CERTIFICATION

AOAC Research Institute

Performance Tested Methods[SM]

Certificate No.

102004

The AOAC Research Institute hereby certifies the method known as:

foodproof® STEC Screening LyoKit and **food**proof® STEC Identification LyoKit with **food**proof® StarPrep Three Kit

manufactured by

Hygiena Diagnostics GmbH
Hermannswerder 17
14473 Potsdam, Germany

This method has been evaluated and certified according to the policies and procedures of the AOAC *Performance Tested Methods*[SM] Program. 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*[SM] 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.

Bradley A. Stawick, Senior Director
Signature for AOAC Research Institute

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AUTHORS
Stefanie Wendrich, Hanna Hartenstein, Benjamin Junge, Cordt Grönewald, Kornelia Berghof-Jäger

SUBMITTING COMPANY
BIOTECON Diagnostics GmbH
Hermannswerder 17
14473 Potsdam, Germany

CURRENT SPONSOR
Hygiena Diagnostics GmbH
Hermannswerder 17
14473 Potsdam, Germany

METHOD NAMES
foodproof® STEC Screening LyoKit and **food**proof® STEC Identification LyoKit **food**proof® StarPrep Three Kit

CATALOG NUMBERS
KIT 2300 77/78; KIT 2300 79/80, KIT 2301 87

INDEPENDENT LABORATORY
Q Laboratories
1930 Radcliff Drive
Cincinnati, OH USA

APPLICABILITY OF METHOD
Target Organisms – *stx1*, *stx2*, *eae*, *Escherichia coli* serogroups O157, O26, O45, O103, O111, O121, O145, O104.

Matrices – (25g and 375 g) – Fresh raw ground beef (~25% fat content), fresh raw beef trim.

Performance claims – The food**proof STEC Screening LyoKit and** food**proof STEC Identification LyoKit with the** food**proof StarPrep Three Kit are comparable to the reference culture method in the U. S. Department of Agriculture-Food Safety and Inspection Service (USDA-FSIS) Microbiology Laboratory Guidebook (MLG), 5C.00, Detection, Isolation and Identification of Top Seven Shiga Toxin-Producing *Escherichia coli* (STEC) from Meat Products and Carcass and Environmental Sponges (2). 375 g test portions were analyzed at 12 and 22 ± 2 h of incubation and 25 g test portions at 8 and 22 ± 2 h of incubation.**

ORIGINAL CERTIFICATION DATE
October 18, 2020

CERTIFICATION RENEWAL RECORD
Renewed through December 2025.

METHOD MODIFICATION RECORD
1. **March 2022 Level 1**
2. **December 2024 Level 1**

SUMMARY OF MODIFICATION
1. **Rebranding to include Hygiena, editing, and formatting changes to inserts and labeling.**

Under this AOAC *Performance Tested Methods*^{SM} License Number, 102004 this method is distributed by:
NONE

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PRINCIPLE OF THE METHOD (1)
The method describes the detection of Shiga toxin-producing *E. coli* in food. The **food**proof® STEC Screening LyoKit and **food**proof STEC Identification LyoKit combined with the **food**proof StarPrep Three Kit DNA extraction method, allows results to be obtained through gene amplification with the use of real time PCR technology. The **food**proof STEC Screening LyoKit enables a rapid and specific detection of the toxin genes *stx 1* and *stx 2* as well as the virulence gene *eae* which encodes the attaching and effacing protein intimin. This kit can be used on any PCR instrument with FAM, HEX, ROX, and Cy5 detection channels. Samples tested positive with the **food**proof STEC Screening LyoKit can be further analyzed with the **food**proof STEC Identification LyoKit for the rapid and specific detection of the STEC serogroups O26, O45, O103, O104, O111, O121, O145, and O157. This kit can be used on any PCR instrument capable of performing a melting curve analysis which also contains FAM, HEX, ROX, and Cy5 detection channels.

DISCUSSION OF THE VALIDATION STUDY (1)

The **food**proof STEC Screening LyoKit and the **food**proof STEC Identification LyoKit combined with the **food**proof StarPrep Three Kit enable the detection of Shiga toxin-producing *E. coli* in food. Following DNA extraction using the **food**proof StarPrep Three Kit, the **food**proof STEC Screening LyoKit allows for screening for the virulence genes *stx1*, *stx2*, and *eae*, and the **food**proof STEC Identification LyoKit enables the detection and identification of the eight most important STEC serogroups O26, O45, O103, O104, O111, O121, O145, and O157.

The **food**proof STEC method successfully detected STEC in fresh raw ground beef and fresh raw beef trim after 8 and 22 ± 2 h incubation time for 25 g test portions, and after 12 and 22 ± 2 h incubation time for 375 g test portions. No statistically significant differences were observed between candidate and reference method results ($dPOD_C$), and between presumptive and confirmed results ($dPOD_{CP}$). In the course of this validation study samples were successfully analyzed on five different real-time PCR platforms (ABI 7500 Fast Real-Time PCR System, CFX96 Touch Real-Time PCR Detection System, LightCycler® 480 Instrument II, LightCycler 96, Agilent AriaMx Real-Time PCR System) with identical results. By having the option to choose between multiple instruments, it offers the end user the flexibility to analyze samples on different platforms that suit the needs of the laboratory.

In comparison to the isolation and confirmation procedure of the reference method, the alternative confirmation procedure offers several advantages. By plating the undiluted column eluate onto mRBA, the sensitivity of the method is increased. An improvement in specificity is achieved by confirming a bacterial colony from a selective agar (e.g. mRBA) and not from non-selective agar (SBA) as in the reference method. This change in protocol also shortens the time to result by one day and reduces material costs. Inclusivity and exclusivity studies demonstrated the specificity of the **food**proof STEC method. By testing 238 STEC strains with the **food**proof STEC Screening LyoKit and 208 STEC strains with the **food**proof® STEC Identification LyoKit without any failure, the inclusivity of the method was highlighted. The exclusivity of the **food**proof® STEC method was proven by testing a total of 184 strains of closely related non-*E. coli* species, non-STEC *E. coli* strains and *E. coli* and STEC strains of known serotypes other than O26, O45, O103, O104, O111, O121, O145, and O157.

In a robustness study the ability of the method to remain unaffected by small variations in method parameters was evaluated. Variations in volume of enriched sample used for DNA extraction, variations in incubation time during DNA extraction and variations in volume of extracted DNA for PCR were chosen because they are might be expected to occur when the method is performed by an end user. The experiments demonstrated that small variations in method parameters were tolerated by the **food**proof StarPrep Three Kit, the **food**proof STEC Screening LyoKit and the **food**proof STEC Identification LyoKit.

Conclusion

The data of this study demonstrate equivalent results in comparison to the USDA FSIS reference method and support the product claims of the **food**proof STEC Screening LyoKit and the **food**proof STEC Identification LyoKit in combination with the **food**proof StarPrep Three Kit for fresh raw ground beef and fresh raw beef trim. The procedure is rapid and simple to perform, providing first results in around 3.5 h post incubation for 30 sample replicates. Both real-time PCR kits, the **food**proof STEC Screening LyoKit and the **food**proof STEC Identification LyoKit, allow for screening and confirmation of the virulence genes *stx1*, *stx2*, and *eae,* and for identification and confirmation of the eight major STEC serogroups from one DNA extract and in two PCR reactions, thereby reducing the number of possible PCR tests needed in comparison to the reference method. For 375 g test portions an enrichment in mTSB with a 1:4 dilution for 12–24 h at 42 ± 1°C and for 25 g test portions an enrichment in mTSB with a 1:10 dilution for 8–24 h at 42 ± 1°C is recommended. In case of positive results, isolation procedure (IMS) and confirmatory tests shall be performed after 15-24 h, so within the same time range as indicated for the reference method. The alternative confirmation procedure provides increased sensitivity and specificity. Furthermore, this improved protocol reduces the time to result as well as material costs. The identical performance of both kits on different real-time PCR devices gives the end user high flexibility in choosing a real-time PCR instrument that meets individual requirements.

