



CERTIFICATION

AOAC Research Institute *Performance Tested Methods*SM

Certificate No.

061101

The AOAC Research Institute hereby certifies the method known as

Microgen GNA ID

manufactured by

Gold Standard Diagnostics Budapest Kft.

Fóti út 56

1047 Budapest

Hungary

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A handwritten signature in black ink, appearing to read "Bradley A. Stawick".

Bradley A. Stawick, AOAC Research Institute Senior Director

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AUTHORS ORIGINAL VALIDATION: Phillip Mugg MODIFICATION FEBRUARY 2018: Microgen Bioproducts Ltd. MODIFICATION DECEMBER 2023: Gold Standard Diagnostics (Veronika Bodnar and Cristina Sánchez Conde)		SUBMITTING COMPANY Microgen Bioproducts Limited 1 Admiralty Way Camberley, Surrey GU15 3DT United Kingdom		CURRENT LOCATION Gold Standard Diagnostics Budapest Ktf., formerly Microgen Bioproducts Ltd. Fóti út 56 A ép. 1047 Budapest, Hungary	
METHOD NAME Microgen GNA ID			CATALOG NUMBER MID64		
INDEPENDENT LABORATORY Silliker, Inc., Food Science Center 160 Armory Drive South Holland, IL 60473 USA					
APPLICABILITY OF METHOD Target organism – <i>Salmonella</i> and <i>E. coli</i> . Matrix – Isolated colonies on Cystine-lactose-electrolyte-deficient Agar. Performance claims – The Microgen GNA ID product has been validated to identify individual isolates of the target food-related bacterial species from a single colony on a selective agar plate and produce a correct identification within 18-24 hours.			REFERENCE METHOD On Line <i>Bacteriological Analytical Manual</i> - www.FDA/CFRAN Bacteriological Analytical Manual Online (5) USDA/BAM Chapter 10. Online Bacteriological Analytical - Chapter 10: Detection of <i>Listeria monocytogenes</i> in Foods and Environmental Samples, and Enumeration of <i>Listeria monocytogenes</i> in Foods. [Online] 04 22, 2022. (7)		
ORIGINAL CERTIFICATION DATE June 13, 2011			CERTIFICATION RENEWAL RECORD Renewed annually through December 2026.		
METHOD MODIFICATION RECORD 1. February 2018 Level 2 2. January 2023 Level 1 3. December 2023 Level 2 4. November 2024 Level 1			SUMMARY OF MODIFICATION 1. Location change from 1 Admiralty Way, Camberley to Unit 1, Watchmoor Point, Camberley. 2. Company rebranded to Gold Standard Diagnostics Budapest, Kft. 3. Location change from Camberley, Surrey UK to Budapest, Hungary with catalog number change. 4. Editorial change.		
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PRINCIPLE OF THE METHOD (1)

Salmonella species and some serotypes of *E. coli* are two of the major food-borne pathogens isolated routinely by food testing laboratories and members of the family Enterobacteriaceae. In addition, *E. coli* is a highly specific indicator of potential contamination with pathogens of fecal origin. The product under test Microgen GNA ID (MID 64) has been designed to enable laboratories to correctly identify these species when sampled from a single colony isolated on a selective agar plate and differentiate them from other closely related species of the family Enterobacteriaceae. The product utilizes the ability of each of these species to metabolize specific chemical substrates. The pattern of substrate metabolism produced in the MID 64 multi-well strip is characteristic for each member of the genus *Salmonella* and each individual isolate of the species *E. coli*. The results from the multi-well strips are converted into four-digit codes which are analyzed using a dedicated computer software program. This program calculates the probability that the isolate being tested is one of the target species. In addition, the software provides a comment as to the level of confidence in the proposed identification e.g. Excellent, Good or Poor Identification (14). Full descriptions of the basis and significance of these comments are found in the On-line help file provided with the software. The most probable species is identified, and this is taken as the result. If a non-target species colony is introduced into the test system, the pattern of results achieved will be analyzed by the dedicated software which will confirm that the isolate under test is a representative of a non-target species or genus. The substrates used in the MID 64 product are taken directly from classical literature³ and include those recommended in the current USDA/ FSIS BAM⁵ method.

