



# CERTIFICATION

## AOAC Research Institute *Performance Tested Methods*<sup>SM</sup>

Certificate No.  
**022202**

The AOAC Research Institute hereby certifies the method known as:

**PathoSEEK<sup>®</sup> Salmonella and STEC E. coli Multiplex Assay with SenSATIVAx<sup>®</sup> Extraction**

manufactured by

**Medicinal Genomics Corp.  
100 Cummings Center, Suite 406L  
Beverly, MA 01915 USA**

This method has been evaluated in the AOAC Research Institute *Performance Tested Methods*<sup>SM</sup> Program and found to perform as stated in the applicability of the method. This certificate indicates an AOAC Research Institute Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC Research Institute *Performance Tested Methods*<sup>SM</sup> certification mark on the above-mentioned method for the period below. Renewal may be granted by the Expiration Date under the rules stated in the licensing agreement.

A handwritten signature in black ink that reads "Scott Coates".

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Scott Coates, Senior Director  
Signature for AOAC Research Institute

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<b>AUTHORS</b> Kevin McKernan and Yvonne Helbert	<b>SUBMITTING COMPANY</b> Medicinal Genomics Corp. 100 Cummings Center, Suite 406L Beverly, MA 01915 USA
<b>METHOD NAME</b> PathoSEEK® Salmonella and STEC E. coli Multiplex Assay with SenSATIVAx® Extraction	<b>CATALOG NUMBERS</b> 420120, 420001, 420004, 420201, 420332
<b>INDEPENDENT LABORATORY</b> TEQ Analytical Laboratories 12635 E. Montview Blvd, Suite 175 Aurora, CO 80045	<b>AOAC EXPERTS AND PEER REVIEWERS</b> Yvonne Salfinger <sup>1</sup> , Jim Agin <sup>2</sup> , Wayne Ziemer <sup>3</sup> <sup>1</sup> Independent Consultant, Colorado, USA <sup>2</sup> Ohio Department of Agriculture (Retired), Ohio, USA <sup>3</sup> USDA FERN (Retired), Georgia, USA
<b>APPLICABILITY OF METHOD</b> Target Organisms – <i>Salmonella</i> spp. and <i>Escherichia coli</i> carrying Shiga toxin 1 and/or 2 ( <i>stx1</i> and/or <i>stx2</i> ).  Matrixes – Dried cannabis flower (delta 9-tetrahydrocannabinol >0.3%; 10 g), cannabis concentrate (5 g) and THC-infused chocolate bars (25 g).  Performance claims – The PathoSEEK Salmonella & STEC E.coli Multiplex Assay with SenSATIVAx® Extraction has been validated according to the AOAC Performance Tested Method <sup>SM</sup> Program for the detection of Salmonella species STEC in dried cannabis flower (>0.3% THC), cannabis concentrates and THC-infused chocolate using the AriaMx and CFX-96 instruments. The validation study met the requirements as set forth in the AOAC Standard Method Performance Requirements <sup>SM</sup> 2020.002 for the detection of Salmonella species and 2020.012 for the detection of Shiga toxin producing E.coli (STEC) in cannabis and cannabis infused products.	<b>REFERENCE GUIDELINES</b> (SMPR) 2020.002 <i>Detection of Salmonella in Cannabis and Cannabis Products</i> (2)  SMPR 2020.012 <i>Detection of Shiga-Toxin Producing E. coli in Cannabis and Cannabis Products</i> (3)
<b>ORIGINAL CERTIFICATION DATE</b> August 10, 2021	<b>CERTIFICATION RENEWAL RECORD</b> Renewed annually through December 2023.
<b>METHOD MODIFICATION RECORD</b> NONE	<b>SUMMARY OF MODIFICATION</b> NONE
Under this AOAC Performance Tested Methods <sup>SM</sup> License Number, 022202 this method is distributed by: NONE	Under this AOAC Performance Tested Methods <sup>SM</sup> License Number, 022202 this method is distributed as: NONE

**PRINCIPLE OF THE METHOD (1)**

The PathoSEEK Microbial Safety Testing Platform utilizes a novel, contamination-free, PCR-based assay and provides an internal plant DNA control for every reaction. It is a two-step protocol (DNA extraction followed by RT-PCR analysis) which is flexible and automation compatible. The PathoSEEK assay is used in combination with the SenSATIVAx extraction kit and qPCR Master Kit. The SenSATIVAx extraction kit allows for a proprietary DNA isolation process that use magnetic particles to isolate and purify both plant and microbial DNA.

