CERTIFICATION

AOAC® *Performance Tested*SM

Certificate No.

071102

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

PDX-SIB

manufactured by

Paradigm Diagnostics, Inc.
800 Transfer Road, Ste 12
Saint Paul, MN 55114
USA

This method has been evaluated in the AOAC® *Performance Tested Methods*SM 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*SM 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 (December 16, 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

December 16, 2020
Date

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SUBMITTING COMPANY
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800 Transfer Road Suite 12
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KIT NAME(S)
PDX-SIB

CATALOG NUMBERS
26003-25, 26009-50, 26005-100

INDEPENDENT LABORATORY
Q-Labs
1400 Harrison Avenue
Cincinnati, Ohio 45214
USA

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APPLICABILITY OF METHOD
Target organism – *Salmonella*
Matrices – Ceramic tile, stainless steel, plastic, and sealed concrete
Performance claims - The overall sensitivity relative to the reference method across all four surfaces was >100% (it is possible bacterial growth occurred during the study period). There were no significant differences between PDX-SIB and the reference method on any of the surfaces tested.

REFERENCE METHOD
U.S. Food and Drug Administration (2011) *Bacteriological Analytical Manual*, Chapter 5 (5)

ORIGINAL CERTIFICATION DATE
July 29, 2011

CERTIFICATION RENEWAL RECORD
Renewed annually through December 2021

METHOD MODIFICATION RECORD
NONE

SUMMARY OF MODIFICATION
NONE

Under this AOAC® *Performance Tested*SM License Number, 071102 this method is distributed by:
NONE

Under this AOAC® *Performance Tested*SM License Number, 071102 this method is distributed as:
NONE

PRINCIPLE OF THE METHOD (1)
The principle of PDX-SIB utilizes two operating conditions, the first selective enrichment of the *Salmonella* population from the background microflora and secondly the simultaneous metabolism of a very specific *Salmonella* substrate. PDX-SIB is a balanced blend of proprietary selective agents highly restrictive to non-*Salmonella* bacteria and combining a highly specific metabolic substrate for *Salmonella.* As the selected population grows out the media becomes acidified and an incorporated pH indicator detects the pH change by a color shift from purple to yellow.

DISCUSSION OF THE VALIDATION STUDY (1)
PDX-SIB is an easy to use and interpret screening test for *Salmonella* species in environmental samples. Inclusivity and exclusivity studies revealed that PDX-SIB is very comprehensive for the detection of *Salmonella* species at very low levels (10-100 CFU/sample). Two strains, *S*. Cubana and *S*. Gallinarum, were originally negative in the inclusivity study. An additional isolate of *S*. Cubana was obtained from a different source, the University of Pennsylvania *Salmonella* Reference Center. This particular isolate was positive in fermenting the indicator compound in SIB in contrast to the isolate obtained from the University of Minnesota's culture collection. These data suggest that the Minnesota isolate was likely defective in a metabolic pathway for fermentation of the indicator compound. In regard to specificity, high levels of some *Citrobacter* species remain to be a possible source of false positive results. False positive results, although not desired by the typical end user, still tells a great deal about the overall microbial cleanliness of the areas sampled. Learning about the presence of *Citrobacter* species is important for another aspect, since many *Citrobacter* species occupy similar niches to *Salmonella* species and arise as contamination sources from the GI tracts of warm blooded animals. This information is potentially useful when monitoring food processing surfaces intended to be free of microflora after sanitation operations. These results demonstrate a cross reaction in two of three *Citrobacter* species tested underscoring the need to confirm all SIB-positive results by the traditional biochemical or genetic methods. PDX-SIB was found to be at least as sensitive as the reference method in all the surfaces studied. In fact PDX-SIB was slightly more sensitive than the reference method in one of the method comparison studies: five positives for PDX-SIB versus three positives for the FDA-BAM method in the stainless steel study.

Table 1a. Results of Inclusivity Test for PDX-SIB (1)