DISCUSSION OF THE VALIDATION STUDY (1)

The results presented clearly indicate that the Microgen GNA ID Identification kit from Microgen Bioproducts is extremely effective for the identification of all target species, *E. coli* and *Salmonella* spp. The ability to identify isolates of these species was successfully demonstrated from a range of classical selective isolation media and the newer chromogenic agars employed routinely for the isolation of these species.

The inclusion of substrate 4, Glucose is effective at highlighting the attempted identification of non – target oxidase positive species. The combination of the inclusion of this key substrate, the warning message which appears in the Microgen ID Software whenever an isolate is negative for glucose, and the potentially extremely low probabilities ascribed to non-target species isolates ensures that the operator is left in no doubt whether the isolate under test is a true target species or not (exclusivity study).

In addition, the inclusion of the specific Additional Comment:

Salmonella cannot be fully identified using biochemistry alone. Perform Polyvalent 'O' and 'H' slide agglutination to confirm, and serotype”, which appears every time the Microgen ID Software returns an identification choice of “Salmonella”, appears as one or more of the identification choices provides additional confirmation of the presence of *Salmonella* spp. In addition, the inclusion of this comment ensures that in the event that a non-target isolate returns an identification of *Salmonella* spp. it can be excluded on the basis of standard *Salmonella* serology (Polyvalent “O” and “H” slide agglutination tests).

The substrates incorporated into the Microgen GNA ID identification system are clearly able to provide accurate identification of all target species even when aberrant biochemical reactions are achieved.

The reproducibility of the Microgen GNA ID test system was evaluated using three different batches and testing performed by three separate operators produced identical results (Batch-to-Batch study).

Table 6: Inclusivity Isolates Tested – Salmonella (1)**(unless indicated, strains are wild strains isolated from indicated sources)**