The PathoSEEK Salmonella & STEC E. coli Multiplex Assay is used to detect a wide variety of species classified as *Salmonella* and STEC. The assay targets STEC using the FAM fluorophore and *Salmonella* using the ROX fluorophore. Positive controls for each target are recommended for use with each analysis.

**DISCUSSION OF THE VALIDATION STUDY (1)**

The data from these studies, within their statistical uncertainty, support the product claims of the PathoSEEK Salmonella and STEC E. coli Multiplex Assay with SenSATIVax Extraction Protocols (Flower/Leaf and MIP/Extracts) for dried cannabis flower (10 g, >0.3% THC), cannabis concentrate (5 g) and THC-infused chocolate (25 g). The results obtained by the POD analysis of the method comparison study demonstrated that there were no statistically significant differences between the number of positive samples detected by the candidate method and the culturally confirmed results. The validation study met the requirements as set forth in the AOAC Standard Method Performance Requirements<sup>SM</sup> 2020.002 for the detection of Salmonella species and 2020.012 for the detection of Shiga toxin producing E.coli (STEC) in cannabis and cannabis infused products.

**Table 3. Inclusivity Results for the PathoSEEK Salmonella and STEC E.coli Multiplex Assay - Salmonella (1)**

#	Organism	Species/subspecies	Serotype	Source	Origin	Results <sup>a, b</sup>	
						STEC	Salmonella
1	<i>S. enterica</i>	<i>arizonae</i>	Not Available	ATCC <sup>c</sup> 33952	Not Available	-	+
2	<i>S. enterica</i>	<i>arizonae</i>	Not Available	ATCC 29933	Not Available	-	+
3	<i>S. enterica</i>	<i>arizonae</i>	Not Available	ATCC BAA-731	Tissue of corn snake	-	+
4	<i>S. enterica</i>	<i>diarizonae</i>	IIIb 35:i:z	ATCC BAA-216	Blood	-	+
5	<i>S. enterica</i>	<i>diarizonae</i>	47:i:z53:z57	ATCC 12325	Not Available	-	+
6	<i>S. enterica</i>	<i>diarizonae</i>	Not Available	ATCC 29934	Not Available	-	+
7	<i>S. enterica</i>	<i>enterica</i>	Aberdeen	NCTC <sup>d</sup> 5791	Not Available	-	+
8	<i>S. enterica</i>	<i>enterica</i>	Abortusequi	NCTC 5727	Not Available	-	+
9	<i>S. enterica</i>	<i>enterica</i>	Abortusovis	ATCC 31684	Not Available	-	+
10	<i>S. enterica</i>	<i>enterica</i>	Adelaide	NCTC 6586	Not Available	-	+
11	<i>S. enterica</i>	<i>enterica</i>	Agona	ATCC 51957	Not Available	-	+
12	<i>S. enterica</i>	<i>enterica</i>	Anatum	ATCC 9270	Pork liver	-	+
13	<i>S. enterica</i>	<i>enterica</i>	Bareilly	ATCC 9115	Not Available	-	+
14	<i>S. enterica</i>	<i>enterica</i>	Berta	ATCC 8392	Not Available	-	+
15	<i>S. enterica</i>	<i>enterica</i>	Bispebjerg	ATCC 9842	Not Available	-	+
16	<i>S. enterica</i>	<i>enterica</i>	Braenderup	ATCC 700136	Not Available	-	+