Serovar	Source	Origin	SIB Medium Color	Presumptive Result	Sero-group
S. Adelaide	U of MN 94679420	Meat meal	Yellow	+	O
S. Agona	U of MN inv 95650951	Soybean meal	Yellow	+	B
S. Albany	U of MN 2009595	Frozen fish paste	Yellow	+	C3
S. Anatum	U of MN 95645854	Chicken feed	Yellow	+	E1
S. Bovismorbificans	U of MN 3064124	Vietnam	Yellow	+	C2
S. Carrau	U of MN 2003413	Frozen shrimp	Yellow	+	H
S. Cerro	U of MN 94713965	Poultry feed	Yellow	+	K
S. Cubana	U of MN 94679421	Swine feed	Blue	-	G2
S. Chester	U of MN 3063650	Frozen tilapia fish	Yellow	+	B
S. Emek	U of MN 3063892	Frozen catfish	Yellow	+	C3
S. Enteritidis	U of MN 95657613	Ice cream	Yellow	+	D1
S. Give	U of MN 1829352	Lobster tail	Yellow	+	E1
S. Gloucester	U of MN 1676771	Sesame seeds	Yellow	+	B
S. Hvittingfoss	U of MN 200373	Frozen frog legs	Yellow	+	I
S. Infantis	U of MN 2015422	Frozen lobster tail	Yellow	+	C1
S. Javiana	U of MN 1842147	Frozen shrimp	Yellow	+	D1
S. Kentucky	U of MN 95-690-012	Cottonseed meal	Yellow	+	C3
S. Lille	U of MN 95-713-959	Chicken feed	Yellow	+	C1
S. Mbandaka	U of MN 95690014	Soybean meal	Yellow	+	C1
S. Meleagridis	U of MN 1949345	Frozen shrimp	Yellow	+	E1
S. Montevideo	U of MN 95573493	Raw eggs	Yellow	+	C1
S. Muenchen	U of MN 1842204	Frozen shrimp	Yellow	+	C2
S. Newbrunswick	U of MN 1842304	Frozen shrimp	Yellow	+	E1
S. Nashua	U of MN 2006036	Poultry feed	Yellow	+	M
S. Newport	U of MN 2006038	Frozen lobster tail	Yellow	+	C2
S. Penilla	U of MN 1949289	Frozen shrimp	Yellow	+	M
S. Poona	U of MN 1103174	White pepper	Yellow	+	G1
S. Sterrenbos	U of MN 1842082	Frozen shrimp	Yellow	+	C3
S. Thompson	U of MN 95657618	Ice cream	Yellow	+	C1
S. Weltevreden	U of MN 1950358	Dried ling shrimp	Yellow	+	E1
S. Typhimurium	U of MN	Salted dune egg	Yellow	+	B

	3019907				
S. Worthington	U of MN 95-713-958	Chicken feed	Yellow	+	G2
S. Kumasi	U of MN 1929854	Frozen crab meat	Yellow	+	N
S. Rubislaw	U of MN 2004976	Frozen shrimp	Yellow	+	F
S. Goodwood	U of MN	Faeces	Yellow	+	E4
S. Senftenberg	U of MN	Sewage	Yellow	+	E4
S. Ohio	U of MN	Animal feed	Yellow	+	C1
S. Limete	U of MN		Yellow	+	B
S. Tennessee	U of MN	Soybean meal	Yellow	+	C1
S. Newington	U of MN	Wild poultry	Yellow	+	B
*S.*Aberdeen	NCTC 5791	Infantile diarrhea	Yellow	+	F
S. Aequatoria	NCTC 7891	African zoonosis	Yellow	+	C1
S. Alabama	NCTC 9868	Human faeces	Yellow	+	B
S. Altendorf	NCTC 10546		Yellow	+	B
S. Austin	NCTC 8447		Yellow	+	C1
S. Ball	NCTC 9870		Yellow	+	B
S. Berkeley	NCTC 8260	Diseased turkey	Yellow	+	U
S. Brookfield	NCTC 10946		Yellow	+	O66
S. California	NCTC 6018	Animal feed	Yellow	+	B
S. Canastel	NCTC 6948	Animal feed	Yellow	+	D1
S. Carmel	NCTC 9872	Infantile diarrhea	Yellow	+	O17
S. Champaign	NCTC 6851	Hen liver	Yellow	+	Q
S. Chicago	NCTC 9873		Yellow	+	M
S. Colombo	NCTC 9922	Sheep	Yellow	+	P
S. Ealing	NCTC 11949	Dried baby milk	Yellow	+	O
S. Dahlem	NCTC 9949	Cattle	Yellow	+	Y
S. Gallinarum	NCTC 10532	Poultry	Blue	-	D1
S. Houten	NCTC 10401	Reptile	Yellow	+	O43
S. Kottbus	NCTC 5753	Faeces	Yellow	+	C2
S. Illinois	NCTC 8498	Poults	Yellow	+	E3
S. Lexington	NCTC 6244	Soybean	Yellow	+	E1
S. Manchester	NCTC 7372		Yellow	+	C2
S. Minnesota	NCTC 5800	Swine	Yellow	+	L
S. Mississippi	NCTC 6487	Faeces	Yellow	+	G2
S. Napoli	NCTC 6853	Food handlers	Yellow	+	D1
S. Pensacola	NCTC 6946		Yellow	+	D1
S. Pretoria	NCTC 6234	Meat	Yellow	+	F
S. Shanghai	NCTC 9791		Yellow	+	I
S. Sunsvall	NCTC 9787	Dried egg	Yellow	+	H
S. Waycross	NCTC 7401	Urine	Yellow	+	S
S. Alachua	U Penn STS 6	Swine	Yellow	+	O
S. Choleraesuis	ATCC 10708	Fish	Yellow	+	C