Table 6. Results of the internal Inclusivity Study- foodproof STEC Screening LyoKit (1)

No.	BCD[a] ID	Strain ID	Species	Serogroup/ Serotype	*stx*1	*stx*2	*eae*	Source[b]	Origin	foodproof STEC Screening Result		
										stx1	*stx2*	*eae*
1	4734	IP 29580	*E. coli*	O26:H11	+[c]	-[d]	+	RKI	unknown	+	-	+
2	4735	E 32511	*E. coli*	O157:H-	-	+	+	RKI	unknown	-	+	+
3	4736	CB 1745	*E. coli*	O26:H11	+	-	+	RKI	unknown	+	-	+
4	4737	CB 1716	*E. coli*	unknown	-	+	+	RKI	unknown	-	+	+
5	4738	CB 571	*E. coli*	O157:H7	+	+	+	RKI	unknown	+	+	+
6	4945	413/89 - 1	*E. coli*	O26:H-	+	-	+	JLU	calf	+	-	+
7	4947	HUS 2	*E. coli*	O111:H-	+	-	+	JLU	human	+	-	+
8	4949	S 102 - 9	*E. coli*	O5	+	-	+	JLU	calf	+	-	+
9	5579	B2	*E. coli*	O157:H7	+	+	+	BgVV Dessau	human	+	+	+
10	5580	2324	*E. coli*	O157:H7	-	+	-	BgVV Dessau	cattle	-	+	-
11	5583	214/085	*E. coli*	O2:K1	+	-	-	BgVV Dessau	chicken	+	-	-
12	5644	1236	*E. coli*	O128	+	+	+	JMU	unknown	+	+	+
13	5645	ED 44	*E. coli*	O55:H-	-	+	-	JMU	unknown	-	+	-
14	5646	4014/95	*E. coli*	O69:H-	+	+	-	JMU	unknown	+	+	-
15	5647	GH VUB 60	*E. coli*	O101:H9	-	+	-	JMU	unknown	-	+	-
16	5648	7828/95	*E. coli*	O103:H2	+	+	+	JMU	unknown	+	+	+
17	5849	H 946/87/1	*E. coli*	O111:H2	-	-	+	JMU	unknown	-	-	+
18	5850	H 282/89	*E. coli*	O22:H8	+	+	-	JMU	unknown	+	+	-
19	5851	H 774/89	*E. coli*	O55:H-	-	+	+	JMU	unknown	-	+	+
20	5852	H 509/95	*E. coli*	O48:H21	-	+	+	JMU	unknown	-	+	+
21	5853	H 73/96/1	*E. coli*	O26:H11	+	-	+	JMU	unknown	+	-	+
22	5854	H352/96/1	*E. coli*	O157:H7	-	+	+	JMU	unknown	-	+	+
23	5855	H 353/96/1	*E. coli*	O157:H-	-	+	+	JMU	unknown	-	+	+
24	5856	H 2459/96/3	*E. coli*	O26:H-	+	-	+	JMU	unknown	+	-	+
25	5857	H 2947/96/1	*E. coli*	O103:H2	+	-	+	JMU	unknown	+	-	+
26	5858	H 2955/96/1	*E. coli*	O26:H11	-	+	+	JMU	unknown	-	+	+
27	7832	U 12	*E. coli*	unknown	-	+	+	LGL	unknown	-	+	+
28	7833	18785	*E. coli*	O-rough:H-	+	+	-	LGL	unknown	+	+	-
29	7834	15818	*E. coli*	ONT:H-	+	-	-	LGL	unknown	+	-	-

30	7835	22956	*E. coli*	O103:H2	-	+	+	LGL	unknown	-	+	+
31	7836	20393	*E. coli*	O57:H-	+	-	-	LGL	unknown	+	-	-
32	7837	18364	*E. coli*	ONT:H-	+	-	-	LGL	unknown	+	-	-
33	7838	22121	*E. coli*	unknown	+	+	-	LGL	unknown	+	+	-
34	7839	21972	*E. coli*	O128:H2	+	+	-	LGL	unknown	+	+	-
35	7840	23573	*E. coli*	O157:H-	-	+	+	LGL	unknown	-	+	+
36	7841	21521	*E. coli*	O23:H-	+	+	-	LGL	unknown	+	+	-
37	7842	15410	*E. coli*	O157:H-	+	+	+	LGL	unknown	+	+	+
38	7843	24368	*E. coli*	unknown	+	+	-	LGL	unknown	+	+	-
39	7844	24612	*E. coli*	O157:H-	-	+	+	LGL	unknown	-	+	+
40	7845	20362	*E. coli*	O103:H2	+	-	+	LGL	unknown	+	-	+
41	7846	20361	*E. coli*	O26:H11	+	-	+	LGL	unknown	+	-	+
42	7847	18559	*E. coli*	O145:H-	+	-	+	LGL	unknown	+	-	+
43	7848	15290	*E. coli*	O157:H-	+	+	+	LGL	unknown	+	+	+
44	7849	17691	*E. coli*	O156:H47	+	-	+	LGL	unknown	+	-	+
45	7850	23686	*E. coli*	unknown	+	+	+	LGL	unknown	+	+	+
46	7851	25855	*E. coli*	O157:H-	-	+	+	LGL	unknown	-	+	+
47	7852	25853	*E. coli*	O157:H-	-	+	+	LGL	unknown	-	+	+
48	7853	18997	*E. coli*	O5:H-	+	-	+	LGL	unknown	+	-	+
49	7854	18784	*E. coli*	O157:H-	-	+	+	LGL	unknown	-	+	+
50	7855	16408	*E. coli*	O157:H-	+	+	+	LGL	unknown	+	+	+
51	7856	15842	*E. coli*	O26:H-	+	+	+	LGL	unknown	+	+	+
52	7857	25605	*E. coli*	unknown	+	-	-	LGL	unknown	+	-	-
53	7858	25930	*E. coli*	unknown	-	+	+	LGL	unknown	-	+	+
54	7859	15302	*E. coli*	ONT:H-	+	+	-	LGL	unknown	+	+	-
55	7860	15858	*E. coli*	O129:H-	+	+	-	LGL	unknown	+	+	-
56	7861	23965	*E. coli*	unknown	-	+	+	LGL	unknown	-	+	+
57	7862	17988	*E. coli*	O103:H2	+	-	+	LGL	unknown	+	-	+
58	7863	23966	*E. coli*	unknown	-	+	+	LGL	unknown	-	+	+
59	7864	19972	*E. coli*	O-rough:H-	+	-	-	LGL	unknown	+	-	-
60	7865	26051	*E. coli*	unknown	+	+	-	LGL	unknown	+	+	-
61	7866	15227	*E. coli*	O26:H-	+	-	+	LGL	unknown	+	-	+
62	7867	23399	*E. coli*	O-rough:H-	+	+	+	LGL	unknown	+	+	+
63	7869	16829	*E. coli*	ONT:H-	+	-	-	LGL	unknown	+	-	-
64	7870	19410	*E. coli*	O113:H-	-	+	-	LGL	unknown	-	+	-
65	7871	21761	*E. coli*	ONT:H-	-	+	-	LGL	unknown	-	+	-
66	7872	19271	*E. coli*	ONT:H-	+	-	-	LGL	unknown	+	-	-
67	7873	22663	*E. coli*	unknown	+	+	+	LGL	unknown	+	+	+
68	7874	22095	*E. coli*	O-rough:H-	+	-	+	LGL	unknown	+	-	+
69	7875	25185	*E. coli*	O157:H-	-	+	+	LGL	unknown	-	+	+
70	7877	18369	*E. coli*	O146:H21	-	+	-	LGL	unknown	-	+	-
71	7878	18558	*E. coli*	O145:H-	+	-	+	LGL	unknown	+	-	+
72	7879	17692	*E. coli*	O22:H8	+	-	-	LGL	unknown	+	-	-
73	7880	18800	*E. coli*	O-rough:H-	+	-	-	LGL	unknown	+	-	-
74	7881	8	*E. coli*	O145:H-	+	+	+	LGL	unknown	+	+	+
75	8275	709/97	*E. coli*	O157:H7	-	+	+	HU Hamburg	unknown	-	+	+
76	8318	774-36/89	*E. coli*	O55:K1:H-	-	+	+	HU Hamburg	unknown	-	+	+
77	8325	1071-36/90	*E. coli*	O157:H7	-	+	+	HU Hamburg	unknown	-	+	+
78	8332	815-36-88	*E. coli*	ONT	-	+	-	HU Hamburg	unknown	-	+	-
79	8333	416-36/91	*E. coli*	unknown	-	+	+	HU Hamburg	unknown	-	+	+
80	12502	LM 680	*E. coli*	O138:H8	-	+	-	JLU	milk	-	+	-
81	12503	LM 681	*E. coli*	O157:H-	-	+	+	JLU	milk	-	+	+
82	12504	LM 841	*E. coli*	O8:H27	-	+	-	JLU	beef	-	+	-
83	12505	LM 872	*E. coli*	O17:H-	-	+	-	JLU	raw milk	-	+	-
84	12506	LM 1046	*E. coli*	O22:H-	+	+	-	JLU	minced beef	+	+	-
85	12507	LM 1087	*E. coli*	O157:H-	-	+	+	JLU	sausage (Bratwurst)	-	+	+
86	12508	LM 1119	*E. coli*	O84:H21	+	+	+	JLU	lamb meat	+	+	+
87	12509	LM 1126	*E. coli*	O7:H-	+	+	-	JLU	lamb meat	+	+	-
88	12510	LM 1247	*E. coli*	Ont:H-	+	+	-	JLU	lamb meat	+	+	-
89	12511	LM 1328	*E. coli*	O23:H15	-	+	-	JLU	raw milk cheese	-	+	-
90	12512	LM 1364	*E. coli*	O8:H-	-	+	-	JLU	beef	-	+	-
91	12513	LM 1389	*E. coli*	O-rough:H23	+	+	-	JLU	beef	+	+	-
92	12514	LM 1394	*E. coli*	O46:H-	-	+	-	JLU	beef	-	+	-
93	12515	LM 1398	*E. coli*	O104:H12	+	-	-	JLU	minced beef	+	-	-
94	12516	LM 1419	*E. coli*	O74:H-	-	+	-	JLU	minced beef	-	+	-