Number	MBCC	Bacterial species	ATCC	NCTC/NCIMB	GNA Result	Identification/Probability	Source	Serogroup	Subspecies	Comments
1	141	<i>Salmonella</i> Hadar		NCIMB 13033	7702	<i>Salmonella</i> spp. (1/1)	Chicken GIBLETS	C2	enterica	
2	146	<i>Salmonella</i> Infantis		NCIMB 13036	7702	<i>Salmonella</i> spp. (1/1)	Chicken Meat	C1	enterica	
3	215	<i>Salmonella</i> Typhimurium	14028		7602	<i>Salmonella</i> spp. (1/41)	Chicken isolate	B	enterica	
4	331	<i>Salmonella</i> Berkeley		NCTC 8260	7702	<i>Salmonella</i> spp. (1/1)	Diseased Turkey	U	enterica	
5	345	<i>Salmonella</i> Cubana		NCTC 7101	7702	<i>Salmonella</i> spp. (1/1)	Chicken, Diarrhoea	G	enterica	
6	818	<i>Salmonella</i> arizonae		NCTC 7355	7742	<i>Salmonella</i> arizonae (1/1)	Viscera of gopher snake			
7	1284	<i>Salmonella</i> Ohio			7702	<i>Salmonella</i> spp. (1/1)	Raw Poultry	C1	enterica	
8	1285	<i>Salmonella</i> Kentucky			7702	<i>Salmonella</i> spp. (1/1)	Environmental swab	C3	enterica	
9	1286	<i>Salmonella</i> Kentucky			7702	<i>Salmonella</i> spp. (1/1)	Lizard faeces	C3	enterica	
10	1287	<i>Salmonella</i> Othmarschen			7702	<i>Salmonella</i> spp. (1/1)	Spice	C1	enterica	
11	1288	<i>Salmonella</i> Weltevreden			7702	<i>Salmonella</i> spp. (1/1)	Dried mushroom	E1	enterica	
12	1289	<i>Salmonella</i> Kottbus			7702	<i>Salmonella</i> spp. (1/1)	Duck's liver	C2	enterica	
13	1290	<i>Salmonella</i> Tranoroa			7742	<i>Salmonella</i> arizoniae (1/1)	Gecko	55	salamae	
14	1291	<i>Salmonella</i> Orion var 15+			7702	<i>Salmonella</i> spp. (1/1)	Sesame seeds	E1	enterica	
15	1292	<i>Salmonella</i> Paratyphi B var Java			7702	<i>Salmonella</i> spp. (1/1)	Betel nuts	B	enterica	
16	1293	<i>Salmonella</i> Sinfior			7702	<i>Salmonella</i> spp. (1/1)	Melon seeds (ground eguiss)	E1	enterica	
17	1294	<i>Salmonella</i> Kentucky			7702	<i>Salmonella</i> spp. (1/1)	bark bedding from reptile	C3	enterica	
18	1295	<i>Salmonella</i> Kentucky			7702	<i>Salmonella</i> spp. (1/1)	cleaning cloth	C3	enterica	
19	1296	<i>Salmonella</i> Enteritidis			7702	<i>Salmonella</i> spp. (1/1)	chocolate swiss roll	D1	enterica	
20	1297	<i>Salmonella</i> Infantis			6702	<i>Salmonella</i> cholera-suis (1/9)	Pasta	C1	enterica	
21	1298	<i>Salmonella</i> Anatum			7602	<i>Salmonella</i> spp. (1/41)	Pork liver	E1	enterica	
22	1299	<i>Salmonella</i> Pullorum			6602	<i>Salmonella</i> cholera-suis (1/433)	Egg	D1	enterica	
23	1300	<i>Salmonella</i> Abaetetuba			7702	<i>Salmonella</i> spp. (1/1)	Creek water	F	enterica	
24	346	<i>Salmonella</i> Sandiego		NCTC 5719	7702	<i>Salmonella</i> spp. (1/1)	Serum inst. Copenhagen	B	enterica	
25	347	<i>Salmonella</i> Banalia		NCTC 8242	7702	<i>Salmonella</i> spp. (1/1)	Serum inst. Copenhagen	C2	enterica	
26	348	<i>Salmonella</i> Waycross		NCTC 7401	7702	<i>Salmonella</i> spp. (1/1)	Edwards, Kentucky	Serogroup	enterica	
27	403	<i>Salmonella</i> Tranoroa		NCTC 10252	7702	<i>Salmonella</i> spp. (1/1)	Serum inst. Copenhagen	55	salamae	
28	1121	<i>Salmonella</i> arizonae	13314	NCTC 8297	7742	<i>Salmonella</i> arizonae (1/1)	Type Strain			
29	329	<i>Salmonella</i> Bispebjerg		NCTC 8486	7702	<i>Salmonella</i> spp. (1/1)	CPHL, <i>Salmonella</i> ref.	B	enterica	
30	330	<i>Salmonella</i> Java		NCTC 5706	7702	<i>Salmonella</i> spp. (1/1)	Serum inst. Copenhagen	B	enterica	
31	332	<i>Salmonella</i> Birkenhead		NCTC 7744	7702	<i>Salmonella</i> spp. (1/1)	CPHL, <i>Salmonella</i> ref.	C1	enterica	
32	333	<i>Salmonella</i> Virginia		NCTC 6947	7702	<i>Salmonella</i> spp. (1/1)	Clinical, gastro-enteritis	C3	enterica	

Table 6: Inclusivity Isolates Tested – Salmonella Cont'd..... (1)
(unless indicated, strains are wild strains isolated from indicated sources)