17	<i>S. enterica</i>	<i>enterica</i>	Bredeney	ATCC 10728	Not Available	-	+
18	<i>S. enterica</i>	<i>enterica</i>	Breukelen	ATCC 15782	Cuscus	-	+
19	<i>S. enterica</i>	<i>enterica</i>	Bristol	ATCC 700136	Not Available	-	+
20	<i>S. enterica</i>	<i>enterica</i>	Caracas	NCTC 9937	Not Available	-	+
21	<i>S. enterica</i>	<i>enterica</i>	Cerro	NCC 5801	Not Available	-	+
22	<i>S. enterica</i>	<i>enterica</i>	Champaign	NCTC 6851	Not Available	-	+
23	<i>S. enterica</i>	<i>enterica</i>	Chester	ATCC 11997	Not Available	-	+
24	<i>S. enterica</i>	<i>enterica</i>	Choleraesuis	ATCC 10708	Not Available	-	+
25	<i>S. enterica</i>	<i>enterica</i>	Crossness	NCTC 11059	Not Available	-	+
26	<i>S. enterica</i>	<i>enterica</i>	Cubana	ATCC 12007	Not Available	-	+
27	<i>S. enterica</i>	<i>enterica</i>	Dahlem	NCTC 9949	Not Available	-	+
28	<i>S. enterica</i>	<i>enterica</i>	Derby	ATCC 6960	Tank water and pork pies	-	+
29	<i>S. enterica</i>	<i>enterica</i>	Deversoir	NCTC 9792	Not Available	-	+
30	<i>S. enterica</i>	<i>enterica</i>	Dublin	ATCC 15480	Not Available	-	+
31	<i>S. enterica</i>	<i>enterica</i>	Enteritidis	ATCC 13076	Not Available	-	+
32	<i>S. enterica</i>	<i>enterica</i>	Essen	ATCC 6961	Not Available	-	+
33	<i>S. enterica</i>	<i>enterica</i>	Gallinarum	NCTC 10532	Not Available	-	+
34	<i>S. enterica</i>	<i>enterica</i>	Gaminara	ATCC 8324	Not Available	-	+
35	<i>S. enterica</i>	<i>enterica</i>	Give	ATCC 9268	Not Available	-	+
36	<i>S. enterica</i>	<i>enterica</i>	Hadar	NCTC 9877	Not Available	-	+
37	<i>S. enterica</i>	<i>enterica</i>	Hartford	NCTC 6802	Not Available	-	+
38	<i>S. enterica</i>	<i>enterica</i>	Havana	NCTC 6086	Not Available	-	+
39	<i>S. enterica</i>	<i>enterica</i>	Heidelberg	ATCC 8326	Not Available	-	+
40	<i>S. enterica</i>	<i>enterica</i>	Hillingdon	ATCC 9184	Not Available	-	+
41	<i>S. enterica</i>	<i>enterica</i>	Indiana	NCTC 11304	Not Available	-	+
42	<i>S. enterica</i>	<i>enterica</i>	Infantis	NCTC 10679	Not Available	-	+
43	<i>S. enterica</i>	<i>enterica</i>	Inverness	NCTC 6591	Not Available	-	+
44	<i>S. enterica</i>	<i>enterica</i>	Javiana	NCTC 6495	Not Available	-	+
45	<i>S. enterica</i>	<i>enterica</i>	Jerusalem	ATCC 700137	Not Available	-	+
46	<i>S. enterica</i>	<i>enterica</i>	Johannesburg	NCTC 8272	Not Available	-	+
47	<i>S. enterica</i>	<i>enterica</i>	Kentucky	NCTC 5799	Not Available	-	+
48	<i>S. enterica</i>	<i>enterica</i>	Krefeld	NCTC 9884	Not Available	-	+
49	<i>S. enterica</i>	<i>enterica</i>	Lille	NCTC 9885	Not Available	-	+
50	<i>S. enterica</i>	<i>enterica</i>	London	ATCC 8389	Not Available	-	+
51	<i>S. enterica</i>	<i>enterica</i>	Matadi	NCTC 9887	Not Available	-	+
52	<i>S. enterica</i>	<i>enterica</i>	Mbandaka	ATCC 51958	Not Available	-	+