95	12517	LM 1436	*E. coli*	O64:H8	+	+	-	JLU	beef	+	+	-
96	12518	LM 1446	*E. coli*	O157:H7	-	+	+	JLU	beef	-	+	+
97	12521	LM 1548	*E. coli*	O65:H-	+	-	-	JLU	pork sausage	+	-	-
98	12522	LM 1552	*E. coli*	O8:H-	-	+	-	JLU	minced beef	-	+	-
99	12523	LM 1553	*E. coli*	O91:H21	+	+	-	JLU	minced beef, mix	+	+	-
100	12524	LM 1561	*E. coli*	O113:H4	-	+	-	JLU	beef	-	+	-
101	12525	LM 1580	*E. coli*	O22:H8	+	+	-	JLU	minced beef	+	+	-
102	12526	LM 1592	*E. coli*	O113:H4	+	+	-	JLU	beef	+	+	-
103	12527	LM 1616	*E. coli*	O113:H21	-	+	-	JLU	beef	-	+	-
104	12528	LM 1626	*E. coli*	O113:H4	+	+	-	JLU	minced beef	+	+	-
105	12529	LM 1634	*E. coli*	O6:H10	+	-	-	JLU	sausage intestine	+	-	-
106	12530	LM 1646	*E. coli*	O156:H-	+	-	+	JLU	beef	+	-	+
107	12531	LM 1664	*E. coli*	Ont:H21	+	+	-	JLU	beef	+	+	-
108	12532	Rd 13	*E. coli*	O39:H40	-	+	-	JLU	feces (cattle)	-	+	-
109	12533	Rd 15	*E. coli*	O136:H19	+	-	-	JLU	feces (cattle)	+	-	-
110	12534	Rd 28	*E. coli*	O3:H-	+	-	-	JLU	feces (cattle)	+	-	-
111	12535	Rd 32	*E. coli*	O116:H21	+	+	-	JLU	feces (cattle)	+	+	-
112	12536	Rd 34	*E. coli*	O113:H21	-	+	-	JLU	feces (cattle)	-	+	-
113	12537	Rd 36	*E. coli*	O-rough:H18	+	+	-	JLU	feces (cattle)	+	+	-
114	12538	Rd 41	*E. coli*	O157:H7	-	+	+	JLU	feces (cattle)	-	+	+
115	12539	Rd 43	*E. coli*	O22:H8	-	+	-	JLU	feces (cattle)	-	+	-
116	12540	Rd 47	*E. coli*	O82:H8	+	+	-	JLU	feces (cattle)	+	+	-
117	12541	Rd 53	*E. coli*	O105:H18	+	-	-	JLU	feces (cattle)	+	-	-
118	12542	Rd 705	*E. coli*	O146:H28	+	+	-	JLU	feces (cattle)	+	+	-
119	12543	Rd 912	*E. coli*	O111:H-	+	-	+	JLU	feces (cattle)	+	-	+
120	12544	Rd 930	*E. coli*	O26:H11	+	-	+	JLU	feces (cattle)	+	-	+
121	12545	Rd 958	*E. coli*	O103:H2	+	-	+	JLU	feces (cattle)	+	-	+
122	12546	Rd 995	*E. coli*	O118:H-	+	+	+	JLU	feces (cattle)	+	+	+
123	12547	Rd 1217	*E. coli*	O118:H-	+	-	+	JLU	feces (cattle)	+	-	+
124	12548	Rd 1454	*E. coli*	O155:H-	-	+	-	JLU	feces (cattle)	-	+	-
125	12549	Rd 1475	*E. coli*	O74:H29	-	+	-	JLU	feces (cattle)	-	+	-
126	12550	Rd 1479	*E. coli*	O129:H-	-	+	-	JLU	feces (cattle)	-	+	-
127	12551	Rd 1484	*E. coli*	O12:H-	-	+	-	JLU	feces (cattle)	-	+	-
128	14173	B 2324	*E. coli*	O157:H7	-	+	+	JLU	feces (cattle)	-	+	+
129	14175	3873 5/1	*E. coli*	O157:H7	+	+	+	JLU	raw milk	+	+	+
130	14176	7597/95	*E. coli*	O157:H-	-	+	+	JLU	human feces	-	+	+
131	14178	15/10/2	*E. coli*	O157:H-	-	+	+	JLU	milk	-	+	+
132	14190	No. 294	*E. coli*	O157:H7	-	+	+	JLU	human feces	-	+	+
133	14191	No. 676	*E. coli*	O26:H11	+	-	+	JLU	human feces	+	-	+
134	14192	No. 647	*E. coli*	O121:H10	-	+	-	JLU	sausage (Bratwurst)	-	+	-
135	14193	No. 1670	*E. coli*	O91:H21	+	+	+	JLU	raw milk	+	+	+
136	14194	No. 924	*E. coli*	O4:H-	+	+	-	JLU	lamb meat	+	+	-
137	14195	No. 1106	*E. coli*	O8:H-	+	-	-	JLU	lamb meat	+	-	-
138	14196	No. 1251	*E. coli*	ONT:H-	+	+	-	JLU	lamb meat	+	+	-
139	14197	No. 1555	*E. coli*	O9:H10	-	+	-	JLU	minced meat	-	+	-
140	14198	No. 1625	*E. coli*	O8:H8	+	-	-	JLU	minced meat	+	-	-
141	14199	No. 1405	*E. coli*	ONT:H23	+	-	-	JLU	minced meat	+	-	-
142	14200	No. 1433	*E. coli*	O157:H7	-	+	+	JLU	minced meat	-	+	+
143	14201	No. 1628	*E. coli*	ONT:H18	+	+	-	JLU	minced meat	+	+	-
144	14202	No. 1631	*E. coli*	O133:H21	-	+	-	JLU	minced meat	-	+	-
145	14203	No. 1633	*E. coli*	O146:H21	+	+	-	JLU	minced meat	+	+	-
146	14204	No. 1361	*E. coli*	O113:H-	+	+	-	JLU	beef	+	+	-
147	14205	No. 1459	*E. coli*	O7:H16	+	-	-	JLU	beef	+	-	-
148	14206	No. 1608	*E. coli*	O22:H8	+	+	-	JLU	beef	+	+	-
149	14207	No. 1614	*E. coli*	ONT:H19	+	+	-	JLU	beef	+	+	-
150	14208	No. 1650	*E. coli*	O153:H25	-	+	-	JLU	beef	-	+	-
151	14209	No. 1657	*E. coli*	O133:H21	-	+	-	JLU	beef	-	+	-
152	14210	No. 1709	*E. coli*	O103:H42	+	+	-	JLU	beef	+	+	-
153	14211	No. 1743	*E. coli*	O157:H7	-	+	+	JLU	beef	-	+	+
154	14212	No. 1667	*E. coli*	O113:H4	+	+	-	JLU	hamburger	+	+	-
155	14213	No. 175	*E. coli*	O10:H4	+	-	+	JLU	carcass (lamb)	+	-	+
156	14214	No. 209	*E. coli*	O156:H25	+	-	+	JLU	carcass (lamb)	+	-	+
157	14215	No. 210	*E. coli*	O156:H-	+	-	+	JLU	carcass (lamb)	+	-	+
158	14216	No. 213	*E. coli*	O156:H25	+	-	+	JLU	carcass (lamb)	+	-	+
159	14217	No. 215	*E. coli*	O107:H11	+	-	+	JLU	carcass (lamb)	+	-	+