Number	MBCC	Bacterial species	ATCC	NCTC/NCIMB	GNA Result	Identification/Probability	Source	Serogroup	Subspecies	Comments
33	334	<i>Salmonella</i> Saintpaul		NCTC 6022	7702	<i>Salmonella</i> spp. (1/1)	Serum inst. Copenhagen	B	enterica	
34	335	<i>Salmonella</i> Rubislaw		NCTC 8497	6702	<i>Salmonella</i> cholera-suis (1/9)	Edwards, Chamblee	F	enterica	
35	336	<i>Salmonella</i> Rostock		NCTC 5767	6702	<i>Salmonella</i> cholera-suis (1/9)	Serum inst. Copenhagen	D1	enterica	
36	337	<i>Salmonella</i> Moscow		NCTC 10480	6702	<i>Salmonella</i> cholera-suis (1/9)	CPHL, <i>Salmonella</i> ref.	D1	enterica	
37	338	<i>Salmonella</i> Montevideo		NCTC 5747	7702	<i>Salmonella</i> spp. (1/1)	Serum inst. Copenhagen	C1	enterica	
38	339	<i>Salmonella</i> Oranienberg		NCTC 5743	6702	<i>Salmonella</i> cholera-suis (1/9)	Serum inst. Copenhagen	C1	enterica	
39	340	<i>Salmonella</i> London		NCTC 5777	7702	<i>Salmonella</i> spp. (1/1)	Serum inst. Copenhagen	E1	enterica	
40	341	<i>Salmonella</i> Meleagridis		NCTC 6023	7702	<i>Salmonella</i> spp. (1/1)	Serum inst. Copenhagen	E1	enterica	
41	342	<i>Salmonella</i> Telaviv		NCTC 6020	7702	<i>Salmonella</i> spp. (1/1)	Serum inst. Copenhagen	M	enterica	
42	343	<i>Salmonella</i> Give		NCTC 5778	7702	<i>Salmonella</i> spp. (1/1)	Serum inst. Copenhagen	E1	enterica	
43	344	<i>Salmonella</i> Blukwa		NCTC 8271	7702	<i>Salmonella</i> spp. (1/1)	Serum inst. Copenhagen	K	enterica	
44	115	<i>Salmonella</i> Albany			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group C, H7	enterica	Group C3
45	116	<i>Salmonella</i> Allandale			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group R, G10	enterica	Group R
46	118	<i>Salmonella</i> Assinie			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group E, H9	enterica	Group E1
47	119	<i>Salmonella</i> Bergen			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group X, I2	enterica	Group X
48	121	<i>Salmonella</i> Bolombo			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group E1, I1	enterica	Group E1
49	122	<i>Salmonella</i> California			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group B, G7	enterica	Group B
50	123	<i>Salmonella</i> Coeln			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group B, G6	enterica	Group B
51	125	<i>Salmonella</i> Derby			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group B, H8	enterica	Group B
52	127	<i>Salmonella</i> Dublin			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group D1, X7	enterica	Group D1
53	138	<i>Salmonella</i> Gaminara			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group I, H4	enterica	Group I
54	144	<i>Salmonella</i> Hvittingfoss			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group B1, Y9	enterica	Group I
55	157	<i>Salmonella</i> Senftenburg			7702	<i>Salmonella</i> spp. (1/1)	Lab M	Group E1, G2	enterica	Group E4
56	159	<i>Salmonella</i> Tennessee			6702	<i>Salmonella</i> cholera-suis (1/9)	Lab M	Group C1, F9	enterica	Group C1

Note: In each case where *Salmonella* spp. was not the first choice it was the second choice (see below)

GNA Result	First Choice	Second Choice
6702	<i>Salmonella</i> Cholera-suis (1/9)	<i>Salmonella</i> spp. (1/24)
6602	<i>Salmonella</i> Cholera-suis (1/433)	<i>Salmonella</i> spp. (1/772)

Table 7: Inclusivity Isolates Tested – *E. coli* (1)

(unless indicated, strains are wild strains isolated from indicated sources)