53	<i>S. enterica</i>	<i>enterica</i>	Meleagridids	NCTC 6023	Not Available	-	+
54	<i>S. enterica</i>	<i>enterica</i>	Menden	ATCC 15992	Feces	-	+
55	<i>S. enterica</i>	<i>enterica</i>	Mgulani	NCTC 8492	Not Available	-	+
56	<i>S. enterica</i>	<i>enterica</i>	Minnesota	NTCT 5800	Not Available	-	+
57	<i>S. enterica</i>	<i>enterica</i>	Montevideo	ATCC 8387	Not Available	-	+
58	<i>S. enterica</i>	<i>enterica</i>	Muenchen	NCTC 6246	Not Available	-	+
59	<i>S. enterica</i>	<i>enterica</i>	Newport	ATCC 6962	Food poisoning	-	+
60	<i>S. enterica</i>	<i>enterica</i>	Nottingham	NCTC 7832	Not Available	-	+
61	<i>S. enterica</i>	<i>enterica</i>	Oranienburg	ATCC 9239	Illinois	-	+
62	<i>S. enterica</i>	<i>enterica</i>	Panama	ATCC 7378	Baby	-	+
63	<i>S. enterica</i>	<i>enterica</i>	Paratyphi A	ATCC 9150	Not Available	-	+
64	<i>S. enterica</i>	<i>enterica</i>	Paratyphi B	ATCC 8759	Gall bladder	-	+
65	<i>S. enterica</i>	<i>enterica</i>	Pomona	NCTC 6589	Turkey intestine	-	+
66	<i>S. enterica</i>	<i>enterica</i>	Poona	NCTC 5792	Not Available	-	+
67	<i>S. enterica</i>	<i>enterica</i>	Potsdam	ATCC 25957	Child	-	+
68	<i>S. enterica</i>	<i>enterica</i>	Pullorum	ATCC 9120	Clinical isolate	-	+
69	<i>S. enterica</i>	<i>enterica</i>	Reading	ATCC 6967	Guinea pig	-	+
70	<i>S. enterica</i>	<i>enterica</i>	Saintpaul	ATCC 9712	Cystitis	-	+
71	<i>S. enterica</i>	<i>enterica</i>	Sandiego	ATCC 231999	Urinary bladder, turtle	-	+
72	<i>S. enterica</i>	<i>enterica</i>	Schwarzengrund	NCTC 6756	Not Available	-	+
73	<i>S. enterica</i>	<i>enterica</i>	Senftenberg	ATCC 8400	Not Available	-	+
74	<i>S. enterica</i>	<i>enterica</i>	Sloterdijk	ATCC 15791	Family outbreak	-	+
75	<i>S. enterica</i>	<i>enterica</i>	Stanley	ATCC 7308	Not Available	-	+
76	<i>S. enterica</i>	<i>enterica</i>	Sundsvall	NCTC 6758	Not Available	-	+
77	<i>S. enterica</i>	<i>enterica</i>	Tennessee	ATCC 10722	Not Available	-	+
78	<i>S. enterica</i>	<i>enterica</i>	Thompson	ATCC 8391	Not Available	-	+
79	<i>S. enterica</i>	<i>enterica</i>	Typhi	ATCC 19430	Not Available	-	+
80	<i>S. enterica</i>	<i>enterica</i>	Typhimurium	ATCC 13311	Feces	-	+
81	<i>S. enterica</i>	<i>enterica</i>	Typhisuis	ATCC 8321	Not Available	-	+
82	<i>S. enterica</i>	<i>enterica</i>	Urbana	NCTC 6248	Not Available	-	+
83	<i>S. enterica</i>	<i>enterica</i>	Utrecht	NCTC 10077	Not Available	-	+
84	<i>S. enterica</i>	<i>enterica</i>	Vellore	ATCC 15611	Rectal swab	-	+
85	<i>S. enterica</i>	<i>enterica</i>	Virchow	ATCC 51955	Not Available	-	+
86	<i>S. enterica</i>	<i>enterica</i>	Waycross	NCTC 7401	Not Available	-	+
87	<i>S. enterica</i>	<i>enterica</i>	Weltevreden	NCTC 6534	Not Available	-	+
88	<i>S. enterica</i>	<i>enterica</i>	Zwickau	ATCC 15804	Not Available	-	+
89	<i>S. enterica</i>	<i>houtenae</i>	45:g,z51:-	ATCC 43974	Not Available	-	+
90	<i>S. enterica</i>	<i>houtenae</i>	Not Available	ATCC BAA-1580	Not Available	-	+
91	<i>S. enterica</i>	<i>houtenae</i>	11:z4,z23: -	ATCC 15788	Not Available	-	+
92	<i>S. enterica</i>	<i>indica</i>	45:a:e,n,x	ATCC BAA-1578	Not Available	-	+
93	<i>S. enterica</i>	<i>indica</i>	1,6,14,25:a:e,n,x	ATC 43976	Not Available	-	+
94	<i>S. enterica</i>	<i>indica</i>	6, 14, 25:a:e,n,x	NCTC 10458	coconut	-	+
95	<i>S. enterica</i>	<i>salamae</i>	56:b:-	ATCC 700149	Not Available	-	+
96	<i>S. enterica</i>	<i>salamae</i>	1,9,12:l,w:e,n	ATCC 6959	Urine	-	+
97	<i>S. enterica</i>	<i>salamae</i>	55:k:z39	ATCC 700148	Not Available	-	+
98	<i>S. enterica</i>	<i>salamae</i>	1,9,12:l,w:e,n,x	ATCC 43972	Not Available	-	+
99	<i>S. bongori</i>		66:z41:-	ATCC 43975	Not Available	-	+
100	<i>S. bongori</i>		48:z35	NCTC 14392	Not Available	-	+