160	14218	No. 216	*E. coli*	O156:H25	+	-	+	JLU	carcass (lamb)	+	-	+
161	14219	No. 177	*E. coli*	O84:H31	+	-	+	JLU	feces (sheep)	+	-	+
162	14220	No. 178	*E. coli*	ONT:H-	+	-	+	JLU	feces (sheep)	+	-	+
163	14221	No. 181	*E. coli*	O84:H31	+	-	+	JLU	feces (sheep)	+	-	+
164	14222	No. 182	*E. coli*	O84:H-	+	-	+	JLU	feces (sheep)	+	-	+
165	14223	No. 194	*E. coli*	O84:H31	+	-	+	JLU	feces (sheep)	+	-	+
166	14224	No. 195	*E. coli*	O84:H-	+	-	+	JLU	feces (sheep)	+	-	+
167	14225	No. 207	*E. coli*	O156:H+ nt	+	-	+	JLU	feces (sheep)	+	-	+
168	14226	No. 19	*E. coli*	O157:H7	-	+	+	JLU	feces (cattle)	-	+	+
169	14227	No. 20	*E. coli*	O157:H7	-	+	+	JLU	feces (cattle)	-	+	+
170	14228	No. 39	*E. coli*	O126:H20	-	+	-	JLU	feces (cattle)	-	+	-
171	14229	No. 45	*E. coli*	O82:H8	+	+	-	JLU	feces (cattle)	+	+	-
172	14230	No. 51	*E. coli*	O116:H21	+	+	-	JLU	feces (cattle)	+	+	-
173	14231	No. 69	*E. coli*	O91:H10	-	+	-	JLU	feces (cattle)	-	+	-
174	14232	No. 668	*E. coli*	O146:H28	+	+	-	JLU	feces (cattle)	+	+	-
175	14233	No. 671	*E. coli*	ONT:H-	+	+	-	JLU	feces (cattle)	+	+	-
176	14234	No. 713	*E. coli*	Or:H3	+	-	-	JLU	feces (cattle)	+	-	-
177	14235	No. 723	*E. coli*	O8:H21	+	-	-	JLU	feces (cattle)	+	-	-
178	14236	No. 859	*E. coli*	O32:H8	-	+	-	JLU	feces (cattle)	-	+	-
179	14237	No. 863	*E. coli*	O77:H18	-	+	-	JLU	feces (cattle)	-	+	-
180	14238	No. 968	*E. coli*	O48:H-	+	-	+	JLU	feces (cattle)	+	-	+
181	14239	No. 994	*E. coli*	O74:H39	+	+	-	JLU	feces (cattle)	+	+	-
182	14240	B2325	*E. coli*	O157:H7	-	+	+	JLU	feces (cattle)	-	+	+
183	14241	B2482	*E. coli*	O157:H7	-	+	+	JLU	feces (cattle)	-	+	+
184	14242	HUS 1249	*E. coli*	O157:H7	+	+	+	JLU	human feces, HUS[e]	+	+	+
185	14243	HC2044	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC[f]	+	+	+
186	14244	1271-84	*E. coli*	O157:H7	-	+	+	JLU	human feces, HUS	-	+	+
187	14245	3526-87	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	+	+	+
188	14246	EDL931	*E. coli*	O157:H7	+	-	+	JLU	human feces, HC	+	-	+
189	14247	A9167	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	+	+	+
190	14248	A9218-C1	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	+	+	+
191	14249	EDL933	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	+	+	+
192	14250	C7-80	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	+	+	+
193	14251	C1011-87	*E. coli*	O157:H7	-	+	+	JLU	human feces, HC	-	+	+
194	14252	E1047	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	+	+	+
195	14253	No. 640	*E. coli*	O157:H7	+	+	+	JLU	human feces, HUS	+	+	+
196	14254	No. 642	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	+	+	+
197	14255	No. 1640	*E. coli*	O157:H7	+	+	+	JLU	human feces, HUS	+	+	+
198	14256	Sal4/LXIV/1	*E. coli*	O157:H7	-	+	+	JLU	human feces, HC	-	+	+
199	14257	Sal57/4/1-99	*E. coli*	O157:H7	-	+	+	JLU	human feces, HC	-	+	+
200	14258	NCTC 12079	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	+	+	+
201	14259	26/22	*E. coli*	O157:H-	+	+	+	JLU	human feces, HC	+	+	+
202	14260	No. 1087 D 1	*E. coli*	O157:H-	-	+	+	JLU	sausage (Bratwurst)	-	+	+
203	14264	730	*E. coli*	O157:H-	-	+	+	JLU	bowel (sheep)	-	+	+
204	16170	-	*E. coli*	O104:H4	-	+	-	RKI Wernigerode	unknown	-	+	-
205	16180	-	*E. coli*	O104:H4	-	+	-	LGL	human feces	-	+	-
206	16181	-	*E. coli*	O121:H-	-	+	+	LGL	human feces	-	+	+
207	16182	-	*E. coli*	O145:H-	-	+	+	LGL	human feces	-	+	+
208	16194	D3522	*E. coli*	O8:K85ab:Hru	+	-	-	SSI	unknown	+	-	-
209	16195	D3602	*E. coli*	O174:K101:H8	+	+	-	SSI	unknown	+	+	-
210	16196	D3435	*E. coli*	O73:H18	-	+	-	SSI	unknown	-	+	-
211	16197	D3510	*E. coli*	O89:K+:H-	-	-	+	SSI	unknown	-	-	+
212	16198	D3509	*E. coli*	O2:K-:H25	-	+	-	SSI	unknown	-	+	-
213	16243	C784-02	*E. coli*	O45:K-:H2	+	-	+	SSI	unknown	+	-	+
214	-	T4/97	*E. coli*	O128:H2	-	-	+	unknown	pigeon	-	-	+
215	-	TW00971	*E. coli*	O26:H11	+	-	+	MSU	human	+	-	+
216	-	TW01188	*E. coli*	O26:H11	+	-	+	MSU	human (infant)	+	-	+
217	-	TW01597	*E. coli*	O26:H11	+	-	+	MSU	cow (calf)	+	-	+
218	-	TW02295	*E. coli*	O26:H11	+	-	+	MSU	human (infant)	+	-	+
219	-	TW04270	*E. coli*	O26:H2	+	-	+	MSU	human	+	-	+
220	-	1,2622	*E. coli*	O45:H12	+	-	-	PSU	cow (bovine)	+	-	-
221	-	11,1079	*E. coli*	O45	+	-	+	PSU	cow (bovine)	+	-	+