Number	MBCC	Bacterial species	ATCC	NCTC/NCIMB	GNA Result	Identification/Probability	Source	Serotype
1	70	<i>E. coli</i>	10536	NCTC 10418	6760	<i>E. coli</i> (1/2)		
2	71	<i>E. coli</i>		NCTC 13148	6760	<i>E. coli</i> (1/2)		
3	72	<i>E. coli</i>		NCTC 9111	6760	<i>E. coli</i> (1/2)	Serum inst. Copenhagen	Serotype 0111
4	206	<i>E. coli</i>		NCTC 12900	6760	<i>E. coli</i> (1/2)		Serotype 0157 (non-VETC)
5	217	<i>E. coli</i>	25922		6760	<i>E. coli</i> (1/2)	TCS, Clinical Isolate	
6	632	<i>E. coli</i>		NCTC 9001	6760	<i>E. coli</i> (1/2)	Human Urine	
7	636	<i>E. coli</i>		NCTC 9103	6760	<i>E. coli</i> (1/2)	Serum Inst. Copenhagen	
8	637	<i>E. coli</i>		NCTC 10279	4760	<i>E. coli</i> (1/4)	CPHL, reference culture	
9	643	<i>E. coli</i>		NCTC 8960	6760	<i>E. coli</i> (1/2)	Serum inst. Copenhagen	Serotype 026
10	1239	<i>E. coli</i>		NCTC 13352	4760	<i>E. coli</i> (1/4)	ESBL Strain	
11	1240	<i>E. coli</i>		NCTC 13353	6760	<i>E. coli</i> (1/2)	ESBL Strain	
12	67	<i>E. coli</i>			4760	<i>E. coli</i> (1/4)	LabM (wild strain)	
13	68	<i>E. coli</i>			4760	<i>E. coli</i> (1/4)	Lab M (wild Strain)	
14	69	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	Lab M (wild Strain)	
15	87	<i>E. coli</i>			4760	<i>E. coli</i> (1/4)	MAFF Isolate	Serotype 0157
16	88	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	MAFF Isolate	Serotype 0157
17	89	<i>E. coli</i>			4760	<i>E. coli</i> (1/4)	MAFF Isolate	Serotype 0157
18	90	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	MAFF Isolate	Serotype 0157
19	418	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	Commercial Food Testing Lab.	Serotype 0157:H7
20	519	<i>E. coli</i>			4760	<i>E. coli</i> (1/4)	VLA, Veterinary Isolate	
21	520	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	VLA, Veterinary Isolate	
22	630	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	Lab M (wild Strain)	
23	633	<i>E. coli</i>			O760	<i>E. coli</i> -inactive (1/9)	Aberdeen, Veterinary isolate	Serotype 0111
24	635	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	Aberdeen, Veterinary isolate	Serotype 0111
25	638	<i>E. coli</i>			6760	<i>E. coli</i> (1.2)	Aberdeen, Veterinary isolate	Serotype 026
26	640	<i>E. coli</i>			4760	<i>E. coli</i> (1/4)	Lab M (wild Strain)	Serotype 0157
27	641	<i>E. coli</i>			4760	<i>E. coli</i> (1/4)	Lab M (wild Strain)	Serotype 0157
28	642	<i>E. coli</i>			6720	<i>E. coli</i> (1/39)	Lab M (wild Strain)	Serotype 0157
29	644	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	Lab M (wild Strain)	Serotype 0157
30	645	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	Lab M (wild Strain)	Serotype 0157
31	646	<i>E. coli</i>			4760	<i>E. coli</i> (1/4)	Lab M (wild Strain)	Serotype 0157
32	647	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	Lab M (wild Strain)	Serotype 0157
33	648	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	Lab M (wild Strain)	Serotype 0157
34	48	<i>E. coli</i>			O760	<i>E. coli</i> -inactive (1/9)	Lab M, Clinical Isolate	
35	167	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	MEDVET, Australia	
36	639	<i>E. coli</i>			4760	<i>E. coli</i> (1/4)	CPHL, reference culture	
37	586	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	West Park Hospital, Clinical Isolate	
38	588	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	West Park Hospital, Clinical Isolate	
39	589	<i>E. coli</i>			O760	<i>E. coli</i> -inactive (1/9)	West Park Hospital, Clinical Isolate	
40	590	<i>E. coli</i>			6760	<i>E. coli</i> (1/2)	West Park Hospital, Clinical Isolate	