<sup>a</sup> + = Positive Result; - = Negative Result; <sup>b</sup> Results identical between extraction protocols (flower or marijuana infused products) and between thermal cyclers (CFX-96, AriaMx); <sup>c</sup> ATCC – American Type Culture Collection, Manassas, VA; <sup>d</sup> NCTC – National Type Culture Collection, London, UK.

**Table 4: Inclusivity Results for the PathoSEEK Salmonella and STEC E.coli Multiplex Assay – STEC (1)**

#	Organism	Source	Origin	Results <sup>a, b</sup>	
				STEC	Salmonella
1	<i>Escherichia coli</i> O3	TW01413 <sup>c</sup>	Germany	+	-
2	<i>Escherichia coli</i> O3	TW01414	Germany	+	-
3	<i>Escherichia coli</i> O5	TW00021	Cow (MI)	+	-
4	<i>Escherichia coli</i> O5	TW05097	Cow (CA)	+	-
5	<i>Escherichia coli</i> O26:H11	ATCC <sup>d</sup> BAA-2205	Feces	+	-
6	<i>Escherichia coli</i> O26:H11	ATCC BAA-2196	Feces	+	-
7	<i>Escherichia coli</i> O26:H11	ATCC BAA-2204	Feces	+	-
8	<i>Escherichia coli</i> O26:H11	ATCC BAA-2181	Not Available	+	-
9	<i>Escherichia coli</i> O26:H11	ATCC BAA-2188	Feces	+	-
10	<i>Escherichia coli</i> O45:H2	ATCC BAA-2193	Feces	+	-
11	<i>Escherichia coli</i> O45:H2	ATCC BAA-2189	Feces	+	-
12	<i>Escherichia coli</i> O45:H2	ATCC BAA-2185	Not Available	+	-
13	<i>Escherichia coli</i> O45:H2	ATCC BAA-2202	Feces	+	-
14	<i>Escherichia coli</i> O45:H2	ATCC BAA-2198	Feces	+	-
15	<i>Escherichia coli</i> O91:H21	ATCC 51434	Not Available	+	-
16	<i>Escherichia coli</i> O91:H21	ATCC 51435	Clinical Isolate	+	-
17	<i>Escherichia coli</i> O103:H11	ATCC BAA-2215	Not Available	+	-
18	<i>Escherichia coli</i> O103:H11	ATCC BAA-2200	Not Available	+	-
19	<i>Escherichia coli</i> O103:H11	NJDPH <sup>e</sup> 151297-1	Not Available	+	-
20	<i>Escherichia coli</i> O103:H11	NJDPH 130928-3	Not Available	+	-
21	<i>Escherichia coli</i> O103:H11	TW08869	Human Isolate	+	-
22	<i>Escherichia coli</i> O103:H11	TW08872	Human Isolate	+	-
23	<i>Escherichia coli</i> O111:H8	ATCC BAA-2201	Feces	+	-
24	<i>Escherichia coli</i> O111:H8	ATCC BAA-2180	Feces	+	-
25	<i>Escherichia coli</i> O111:H8	ATCC BAA-184	Feces	+	-
26	<i>Escherichia coli</i> O111:H8	ATCC BAA-180	Feces	+	-
27	<i>Escherichia coli</i> O111:H8	ATCC BAA-181	Feces	+	-
28	<i>Escherichia coli</i> O113	ATCC BAA-177	Feces	+	-
29	<i>Escherichia coli</i> O113	ATCC BAA-176	Feces	+	-
30	<i>Escherichia coli</i> O113	ATCC BAA-183	Urine	+	-
31	<i>Escherichia coli</i> O118	TW08644	Feces	+	-
32	<i>Escherichia coli</i> O118	TW08134	Cow Feces	+	-
33	<i>Escherichia coli</i> O121:H19	ATCC BAA-2219	Feces	+	-
34	<i>Escherichia coli</i> O121:H19	ATCC BAA-2203	Feces	+	-
35	<i>Escherichia coli</i> O121:H19	ATCC BAA-2187	Not Available	+	-
36	<i>Escherichia coli</i> O121:H19	ATCC BAA-2220	Feces	+	-
37	<i>Escherichia coli</i> O121:H19	TW08868	Feces	+	-
38	<i>Escherichia coli</i> O145:NM	TW09356	Human Isolate	+	-
39	<i>Escherichia coli</i> O145:NM	TW07596	Feces	+	-
40	<i>Escherichia coli</i> O145:NM	ATCC BAA-2223	Feces	+	-
41	<i>Escherichia coli</i> O145:NM	ATCC BAA-2192	Feces	+	-
42	<i>Escherichia coli</i> O145:NM	NJDPH 17257-1	Not Available	+	-
43	<i>Escherichia coli</i> O145:NM	NJDPH 161296-1	Not Available	+	-
44	<i>Escherichia coli</i> O157:H7	ATCC 35150	Feces	+	-
45	<i>Escherichia coli</i> O157:H7	ATCC 43889	Feces	+	-
46	<i>Escherichia coli</i> O157:H7	ATCC 43894	Feces	+	-
47	<i>Escherichia coli</i> O157:H7	ATCC 700599	Salami	+	-
48	<i>Escherichia coli</i> O157:H7	TW00116	Feces	+	-
49	<i>Escherichia coli</i> O157:H7	TW00975	Human Isolate	+	-
50	<i>Escherichia coli</i> O157:H7	TW02302	Human Isolate	+	-
51	<i>Escherichia coli</i> O157:H7	TW04863	Feces	+	-