222	-	TW00965	*E. coli*	O45:H2	+	-	-	MSU	human	+	-	-
223	-	TW07947	*E. coli*	O45:HNM	+	-	+	MSU	human (F[g], 77y[h])	+	-	+
224	-	TW09183	*E. coli*	O45:H2	+	-	-	MSU	human (M[i], 45y)	+	-	-
225	-	TW10121	*E. coli*	O45:H2	+	-	-	MSU	human (F, 38y)	+	-	-
226	-	TW14003	*E. coli*	O45:H2	+	-	-	MSU	human (M, 12y)	+	-	-
227	-	TW08101	*E. coli*	O103:H2	+	-	+	MSU	human	+	-	+
228	-	TW04162	*E. coli*	O103:H2	+	-	+	MSU	human (M, 51y)	+	-	+
229	-	TW00186	*E. coli*	O111:H8	+	+	+	MSU	human	+	+	+
230	-	TW01387	*E. coli*	O111:H8	+	-	+	MSU	human	+	-	+
231	-	TW06315	*E. coli*	O111:HNM	+	+	+	MSU	human (M, 67y)	+	+	+
232	-	TW07926	*E. coli*	O111:H8	+	+	+	MSU	human (F, 18y)	+	+	+
233	-	5,0959	*E. coli*	O121:H19	-	+	+	PSU	unknown	-	+	+
234	-	TW07614	*E. coli*	O121:H19	-	+	-	MSU	human (F, 51y)	-	+	-
235	-	TW08023	*E. coli*	O121:H19	-	+	+	MSU	human	-	+	+
236	-	TW08039	*E. coli*	O121	-	+	+	MSU	human	-	+	+
237	-	TW07931	*E. coli*	O121:[H19]	-	+	+	MSU	human (F, 51y)	-	+	+
238	-	TW07596	E. coli	O145:HNM	+	-	+	MSU	human	+	-	+

[a]BCD - Biotecon Diagnostics GmbH culture collection.
[b]BgVV - Federal Institute for Consumer Health Protection and Veterinary Medicine, Dessau, Germany. HU - Institute for Hygiene and Environment, Hamburg, Germany. JLU – Justus Liebig University, Gießen, Germany. JMU – Julius Maximilians University, Würzburg, Germany. LGL - Bavarian Health and Food Safety Authority, Erlangen, Germany. MSU – Michigan State University, East Lansing, Michigan, USA. PSU – Pennsylvania State University, State College, Pennsylvania, USA. RKI - Robert Koch Institute, Berlin, Germany. RKI Wernigerode – Robert Koch Institute, Wernigerode, Germany. SSI - Statens Serum Institute, Copenhagen, Denmark.
[c]"+" – Positive for the respective virulence gene (*stx1*, *stx2*, *eae*).
[d]"-" – Negative for the respective virulence gene (*stx1*, *stx2*, *eae)*.
[e]HUS - Hemolytic–uremic syndrome.
[f]HC - Haemorrhagic colitis.
[g]F – Female.
[h]y – Years.
[i]M – Male.

Table 7. Results of the internal Exclusivity Study- foodproof **STEC Screening LyoKit (1)**

No.	Strain ID[a]	Genus	Species	Subspecies/ Serotype	Source[b]	Origin	**food**proof **STEC Screening Result**		
							stx1	***stx2***	***eae***
1	DSM 1530	*Bacillus*	firmus	Not applicable	DSMZ	unknown	-[c]	-	-
2	DSM 5075	*Budvicia*	*aquatica*	Not applicable	DSMZ	unknown	-	-	-
3	BCD 13814	*Citrobacter*	*freundii*	Not applicable	unknown	unknown	-	-	-
4	DSM 4596	*Citrobacter*	*koseri*	Not applicable	DSMZ	unknown	-	-	-
5	DSM 4485	*Cronobacter*	*sakazakii*	Not applicable	DSMZ	child´s throat	-	-	-
6	DSM 30054	*Enterobacter*	*cloacae*	Not applicable	DSMZ	unknown	-	-	-
7	DSM 18396	*Enterobacter*	*helveticus*	Not applicable	DSMZ	unknown	-	-	-
8	DSM 12409	*Enterobacter*	*hormaechei*	Not applicable	DSMZ	unknown	-	-	-
9	DSM 18397	*Enterobacter*	*turicensis*	Not applicable	DSMZ	unknown	-	-	-
10	BCD 3008	*Klebsiella*	*pneumoniae*	Not applicable	unknown	unknown	-	-	-
11	DSM 30083	*Escherichia*	coli	O1:K1:H7	TU Berlin	unknown	-	-	-
12	BCD 8233	*Escherichia*	coli	O148	HU Hamburg	unknown	-	-	-
13	BCD 8235	*Escherichia*	coli	O118	HU Hamburg	unknown	-	-	-
14	BCD 8253	*Escherichia*	coli	O143:H-	HU Hamburg	unknown	-	-	-
15	BCD 8254	*Escherichia*	coli	O143	HU Hamburg	unknown	-	-	-
16	BCD 8262	*Escherichia*	coli	O164:K-:H-	HU Hamburg	unknown	-	-	-
17	BCD 8313	*Escherichia*	coli	O6:H6	HU Hamburg	unknown	-	-	-
18	BCD 8554	*Escherichia*	coli	O158	HU Hamburg	unknown	-	-	-
19	BCD 8560	*Escherichia*	coli	O158	HU Hamburg	unknown	-	-	-
20	BCD 8583	*Escherichia*	coli	O128	HU Hamburg	unknown	-	-	-
21	BCD 16242	*Escherichia*	coli	O45:K1:H10	SSI	unknown	-	-	-
22	DSM 20021	*Lactobacillus*	*rhamnosus*	Not applicable	DSMZ	unknown	-	-	-
23	DSM 20750	*Listeria*	*ivanovii*	Not applicable	DSMZ	unknown	-	-	-
24	DSM 3493	*Pantoea*	*agglomerans*	Not applicable	DSMZ	unknown	-	-	-
25	DSM 30070	*Pantoea*	*ananatis*	Not applicable	DSMZ	unknown	-	-	-
26	DSM 20331	*Pediococcus*	*damnosus*	Not applicable	DSMZ	unknown	-	-	-
27	DSM 30118	*Proteus*	*hauseri*	Not applicable	DSMZ	unknown	-	-	-
28	DSM 30120	*Providencia*	*alcalifaciens*	Not applicable	DSMZ	unknown	-	-	-
29	BCD 4940	*Pseudomonas*	*stutzeri*	Not applicable	University of	unknown	-	-	-
30	DSM 4594	*Rahnella*	*aquatilis*	Not applicable	DSMZ	unknown	-	-	-

31	DSM 2687	*Raoultella*	*terrigena*	Not applicable	DSMZ	unknown	-	-	-
32	DSM 4224	*Salmonella*	Abony	Not applicable	DSMZ	unknown	-	-	-
33	BCD 6173	*Salmonella*	Senftenberg	Not applicable	DSMZ	unknown	-	-	-
34	DSM 4569	*Serratia*	*ficaria*	Not applicable	BgVV Berlin	unknown	-	-	-
35	DSM 7532	*Shigella*	*boydii*	2	DSMZ	unknown	-	-	-
36	BCD 7553	*Shigella*	*dysenteriae*	2	HU Hamburg	unknown	-	-	-
37	DSM 4782	*Shigella*	*flexneri*	2a	DSMZ	unknown	-	-	-
38	DSM 20231	*Staphylococcus*	*aureus*	Not applicable	DSMZ	unknown	-	-	-
39	ATCC 33641	*Yersinia*	*frederiksenii*	Not applicable	unknown	unknown	-	-	-