Table 8: Exclusivity Isolates Tested (included in the Microgen GNA ID Database) (1)

Sample	MBCC no.	ATCC No	Organism	Source Laboratory	Microgen GNA ID Software result	API 20E Software result	Isolated From (or other comments):
1	164		<i>Acinetobacter baumani</i>	Medvet, Australia	<i>A. baumannii</i> (1/3) (very good)	<i>A. baumannii</i> (good)	
2	208	19606	<i>Acinetobacter baumani</i>	TCS	<i>A. baumannii</i> (1/3) (very good)	<i>A. baumannii</i> (very good)	ATCC Type Strain
3	38		<i>Acinetobacter sp.</i>	LabM	<i>A. baumannii</i> (1/3) (very good)	<i>A. baum/calco</i> (good)	
4	60		<i>C. freundii</i>	LabM	<i>C. freundii</i> (1/7) (excellent)	<i>C. freundii</i> (very good)	
5	61		<i>C. freundii</i>	LabM	<i>C. freundii</i> (1/6) (excellent)	<i>C. youngae</i> (very good)	
6	62		<i>C. freundii</i>	LabM	<i>C. freundii</i> (1/45) (acceptable)	<i>C. youngae</i> (very good)	
7	63		<i>C. freundii</i>	LabM	<i>C. freundii</i> (1/7) (excellent)	<i>C. freundii</i> (excellent)	
8	64	0890	<i>C. freundii</i>	LabM (NCTC 9750)	<i>C. freundii</i> (1/7) (excellent)	<i>C. freundii</i> (very good)	ATCC Type Strain
9	65		<i>C. diversus</i>	LabM	<i>C. diversus</i> (1/1) (excellent)	No identification	
10	631		<i>E. hermannii</i>	LabM	<i>E.coli</i> (1/2) (excellent)	<i>E. coli</i> (low)	Supplied as <i>E. hermannii</i>
11	49		<i>Enterobacter cloacae</i>	LabM	<i>E. cloacae</i> (1/2) (very good)	<i>E. cloacae</i> (good)	
12	50		<i>Enterobacter cloacae</i>	LabM	<i>E. cloacae</i> (1/2) (very good)	<i>E. cloacae</i> (good)	
13	51		<i>Enterobacter cloacae</i>	LabM	<i>E. cloacae</i> (1/163) (inconclusive*)	<i>E. cloacae</i> (good)	
14	162		<i>Enterobacter cloacae</i>	Medvet, Australia	<i>E. cloacae</i> (1/2) (very good)	<i>E. cloacae</i> (good)	
15	53		<i>Enterobacter aerogenes</i>	LabM	<i>E. aerogenes</i> (1/1) (acceptable)	<i>E. aerogenes</i> (good)	
16	209	13048	<i>Enterobacter aerogenes</i>	TCS (NCTC 10006)	<i>E. aerogenes</i> (1/1) (acceptable)	<i>Serratia fonticola</i> (poor)	ATCC Type Strain
17	45		<i>K. oxytoca</i>	LabM	<i>K oxytoca</i> (1/1) (excellent)	<i>K oxytoca</i> (poor)	
18	46		<i>K oxytoca</i>	LabM	<i>K oxytoca</i> (1/1) (excellent)	<i>K oxytoca</i> (good)	
19	47		<i>K. pneumoniae</i>	LabM	<i>K. pneumoniae</i> (1/1) (excellent)	<i>K. pneumoniae</i> (good)	
20	161		<i>K. pneumoniae</i>	Medvet, Australia	<i>K. pneumoniae</i> (1/1) (excellent)	<i>K. pneumoniae</i> (good)	
