.00	0	-0.43, 0.43
	L. welshimeri ATCC 35897	-	5	0	0	-	0	0	0.00, 0.43	0	-0.43, 0.43
		70	20	7	7	100	7	0.35	0.18, 0.57	0	-0.28, 0.28
		180	5	5	5	100	5	1	0.57,1.00	0	-0.43, 0.43
	L. monocytogenes 1/2a ATCC 15313	-	5	0	0	-	0	0	0.00, 0.43	0	-0.43, 0.43
		60	20	7	7	100	8	0.4	0.22, 0.61	-0.05	-0.32, 0.23
		190	5	5	5	100	5	1	0.57,1.00	0	-0.43, 0.43
Sealed Concrete (4" x 4")	*Salmonella* Newport ATCC 6962	-	5	0	0	-	0	0	0.00, 0.43	0	-0.43, 0.43
		47	20	9	0.45	100	9	0.45	0.26, 0.66	0	-0.28, 0.28
		220	5	5	1	100	5	1	0.57,1.00	0	-0.43, 0.43
	L. seeligeri ATCC 11289	-	5	0	0	-	0	0	0.00, 0.43	0	-0.43, 0.43
		45	20	8	0.4	100	8	0.4	0.22, 0.61	0	-0.28, 0.28
		180	5	5	1	100	5	1	0.57,1.00	0	-0.43, 0.43
	L. monocytogenes 1/2a FSL J1-129	-	5	0	0	-	0	0	0.00, 0.43	0	-0.43, 0.43
		73	20	9	0.45	100	8	0.4	0.22, 0.61	0.05	-0.24, 0.33
		210	5	5	1	100	5	1	0.57,1.00	0	-0.43, 0.43

aCFU/Test Area = Results of the CFU/Test area were determined by plating the inoculum for each matrix in triplicate
bN = Number of test portions
cx = Number of positive test portions
dPODC = Candidate method confirmed positive outcomes divided by the total number of trials
ePODR = Reference method confirmed positive outcomes divided by the total number of trials
fdPODC= Difference between the confirmed candidate method result and reference method confirmed result POD values
g95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level
h95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

AT PATHOGENDx, WE'RE SETTING THE STANDARD IN DNA TESTING.

PathogenDx is a biotechnology company based in Arizona, developing diagnostic solutions to more rapidly and accurately identify pathogens, through our AOAC-certified flexible assay, that can lead to recalls in the Food industry. We are expanding the possibilities of DNA-based testing to identify pathogens faster and easier through our game-changing microarray technology— driving a higher standard of sensitivity and specificity in testing. We deliver innovative solutions that are efficient, robust, that are cost effective and save lives, and drive us all towards the future of safe.

MICHAEL HOGAN, PhD, CHIEF SCIENTIFIC OFFICER

Dr. Michael Hogan's expertise is in the area of physical chemistry, bio-sample processing and genetic testing. He is leading multiple programs in technology development at PDx, with special emphasis on productizing its proprietary DNA microarray technology into the clinical diagnostics, food safety and agricultural markets. Dr. Hogan has 30 years of experience in translational science, with special emphasis on the application of physical biochemistry to commerce. Hogan has invented, developed and commercialized multiple technologies for medical devices, therapeutics, in vitro diagnostics, genomic testing and biological sample preservation. He has been awarded more than 50 patents and has more than 90 peer reviewed publications in those several areas. His team's work in the area of biological sample stabilization was awarded a Frost & Sullivan Award in 2014 and 2019, for the Best Microbial DNA Testing Technology Innovation.

PathogenDx

Setting the standard in DNA testing

For more information or ordering, call 800-641-5751
or visit pathogendx.com

Enviro X-F

PathogenDx | 9375 E Shea Blvd, Scottsdale, AZ 85260