[a]ATCC - American Type Culture Collection, Manassas, VA. BCD – Biotecon Diagnostics GmbH culture collection. DSM - strain number of the DSMZ.
[b]BgVV - Federal Institute for Consumer Health Protection and Veterinary Medicine, Berlin, Germany. DSMZ - German Collection of Microorganisms and Cell Cultures, Braunschweig, Germany. HU - Institute for Hygiene and Environment, Hamburg, Germany. . SSI - Statens Serum Institute, Copenhagen, Denmark. TU Berlin - Technical University of Berlin, Germany. University of Bielefeld – Bielefeld, Germany.
[c]"-" – Negative for the respective virulence gene (*stx1*, *stx2*, *eae*).

Table 8. Results of the internal Inclusivity Study- foodproof STEC Identification LyoKit (1)

No.	BCD[a] ID	Strain ID	Species	Serogroup/ Serotype	*stx*1	*stx*2	*eae*	Source[b]	Origin	foodproof STEC Identification Result
1	4734	IP 29580	*E. coli*	O26:H11	+[c]	-[d]	+	RKI	unknown	positive for O26
2	4736	CB 1745	*E. coli*	O26:H11	+	-	+	RKI	unknown	positive for O26
3	4945	413/89 - 1	*E. coli*	O26:H-	+	-	+	JLU	calf	positive for O26
4	5853	H 73/96/1	*E. coli*	O26:H11	+	-	+	HU Hamburg	unknown	positive for O26
5	5856	H 2459/96/3	*E. coli*	O26:H-	+	-	+	HU Hamburg	unknown	positive for O26
6	5858	H 2955/96/1	*E. coli*	O26:H11	-	+	+	HU Hamburg	unknown	positive for O26
7	7846	20361	*E. coli*	O26:H11	+	-	+	LGL	unknown	positive for O26
8	7856	15842	*E. coli*	O26:H-	+	+	+	LGL	unknown	positive for O26
9	7866	15227	*E. coli*	O26:H-	+	-	+	LGL	unknown	positive for O26
10	12544	Rd 930	*E. coli*	O26:H11	+	-	+	JLU	feces (cattle)	positive for O26
11	14191	No. 676	*E. coli*	O26:H11	+	-	+	JLU	human feces	positive for O26
12	17385	WH-01/02/003-01	*E. coli*	O26:H11	+	-	-	FLI	cattle	positive for O26
13	17386	WH-01/02/003-03	*E. coli*	O26:H11	+	-	-	FLI	cattle	positive for O26
14	17387	WH-01/02/003-05	*E. coli*	O26:H11	+	-	-	FLI	cattle	positive for O26
15	17388	WH-01/02/003-07	*E. coli*	O26:H11	+	-	-	FLI	cattle	positive for O26
16	17389	WH-01/02/003-08	*E. coli*	O26:H11	+	-	-	FLI	cattle	positive for O26
17	17390	WH-01/26/002-01	*E. coli*	O26:H11	+	-	-	FLI	cattle	positive for O26
18	17391	WH-01/27/009-02	*E. coli*	O26:H11	+	-	-	FLI	cattle	positive for O26
19	17392	WH-01/27/017-07	*E. coli*	O26:H11	+	-	-	FLI	cattle	positive for O26
20	17393	WH-01/29/002-04	*E. coli*	O26:H11	+	-	-	FLI	cattle	positive for O26
21	17518	1530/99	*E. coli*	O26:H11	-	+	+	WWU	human	positive for O26
22	-	2245/98	*E. coli*	O26:H11	+	-	+	WWU	human	positive for O26
23	-	TW00971	*E. coli*	O26:H11	+	-	+	MSU	human	positive for O26
24	-	TW01188	*E. coli*	O26:H11	+	-	+	MSU	human (infant)	positive for O26
25	-	TW01597	*E. coli*	O26:H11	+	-	+	MSU	cow (calf)	positive for O26
26	-	TW02295	*E. coli*	O26:H11	+	-	+	MSU	human (infant)	positive for O26
27	-	TW04270	*E. coli*	O26:H2	+	-	+	MSU	human	positive for O26
28	-	TW08031	*E. coli*	O26	+	-	+	MSU	human	positive for O26
29	16243	c784-02	*E. coli*	O45:K-:H2	+	-	+	SSI	unknown	positive for O45
30	17331	BfR-EC-16692	*E. coli*	O45:H2	-	+	+	BfR	unknown	positive for O45
31	17332	BfR-EC-14634	*E. coli*	O45:HNM/[H2]	+	-	+	BfR	unknown	positive for O45
32	-	LB412761 i1	*E. coli*	O45:H2	-	+	+	WWU	human	positive for O45
33	-	1,2622	*E. coli*	O45:H12	+	-	-	PSU	cow (bovine)	positive for O45
34	-	11,1079	*E. coli*	O45	+	-	+	PSU	cow (bovine)	positive for O45
35	-	TW00965	*E. coli*	O45:H2	+	-	-	MSU	human	positive for O45
36	-	TW07947	*E. coli*	O45:HNM	+	-	+	MSU	human (F[e], 77y[f])	positive for O45
37	-	TW09183	*E. coli*	O45:H2	+	-	+	MSU	human (M[g], 45y)	positive for O45
38	-	TW10121	*E. coli*	O45:H2	+	-	+	MSU	human (F, 38y)	positive for O45
39	-	TW14003	*E. coli*	O45:H2	+	-	+	MSU	human (M, 12y)	positive for O45