21	211		<i>K. pneumoniae</i>	TCS (NCTC 9528)	<i>K. pneumoniae</i> (1/1) (excellent)	<i>K. pneumoniae</i> (good)	Butter
22	77	29906	<i>P. mirabilis</i>	LabM	<i>P. mirabilis</i> (1/3) (excellent)	<i>P. mirabilis</i> (excellent)	ATCC Type Strain
23	78		<i>P. mirabilis</i>	LabM	<i>P. mirabilis</i> (1/3) (excellent)	<i>P. mirabilis</i> (excellent)	
24	166		<i>P. mirabilis</i>	Medvet, Australia	<i>P. mirabilis</i> (1/169) (acceptable)	<i>P. mirabilis</i> (very good)	
25	212	14153	<i>P. mirabilis</i>	TCS (NCTC 13376)	<i>P. mirabilis</i> (1/169) (acceptable)	<i>M. morganni</i> (good)	ATCC Type Strain
26	168		<i>P. stuartii</i>	Medvet, Australia	<i>P. stuartii</i> (1/6) (good)	<i>P. stuartii</i> (good)	
27	627		<i>Providencia sp.</i>	West Park Hospital	<i>P. stuartii</i> (1/6) (good)	<i>P. stuartii</i> (good)	
Sample	MBCC no.	ATCC No	Organism	Source Laboratory	Microgen GNA ID Software result	API 20E Software result	Isolated From (or other comments):
28	57		<i>S. marcescens</i>	LabM	<i>S. marcescens</i> (1/1) (excellent)	<i>S. marcescens</i> (very good)	
29	58		<i>S. marcescens</i>	LabM	<i>S. marcescens</i> (1/1) (excellent)	<i>S. marcescens</i> (excellent)	
30	59	274	<i>S. marcescens</i>	LabM (NCTC 1377)	<i>S. marcescens</i> (1/1) (excellent)	<i>S. marcescens</i> (very good)	ATCC Type Strain
31	163		<i>S. marcescens</i>	Medvet, Australia	<i>S. marcescens</i> (1/1) (excellent)	<i>S. marcescens</i> (excellent)	
32	1		<i>S. flexneri</i>	LabM	<i>Shigella</i> subgroup A,B,C (1/2) (very good)	No identification	
33	42		<i>S. flexneri</i>	LabM	<i>Shigella</i> subgroup A,B,C (1/2) (very good)	<i>Shigella</i> species (poor)	
34	43		<i>S. flexneri</i>	LabM	<i>Shigella</i> subgroup A,B,C (1/2) (very good)	<i>Shigella</i> species (good)	
35	39		<i>S. sonnei</i>	LabM	<i>Sh. sonnei</i> (1/1) (excellent)	<i>Sh. sonnei</i> (very good)	
36	40		<i>S. sonnei</i>	LabM	<i>Sh. sonnei</i> (1/1) (excellent)	<i>Sh. sonnei</i> (very good)	
37	214	25931	<i>S. sonnei</i>	TCS	<i>Sh. sonnei</i> (1/1) (excellent)	<i>Sh. sonnei</i> (very good)	ATCC Type Strain
38	506		<i>Y. enterocolitica</i>	VLA	<i>Y. enterocolitica</i> (1/10) (good)	<i>Y. enterocolitica</i> (good)	
39	507		<i>Y. enterocolitica</i>	VLA	<i>Y. enterocolitica</i> (1/10) (acceptable)	<i>Y. enterocolitica</i> (very good)	
40	515		<i>Y. enterocolitica</i>	VLA	<i>Y. enterocolitica</i> (1/4) (excellent)	<i>Y. enterocolitica</i> (very good)	