<sup>a</sup> + = Positive Result; - = Negative Result; <sup>b</sup> Results identical between extraction protocols (flower or marijuana infused products) and between thermal cyclers (CFX-96, AriaMx); <sup>c</sup>TW – Michigan St. STEC Center, Lansing, MI; <sup>d</sup>ATCC – American Type Culture Collection, Manassas, VA; <sup>e</sup> NJDPH – New Jersey Department of Public Health, Trenton, New Jersey.

**Table 5. Exclusivity Results for the PathoSEEK Salmonella and STEC E.coli Multiplex Assay (1)**

#	Organism	Source	Origin	Results <sup>a, b</sup>	
				STEC	Salmonella
1	<i>Aeromonas bestiarum</i>	ATCC <sup>c</sup> BAA-231	Cake	-	-
2	<i>Aeromonas hydrophila</i>	ATCC 7966	Milk	-	-
3	<i>Burkholderia multivorans</i>	ATCC 17616	Soil	-	-
4	<i>Bacillus subtilis</i>	ATCC 11774	Not Available	-	-
5	<i>Campylobacter jejuni</i>	ATCC 29428	Feces	-	-
6	<i>Candida tropicalis</i>	ATCC 13803	Not Available	-	-
7	<i>Citrobacter braakii</i>	ATCC 3037	Urine	-	-
8	<i>Citrobacter farmerii</i>	ATCC 51112	Feces	-	-
9	<i>Citrobacter freundii</i>	ATCC 8090	Not Available	-	-
10	<i>Citrobacter koseri</i>	ATCC 25408	Throat	-	-
11	<i>Citrobacter murliae</i>	ATCC 51118	United States; Illinois	-	-
12	<i>Citrobacter youngae</i>	ATCC 29935	Meat scraps	-	-
13	<i>Edwardsiella tarda</i>	ATCC 23672	Not Available	-	-
14	<i>Enterobacter aerogenes</i>	ATCC 13048	Sputum	-	-
15	<i>Enterobacter cloacae</i>	ATCC 13047	Spinal fluid	-	-
16	<i>Enterobacter gergoviae</i>	ATCC 33028	Urine	-	-
17	<i>Enterobacter sakazakii</i>	ATCC BAA-894	Clinical specimen	-	-
18	<i>Enterobacter amnigenus</i>	ATCC 51818	Milk	-	-
19	<i>Enterobacter cancerogenus</i>	ATCC 35318	Cerebrospinal fluid	-	-
20	<i>Erwinia rhapontici</i>	ATCC 29290	English pink wheat grains	-	-
21	<i>Escherichia coli</i>	ATCC 25922	Clinical isolate	-	-
22	<i>Escherichia fergusonii</i>	ATCC 35469	Feces	-	-
23	<i>Escherichia hermannii</i>	ATCC 700368	Not Available	-	-
24	<i>Escherichia vulneris</i>	ATCC 33821	Wound	-	-
25	<i>Hafnia alvei</i>	ATCC 51873	Feces	-	-
26	<i>Klebsiella oxytoca</i>	ATCC 51983	Blood	-	-
27	<i>Klebsiella pneumonia</i>	ATCC BAA-2146	Urine	-	-
28	<i>Listeria monocytogenes</i>	ATCC 7647	Bovine	-	-
29	<i>Morganella morganii</i>	ATCC 25829	Stool	-	-
30	<i>Pantoea agglomerans</i>	ATCC 43348	Gypsophila paniculata galls	-	-
31	<i>Proteus hauseri</i>	ATCC 13315	Not Available	-	-
32	<i>Proteus mirabilis</i>	ATCC 43071	Rectum	-	-
33	<i>Proteus vulgaris</i>	ATCC 8427	Inner ear infection	-	-
34	<i>Pseudomonas aeruginosa</i>	ATCC 15442	Water bottle in animal room	-	-
35	<i>Pseudomonas fluorescens</i>	ATCC 13525	Pre-filter tanks	-	-
36	<i>Pseudomonas putida</i>	ATCC 47054	Not Available	-	-
37	<i>Rahnella aquatilis</i>	ATCC 33991	Soil	-	-
38	<i>Ralstonia insidiosa</i>	ATCC 49129	Clinical isolate	-	-
39	<i>Serratia marcescens</i>	ATCC	Not Available	-	-
40	<i>Shigella dysenteriae</i>	ATCC 13313	Foreign seaman	+	-
41	<i>Shigella flexneri</i>	ATCC 12022	Not Available	-	-
42	<i>Shigella sonnei</i>	ATCC 9290	Not Available	-	-
43	<i>Trichoderma harzianum</i>	ATCC 60850	Soil	-	-
44	<i>Vibrio vulnificus</i>	ATCC 29307	Blood	-	-
45	<i>Yersinia ruckeri</i>	ATCC 29473	Rainbow trout	-	-