40	-	1,2635	*E. coli*	O45	n/s[h]	n/s	n/s	PSU	cow (bovine)	positive for O45
41	-	6,3127	*E. coli*	O45	n/s	n/s	n/s	PSU	cow (bovine), feces	positive for O45
42	5648	7828/95	*E. coli*	O103:H2	+	+	+	JMU	unknown	positive for O103
43	5857	H 2947/96/1	*E. coli*	O103:H2	+	-	+	HU Hamburg	unknown	positive for O103
44	7835	22956	*E. coli*	O103:H2	-	+	+	LGL	unknown	positive for O103
45	7845	20362	*E. coli*	O103:H2	+	-	+	LGL	unknown	positive for O103
46	7862	17988	*E. coli*	O103:H2	+	-	+	LGL	unknown	positive for O103
47	12545	Rd 958	*E. coli*	O103:H2	+	-	+	JLU	feces (cattle)	positive for O103
48	14210	No. 1709	*E. coli*	O103:H42	+	+	-	JLU	raw ground beef	positive for O103
49	17380	x-713/08	*E. coli*	O103:H2	+	-	-	FLI	cattle	positive for O103
50	17381	x-719/08	*E. coli*	O103:H2	+	-	-	FLI	cattle	positive for O103
51	17383	x-757/08	*E. coli*	O103:H2	+	-	-	FLI	cattle	positive for O103
52	17384	WH-03/21/011-	*E. coli*	O103:H2	+	-	-	FLI	cattle	positive for O103
53	-	7382/96	*E. coli*	O103:H2	-	+	+	WWU	human	positive for O103
54	-	TW08101	*E. coli*	O103:H2	+	-	+	MSU	human	positive for O103
55	-	TW04162	*E. coli*	O103:H2	+	-	+	MSU	human (M, 51y)	positive for O103
56	-	7,1691	*E. coli*	O103:H2	n/s	n/s	n/s	PSU	cow (bovine)	positive for O103
57	-	9,0036	*E. coli*	O103	n/s	n/s	n/s	PSU	cow (bovine)	positive for O103
58	-	TW07971	*E. coli*	O103:H6	+	-	n/s	MSU	human	positive for O103
59	-	TW11239	*E. coli*	O103:H25	+	-	n/s	MSU	human (F, 3y)	positive for O103
60	-	TW07697	*E. coli*	O103:HN	+	-	+	MSU	human	positive for O103
61	-	TW05997	*E. coli*	O103:HN	+	-	n/s	MSU	human	positive for O103
62	-	TW08101	*E. coli*	O103:H2	+	-	+	MSU	human	positive for O103
63	17519	2969/99	*E. coli*	O103:H2	-	+	+	WWU	human	positive for O103
64	-	No. 6/O103	*E. coli*	O103	+	-	+	RIPAC	unknown	positive for O103
65	-	No. 8/O103	*E. coli*	O103	n/s	n/s	n/s	RIPAC	unknown	positive for O103
66	-	No. 9/O103	*E. coli*	O103	n/s	n/s	n/s	RIPAC	unknown	positive for O103
67	-	No. 20/O103	*E. coli*	O103	n/s	n/s	n/s	RIPAC	unknown	positive for O103
68	12515	LM 1398	*E. coli*	O104:H12	+	-	-	JLU	unknown	positive for O104
69	16170	EHEC/STEC SEC041	*E. coli*	O104:H4	-	+	-	RKI Wernigerode	unknown	positive for O104
70	16180	11-0070835-001-01	*E. coli*	O104:H4	-	+	-	LGL	human feces	positive for O104
71	17336	BfR-EC-17614	*E. coli*	O104:[H7]	+	-	-	BfR	unknown	positive for O104
72	17338	BfR-EC-14633	*E. coli*	O104:HNT/[H7]	-	+	-	BfR	unknown	positive for O104
73	17375	15-0314827-001-01	*E. coli*	O104:H7	+	-	-	LGL	venison	positive for O104
74	17523	TY3730	*E. coli*	O104:H4	-	+	-	UKE	human	positive for O104
75	-	01-09591	*E. coli*	O104:H4	-	+	-	WWU	human	positive for O104
76	-	0,0122	*E. coli*	O104	-	+	-	PSU	unknown	positive for O104
77	-	1,2633	*E. coli*	O104	+	-	-	PSU	cow (bovine)	positive for O104
78	-	1,2673	*E. coli*	O104:H12	+	-	-	PSU	cow (bovine)	positive for O104
79	-	1,2806	*E. coli*	O104	+	-	-	PSU	cow (bovine)	positive for O104
80	-	1,2807	*E. coli*	O104	+	-	-	PSU	cow (bovine)	positive for O104
81	-	1,2824	*E. coli*	O104	+	-	-	PSU	cow (bovine)	positive for O104
82	-	1,2825	*E. coli*	O104	+	-	-	PSU	cow (bovine)	positive for O104
83	-	5,3526	*E. coli*	O104:H7	+	-	-	PSU	sheep	positive for O104
84	-	6,0778	*E. coli*	O104:H7	+	-	-	PSU	carcass	positive for O104
85	-	6,0779	*E. coli*	O104:H7	+	-	-	PSU	carcass	positive for O104
86	-	6,0800	*E. coli*	O104:H7	+	-	-	PSU	carcass	positive for O104
87	-	6,0829	*E. coli*	O104:H7	+	-	-	PSU	carcass	positive for O104
88	-	6,0830	*E. coli*	O104:H7	+	-	-	PSU	carcass	positive for O104
89	-	9,0124	*E. coli*	O104	-	+	-	PSU	cow (bovine)	positive for O104
90	4947	HUS 2	*E. coli*	O111:H-	+	-	+	JLU	human	positive for O111
91	5849	H 946/87/1	*E. coli*	O111:H2	-	-	+	HU Hamburg	unknown	positive for O111
92	7876	17870	*E. coli*	O111:H-	+	+	+	LGL	unknown	positive for O111
93	12543	Rd 912	*E. coli*	O111:H-	+	-	+	JLU	feces (cattle)	positive for O111
94	16708	CB14651	*E. coli*	O111:H8	+	-	+	BfR	unknown	positive for O111
95	-	05-946	*E. coli*	O111:H10	-	+	+	WWU	human	positive for O111
96	-	TW00186	*E. coli*	O111:H8	+	+	+	MSU	human	positive for O111
97	-	TW01387	*E. coli*	O111:H8	+	-	+	MSU	human	positive for O111
98	-	TW06315	*E. coli*	O111:HNM	+	+	+	MSU	human (M, 67y)	positive for O111
99	-	TW07926	*E. coli*	O111:H8	+	+	+	MSU	human (F, 18y)	positive for O111
100	-	TW01387	*E. coli*	O111:H8	+	-	+	MSU	human	positive for O111