Table 9: Exclusivity Isolates Tested (not included in the Microgen GNA ID Database) (1)

Sample	MBCC no.	ATCC No	Organism	Source Laboratory	Microgen GNA ID Software result	Isolated From (or other comments)	Notes
1	61		<i>Citrobacter youngae</i>	Lab M	<i>C. freundii</i> (1/6) (Excellent)		
2	80		<i>Pseudomonas. aeruginosa</i>	Lab M	<i>A.baumannii</i> (1/31) (Acceptable)	NCTC 10662	
3	81	27853	<i>Pseudomonas aeruginosa</i>	Lab M	<i>A.baumannii</i> (1/21) (Acceptable)		
4	170	7966	<i>Aeromonas hydrophila</i>	Microbiologics	<i>C. freundii</i> (1/323,721) (Unacceptable)		
5	195		<i>Staphylococcus aureus</i>	NCTC	<i>P.agglomerans</i> (1/801) (Doubtful)	NCTC 8532	
6	207	6633	<i>Bacillus subtilis</i>	TCS	<i>P.agglomerans</i> (1/89) (Acceptable)		
7	516		<i>Yersinia frederiksenii</i>	VLA	<i>Y. enterocolitica</i> (1/163) (Acceptable)		
8	517		<i>Yersinia ruckeri</i>	VLA	<i>S. ParaTyphi A</i> (1/1) (Very Good)		1
9	679		<i>Burkholderia cepacia</i>	Southampton HPA	<i>K. ozaenae</i> (1/2,161) (Doubtful)		
10	690		<i>Stenotrophomonas maltophilia</i>	Southampton HPA	<i>A. lwoffii</i> (1/3) (Acceptable)		2
11	810		<i>Bacillus cereus</i>	NCTC	<i>S. marcescens</i> (1/8,196) (Acceptable)	NCTC 10320	
12	1025		<i>Enterococcus faecalis</i>	NCTC	<i>P.agglomerans</i> (1/801) (Doubtful)	NCTC 12204	
13	1204		<i>Burkholderia stabilis</i>	University Edinburgh	<i>S.marcescens</i> (1/7,638) (Acceptable)		
14	1205		<i>Burkholderiacenocepacia</i>	University Edinburgh	<i>A.baumannii</i> (1/769) (Acceptable)		
15	1206		<i>Burkholderia multivorans</i>	University Edinburgh	<i>S.marcescens</i> (1/7,360.060) (Acceptable)		2
16	1208		<i>Achromobacter xylosoxidans</i>	University Edinburgh	<i>A.baumannii</i> (1/23,768) (Acceptable)		2
17	1209		<i>Burkholderia cepacia</i>	University Edinburgh	<i>A.baumannii</i> (1/66,825)(Unacceptable)		
18	1210		<i>Ralstonia mannitolytica</i>	University Edinburgh	<i>A.lwoffii</i> (1/89) (Inconclusive)		2
19	1213		<i>Pseudomonas putida</i>	University Edinburgh	<i>A.lwoffii</i> (1/89) (Inconclusive)		2
20	1214		<i>Burkholderia vietnamiensis</i>	University Edinburgh	<i>A.lwoffii</i> (1/43) (Acceptable)		
21	1215		<i>Chryseobacterium indologenes</i>	University Edinburgh	<i>K. pneumoniae</i> (1/556,329) (Unacceptable)		
22	1307	17802	<i>Vibrio parahaemolyticus</i>	Microbiologics	<i>P.rettgeri</i> (1/24,701,003) (Unacceptable)		

DISCUSSION OF MODIFICATION APPROVED DECEMBER 2023 (10)

MID64 results are shown at three levels: (1) the final identification of the “GN” species (Level 3), (2) the octal code obtained for the identification of the species (Level 2), and (3) the detailed results of the chemical substrates per “GN” species (Level 1). The results obtained at level 3, for the identification of the Gram-negative oxidase-negative species, no difference was encountered between the lots analyzed. All manufactured lots, both in Budapest 3 tested lots as well as in the UK survey lot, correctly identified the respective species (level 3) in all replicates. The discussed variability encountered at level 1 or level 2 results for the identification show variability against the expected identification of the pathogen, defining the probability of identification of each lot or production site methods. As per the scope of this study, the probability of identification of each manufactured lot has been statistically compared. In all of the discussions analyzed, the study data indicate with 95% confidence that the method produced at Budapest and method produced at Surrey are equivalent for the identification of Gram-negative oxidase-negative bacteria.

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