<sup>a</sup> + = Positive Result; - = Negative Result; <sup>b</sup> Results identical between extraction protocols (flower or marijuana infused products) and between thermal cyclers (CFX-96, AriaMx); <sup>c</sup>ATCC – American Type Culture Collection, Manassas, VA.

**Table 7: PathoSEEK Salmonella and STEC E. coli Multiplex Assays with SenSATIVAx Extraction Presumptive vs Confirmed Results (Paired) for AriaMx – POD Results (1)**

Matrix and Inoculum	Enrichment Time Point	MPN <sub>3</sub> / Test Portion	N <sup>b</sup>	x <sup>c</sup>	Presumptive		x	Confirmed		dPOD <sub>cp</sub> <sup>f</sup>	95% CI <sup>g</sup>
					POD <sub>cp</sub> <sup>d</sup>	95% CI		POD <sub>cc</sub> <sup>e</sup>	95% CI		
Dried cannabis flower (>0.3% THC) <sup>h</sup> ; 10g	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.08 (0.60, 1.86)	20	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Salmonella Typhimurium ATCC 13311	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.08 (0.60, 1.86)	20	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Dried cannabis flower (>0.3% THC) <sup>h</sup> ; 10g	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.09 (0.52, 1.67)	20	11	0.55	0.34, 0.74	12	0.60	0.39, 0.78	-0.05	-0.21, 0.11
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
E. coli O26 ATCC BAA-2188	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.09 (0.52, 1.67)	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Cannabis concentrates <sup>h</sup> ; 5 g	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.41 (0.83, 2.47)	20	14	0.70	0.48, 0.86	14	0.70	0.48, 0.86	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Salmonella Newport ATCC 6962	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.41 (0.83, 2.47)	20	14	0.70	0.48, 0.86	14	0.70	0.48, 0.86	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Cannabis concentrates <sup>h</sup> ; 5 g	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.59 (0.95, 2.79)	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
E. coli O103 ATCC BAA-2215	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.59 (0.95, 2.79)	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
THC-Infused Chocolate <sup>h</sup> ; 25 g	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.08 (0.60, 1.85)	20	14	0.70	0.48, 0.86	13	0.65	0.43, 0.82	0.05	-0.11, 0.21
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Salmonella Heidelberg ATCC 8326	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.08 (0.60, 1.85)	20	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
THC-Infused Chocolate <sup>h</sup> ; 25 g	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.85 (0.45, 1.49)	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
E. coli O145 ATCC BAA-2192	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.85 (0.45, 1.49)	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Dried cannabis flower <sup>h</sup> (>0.3% THC); 10g	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.44 (0.85, 2.57)	20	13	0.65	0.43, 0.82	14	0.70	0.48, 0.86	-0.05	-0.21, 0.11
		11.4 (2.97, 43.3)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Salmonella Typhimurium ATCC 16888 (Independent Laboratory)	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.44 (0.85, 2.57)	20	14	0.70	0.48, 0.86	14	0.70	0.48, 0.86	0.00	-0.13, 0.13
		11.4 (2.97, 43.3)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Dried cannabis flower (>0.3% THC) <sup>h</sup> ; 10g	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.87 (0.46, 1.46)	20	10	0.50	0.30, 0.70	11	0.55	0.34, 0.74	-0.05	-0.21, 0.11
		6.16 (1.91, 19.9)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
E. coli O26 ATCC 16888 (Independent Laboratory)	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.87 (0.46, 1.46)	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.13, 0.13
		6.16 (1.91, 19.9)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47

<sup>a</sup>MPN = Most Probable Number is based on the POD of reference method test portions using the Least Cost Formulations MPN calculator, with 95% confidence interval.

<sup>b</sup>N = Number of test portions.

<sup>c</sup>x = Number of positive test portions.

<sup>d</sup>POD<sub>cp</sub> = Candidate method presumptive positive outcomes divided by the total number of trials.

<sup>e</sup>POD<sub>cc</sub> = Candidate method confirmed positive outcomes divided by the total number of trials.

<sup>f</sup>dPOD<sub>cp</sub> = Difference between the candidate method presumptive result and candidate method confirmed result POD values.