S. Arkansas	U Penn STS 11		Yellow	+	B
S. Blockley	U Penn STS 15	Environment	Yellow	+	C2
S. Brandenburg	U Penn STS 18	Swine	Yellow	+	B
S. Derby	U Penn STS 22	Polluted water	Yellow	+	B
S. Dublin	U Penn STS 27	Cattle	Yellow	+	D1
S. Hadar	U Penn STS 45	Turkey	Yellow	+	C2
S. Heidelberg	U Penn STS 48	Poultry	Yellow	+	B
S. London	U Penn STS 64	Polluted water	Yellow	+	E1
S. Manhattan	U Penn STS 65	Avian	Yellow	+	C2
S. Oranienburg	U Penn STS 83	Egg	Yellow	+	C1
S. Panama	U Penn STS 86	Infantile diarrhea	Yellow	+	D1
S. Paratyphis	ATCC 13314	Sewage	Yellow	+	A
S. Saint Paul	U of MN	Milk powder	Yellow	+	B
S. Schwarzengrund	U Penn STS 95	Chicken	Yellow	+	B
S. Stanley	U Penn STS100	Reptile	Yellow	+	B
S. Urbana	U Penn STS110	Reptile	Yellow	+	N
S. Johannesburg	U Penn STS 56	Meat meal	Yellow	+	R
S. Thomasville	U Penn STS103	Poultry meal	Yellow	+	E3
S. Virchow	U Penn STS 112	Basil	Yellow	+	C1
S. Abaetetuba	ATCC 35640	Fresh water	Yellow	+	F
S. Choleraesuis var. Kunzendorf	ATCC 12011	Swine	Yellow	+	B
S. Vallore	ATCC 15611		Yellow	+	B
S. Paratyphis	U of MN 2014696	Frozen frog legs	Yellow	+	B
S. Tallahassee	ATCC 12002		Yellow	+	C3
S. Salford	U of MN 2009532	Oregano turkey	Yellow	+	I
S. Birmingham	U of MN DI95764802	Alfalfa seed	Yellow	+	E1
S. Brunei	U of MN 1680318	Frozen Shrimp	Yellow	+	C3
S. Ikeja	U of MN 3019543	Frozen Shrimp	Yellow	+	E1
S. Cubana	UPenn	Swine	Yellow	+	G2

Table 1b. Results of Exclusivity Test for PDX-SIB (1)

Species	Source	Origin	SIB Result
Klebsiella pneumoniae	NCTC 9633	Sputum	-
Proteus mirabilis	ATCC 12453	GI tract	-
Citrobacter freundii	NCTC 9750	Soil	-
Escherichia coli	ATCC 13706	GI tract	-
Escherichia coli	ATCC 14948	GI tract	-
Hafnia alvei	ATCC 700025	Brewery fermentation samples	-
Serratia liquefaciens	ATCC 27592		-
Morganella morganii subsp. morganii	ATCC 25829		-
Pseudomonas aeruginosa	ATCC 10145		-
Providencia rettgeri	ATCC 9250		-
Enterobacter amnigenus	ATCC 51816		-
Enterobacter aerogenes	ATCC 13048		-
Shigella sonnei	ATCC 25931		-
Shigella flexneri	ATCC 9199		-
Staphylococcus epidermidis	ATCC 14990		-
Staphylococcus aureus	ATCC 700699		-
Serratia marcescens	ATCC 13880	Polenta	-
Enterobacter cloacae subsp. cloacae	ATCC 23355		-
Enterobacter gergoviae	ATCC 33028		-
Klebsiella oxytoca	ATCC 13182		-
Providencia wickerhamii	ATCC 16529		-
Shigella boydii	ATCC 9207		-
Staphylococcus aureus	NCTC 12973		-
Yersinia enterocolitica subsp. enterocolitica	ATCC 23715		-
Yersinia ruckerii	ATCC 29473		-
Citrobacter freundii	ATCC 8090		+
Citrobacter braakii	ATCC 43162		-
Citrobacter koseri	ATCC 27156		+
Escherichia coli	NCIMB 11943		-
Escherichia coli	NCTC 10538		-
Listeria monocytogenes	ATCC 13932		-
Listeria innocua	ATCC 33090		-
Pasteurella multocida subsp. multocida	ATCC 12945		-
Providencia stuartii	ATCC 33672		-
Edwardsiella tarda	ATCC 15947		-

Table 2. Summary of Method Comparison Studies of SIB at 48 Hour Incubation. (1)

Matrix	Strain	N[a]	PDX-SIB		FDA -BAM	Chi Square[b]	Relative Sensitivity[c]
			Presumptive Pos.	Confirmed Pos.	Positive		
Plastic	*S*. Newport	5	0	0	0	-	-
		20 Low level	11	11	13	0.406	84.6%
		20 High level	20	20	20	0	100%
Sealed concrete	*S*. Anatum	5	0	0	0	-	-
		20 Low level	7	7	8	0.104	87.5%
		20 High level	20	20	20	0	100%
Ceramic tile	*S.* Abaetetuba	5	0	0	0	-	-
		20 Low level	10	10	7	0.898	142.9%
		20 High level	20	20	20	0	100%
Stainless steel[d]	*S*. Typhimurium : 10X *C. freundii*	5	0	0	0	-	-
		20 Low level	0	0	2	2.05	0
		20 High level	5	5	3	0.609	166.7%

[a]N = Number of test portions

[b]Chi Square = Mantel-Haenszel: $\chi^2 = (n-1)(ad-bc)^2/[(a+b)(a+c)(b+d)(c+d)]$, where n = total number of samples

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