<sup>g</sup>95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>h</sup>Dried cannabis flower evaluated using SenSATIVAx Flower/Leaf extraction kit, all other matrixes used SenSATIVAx MIP/Extract.

**Table 8: PathoSEEK Salmonella and STEC E. coli Multiplex Assays with SenSATIVax Extraction Presumptive vs Confirmed Results (Paired) for CFX-96 – POD Results (1)**

Matrix and Inoculum	Enrichment Time Point	MPN <sub>a</sub> / Test Portion	N <sup>b</sup>	x <sup>c</sup>	Presumptive		x	Confirmed		dPOD <sub>cp</sub> <sup>f</sup>	95% CI <sup>g</sup>
					POD <sub>cp</sub> <sup>d</sup>	95% CI		POD <sub>cc</sub> <sup>e</sup>	95% CI		
Dried cannabis flower (>0.3% THC) <sup>h</sup> ; 10g <i>Salmonella</i> Typhimurium ATCC 13311	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.08 (0.60, 1.86)	20	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.08 (0.60, 1.86)	20	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Dried cannabis flower (>0.3% THC) <sup>h</sup> ; 10g <i>E. coli</i> O26 ATCC BAA-2188	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.09 (0.52, 1.67)	20	11	0.55	0.34, 0.74	12	0.60	0.39, 0.78	-0.05	-0.21, 0.11
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.09 (0.52, 1.67)	20	11	0.55	0.34, 0.74	12	0.60	0.39, 0.78	-0.05	-0.21, 0.11
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Cannabis concentrates <sup>h</sup> ; 5 g <i>Salmonella</i> Newport ATCC 6962	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.41 (0.83, 2.47)	20	14	0.70	0.48, 0.86	14	0.70	0.48, 0.86	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.41 (0.83, 2.47)	20	14	0.70	0.48, 0.86	14	0.70	0.48, 0.86	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Cannabis concentrates <sup>h</sup> ; 5 g <i>E. coli</i> O103 ATCC BAA-2215	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.59 (0.95, 2.79)	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.59 (0.95, 2.79)	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
THC-Infused Chocolate <sup>h</sup> ; 25 g <i>Salmonella</i> Heidelberg ATCC 8326	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.08 (0.60, 1.85)	20	14	0.70	0.48, 0.86	13	0.65	0.43, 0.82	0.05	-0.11, 0.21
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.08 (0.60, 1.85)	20	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
THC-Infused Chocolate <sup>h</sup> ; 25 g <i>E. coli</i> O145 ATCC BAA-2192	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.85 (0.45, 1.49)	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.85 (0.45, 1.49)	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.13, 0.13
		>10 (8.00, >30.0)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Dried cannabis flower (>0.3% THC) <sup>h</sup> ; 10g <i>Salmonella</i> Typhimurium ATCC 16888 (Independent Laboratory)	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.44 (0.85, 2.57)	20	13	0.65	0.43, 0.82	14	0.70	0.48, 0.86	-0.05	-0.21, 0.11
		11.4 (2.97, 43.3)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.44 (0.85, 2.57)	20	14	0.70	0.48, 0.86	14	0.70	0.48, 0.86	0.00	-0.13, 0.13
		11.4 (2.97, 43.3)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Dried cannabis flower (>0.3% THC) <sup>h</sup> ; 10g <i>E. coli</i> O26 ATCC 16888 (Independent Laboratory)	16 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.87 (0.46, 1.46)	20	4	0.20	0.08, 0.42	11	0.55	0.34, 0.74	-0.35	-0.59, -0.11
		6.16 (1.91, 19.9)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	24 h	NA	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.87 (0.46, 1.46)	20	9	0.45	0.26, 0.66	11	0.55	0.34, 0.74	-0.10	-0.28, 0.83
		6.16 (1.91, 19.9)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47

<sup>a</sup>MPN = Most Probable Number is based on the POD of reference method test portions using the Least Cost Formulations MPN calculator, with 95% confidence interval.

<sup>b</sup>N = Number of test portions.

<sup>c</sup>x = Number of positive test portions.

<sup>d</sup>POD<sub>cp</sub> = Candidate method presumptive positive outcomes divided by the total number of trials.

<sup>e</sup>POD<sub>cc</sub> = Candidate method confirmed positive outcomes divided by the total number of trials.

<sup>f</sup>dPOD<sub>cp</sub> = Difference between the candidate method presumptive result and candidate method confirmed result POD values.

<sup>g</sup>95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>h</sup>Dried cannabis flower evaluated using SenSATIVax Flower/Leaf extraction kit, all other matrixes used SenSATIVax MIP/Extract.



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