101	-	TW00186	*E. coli*	O111:H8	+	+	+	MSU	human	positive for O111
102	-	TW06315	*E. coli*	O111:HNM	+	+	+	MSU	human (M, 67y)	positive for O111
103	-	TW04257	*E. coli*	O111:H-	+	+	+	MSU	human	positive for O111
104	-	TW05651	*E. coli*	O111:H-	+	-	+	MSU	human	positive for O111
105	-	TW01378	*E. coli*	O111:HNM	+	-	+	MSU	cow (calf)	positive for O111
106	-	TW04519	*E. coli*	O111	+	-	+	MSU	cow (calf)	positive for O111
107	-	TW14960	*E. coli*	O111:H11	+	-	n/s	MSU	human	positive for O111
108	-	TW06296	*E. coli*	O111:H2	-	+	-	MSU	human (child)	positive for O111
109	-	TW05614	*E. coli*	O111:H-	+	+	+	MSU	human	positive for O111
110	-	TW07502	*E. coli*	O111	+	-	+	MSU	human	positive for O111
111	-	TW00047	*E. coli*	O111:H12	n/s	n/s	n/s	MSU	human	positive for O111
112	-	TW00073	*E. coli*	O111:H21	n/s	n/s	n/s	MSU	human (infant)	positive for O111
113	-	TW00074	*E. coli*	O111:H21	n/s	n/s	n/s	MSU	human	positive for O111
114	-	12289-3A	*E. coli*	O111:H8	n/s	n/s	n/s	QLabs	unknown	positive for O111
115	17549	08-47917	*E. coli*	O111:H-	+	+	+	LGL	unknown	positive for O111
116	17520	LB366332i2	*E. coli*	O111:H8	+	+	+	WWU	human	positive for O111
117	-	No. 4/O111	*E. coli*	O111	n/s	n/s	n/s	RIPAC	unknown	positive for O111
118	14192	No. 647	*E. coli*	O121:H10	-	+	-	JLU	unknown	positive for O121
119	16181	10-0103331-001-01	*E. coli*	O121:H-	-	+	+	LGL	unknown	positive for O121
120	16709	CB14655	*E. coli*	O121:H19	-	+	+	BfR	unknown	positive for O121
121	17333	BfR-EC-17223	*E. coli*	O121:[H14]	+	-	-	BfR	unknown	positive for O121
122	17334	BfR-EC-16734	*E. coli*	O121:[H10]	-	+	-	BfR	unknown	positive for O121
123	17335	BfR-EC-15219	*E. coli*	O121:HNM/[H9]	-	+	-	BfR	unknown	positive for O121
124	17376	15-0298617-001-01	*E. coli*	O121:H10	-	+	+	LGL	barbecue sausage	positive for O121
125	-	1529/98	*E. coli*	O121:H19	-	+	+	WWU	human	positive for O121
126	-	5,0959	*E. coli*	O121:H19	-	+	+	PSU	unknown	positive for O121
127	-	TW07614	*E. coli*	O121:H19	-	+	+	MSU	human (F, 51y)	positive for O121
128	-	TW08023	*E. coli*	O121:H19	-	+	+	MSU	human	positive for O121
129	-	TW08039	*E. coli*	O121	-	+	+	MSU	human	positive for O121
130	-	TW07931	*E. coli*	O121:[H19]	-	+	+	MSU	human (F, 51y)	positive for O121
131	-	7,1686	*E. coli*	O121:H7	n/s	n/s	n/s	PSU	cow (bovine)	positive for O121
132	-	7,1709	*E. coli*	O121:H7	n/s	n/s	n/s	PSU	cow (bovine)	positive for O121
133	-	7,1732	*E. coli*	O121:H14	n/s	n/s	n/s	PSU	cow (bovine)	positive for O121
134	-	10,0709	*E. coli*	O121:H7	n/s	n/s	n/s	PSU	cow (bovine)	positive for O121
135	-	9121	*E. coli*	O121:H12	n/s	n/s	n/s	NCTC	unknown	positive for O121
136	7847	18559	*E. coli*	O145:H-	+	-	+	LGL	unknown	positive for O145
137	7878	18558	*E. coli*	O145:H-	+	-	+	LGL	unknown	positive for O145
138	7881	8	*E. coli*	O145:H-	+	+	+	LGL	unknown	positive for O145
139	16182	10-0107670-001-01	*E. coli*	O145:H-	-	+	+	LGL	unknown	positive for O145
140	016711	CB12513	*E. coli*	O145:H28	+	+	+	BfR	unknown	positive for O145
141	-	0488/99	*E. coli*	O145:H28	-	+	+	WWU	human	positive for O145
142	-	TW07596	*E. coli*	O145:HNM	+	-	+	MSU	human	positive for O145
143	-	TW09356	*E. coli*	O145:[H28]	+	-	n/s	MSU	human	positive for O145
144	-	TW01664	*E. coli*	O145:H16	+	-	+	MSU	human	positive for O145
145	-	TW09153	*E. coli*	O145	-	+	+	MSU	human	positive for O145
146	-	7,1711	*E. coli*	O145	n/s	n/s	n/s	PSU	cow (bovine)	positive for O145
147	-	10,0707	*E. coli*	O145:H28	n/s	n/s	n/s	PSU	cow (bovine)	positive for O145
148	-	10,0708	*E. coli*	O145:H28	n/s	n/s	n/s	PSU	cow (bovine)	positive for O145
149	-	10,1438	*E. coli*	O145	n/s	n/s	n/s	PSU	cow (bovine)	positive for O145
150	-	10279	*E. coli*	O145	n/s	n/s	n/s	NCTC	unknown	positive for O145
151	-	QL 15071-1	*E. coli*	O145	n/s	n/s	n/s	QLabs	unknown	positive for O145
152	17554	41274-012	*E. coli*	O145:H-	-	+	-	LGL	unknown	positive for O145
153	17555	41274-029	*E. coli*	O145:H-	+	+	+	LGL	unknown	positive for O145
154	17521	4392/97	*E. coli*	O145:H25	-	+	+	WWU	human	positive for O145
155	-	No. 11/O145	*E. coli*	O145	n/s	n/s	n/s	RIPAC	unknown	positive for O145
156	-	No. 12/O145	*E. coli*	O145	n/s	n/s	n/s	RIPAC	unknown	positive for O145
157	-	No. 14/O145	*E. coli*	O145	n/s	n/s	n/s	RIPAC	unknown	positive for O145
158	-	No. 15/O145	*E. coli*	O145	n/s	n/s	n/s	RIPAC	unknown	positive for O145
159	-	No. 16/O145	*E. coli*	O145	n/s	n/s	n/s	RIPAC	unknown	positive for O145
160	-	No. 21/O145	*E. coli*	O145	n/s	n/s	n/s	RIPAC	unknown	positive for O145
161	-	No. 23/O145	*E. coli*	O145	n/s	n/s	n/s	RIPAC	unknown	positive for O145
162	4735	E 32511	*E. coli*	O157:H-	-	+	+	RKI	human feces, HUS[i]	positive for O157

163	5855	H 353/96/1	*E. coli*	O157:H-	-	+	+	HU Hamburg	human feces, HUS	positive for O157
164	7840	23573	*E. coli*	O157:H-	-	+	+	LGL	unknown	positive for O157
165	12503	LM 681	*E. coli*	O157:H-	-	+	+	JLU	certified raw milk	positive for O157
166	12507	LM 1087	*E. coli*	O157:H-	-	+	+	JLU	sausage (Bratwurst)	positive for O157
167	14176	7597/95	*E. coli*	O157:H-	-	+	+	JLU	human feces, HUS	positive for O157
168	14259	No. 688	*E. coli*	O157:H-	+	+	+	JLU	human feces, HC[j]	positive for O157
169	14260	No. 1087	*E. coli*	O157:H-	-	+	+	JLU	sausage (Bratwurst)	positive for O157
170	14264	No. 666	*E. coli*	O157:H-	-	+	+	JLU	sheep offal	positive for O157
171	4738	CB 571	*E. coli*	O157:H7	+	+	+	RKI	unknown	positive for O157
172	5854	H352/96/1	*E. coli*	O157:H7	-	+	+	HU Hamburg	human feces, HUS	positive for O157
173	12518	LM 1446	*E. coli*	O157:H7	-	+	+	JLU	beef	positive for O157
174	12538	Rd 41	*E. coli*	O157:H7	-	+	+	JLU	feces (cattle)	positive for O157
175	14173	B 2324	*E. coli*	O157:H7	-	+	+	JLU	feces (cattle)	positive for O157
176	14175	3873 5/1	*E. coli*	O157:H7	+	+	+	JLU	raw milk	positive for O157
177	14190	No. 294	*E. coli*	O157:H7	-	+	+	JLU	human feces	positive for O157
178	14200	No. 1433	*E. coli*	O157:H7	-	+	+	JLU	ground beef	positive for O157
179	14211	No. 1743	*E. coli*	O157:H7	-	+	+	JLU	ground beef	positive for O157
180	14226	No. 19	*E. coli*	O157:H7	-	+	+	JLU	feces (cattle)	positive for O157
181	14227	No. 20	*E. coli*	O157:H7	-	+	+	JLU	feces (cattle)	positive for O157
182	14241	B 2482	*E. coli*	O157:H7	-	+	+	JLU	feces (cattle)	positive for O157
183	14242	HUS 1249	*E. coli*	O157:H7	+	+	+	JLU	human feces, HUS	positive for O157
184	14243	HC 2044	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	positive for O157
185	14244	1271-84	*E. coli*	O157:H7	-	+	+	JLU	human feces, HUS	positive for O157
186	14245	3526-87	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	positive for O157
187	14246	EDL931	*E. coli*	O157:H7	+	-	+	JLU	human feces, HC	positive for O157
188	14247	A9167	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	positive for O157
189	14248	A9218-C1	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	positive for O157
190	14249	EDL933	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	positive for O157
191	14250	C7-80	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	positive for O157
192	14251	C1011-87	*E. coli*	O157:H7	-	+	+	JLU	human feces, HC	positive for O157
193	14252	E1047	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	positive for O157
194	14253	No. 640	*E. coli*	O157:H7	+	+	+	JLU	human feces, HUS	positive for O157
195	14254	No. 642	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	positive for O157
196	14255	No. 1640	*E. coli*	O157:H7	-	+	+	JLU	human feces, HUS	positive for O157
197	14256	Sal4/LXIV/1	*E. coli*	O157:H7	-	+	+	JLU	human feces, HC	positive for O157
198	14257	Sal57/4/1-99	*E. coli*	O157:H7	-	+	+	JLU	human feces, HC	positive for O157
199	14258	NCTC 12079	*E. coli*	O157:H7	+	+	+	JLU	human feces, HC	positive for O157
200	17517	RIMD 509952	*E. coli*	O157:H7	+	+	+	WWU	human	positive for O157

[a]BCD - BCD – Biotecon Diagnostics GmbH culture collection.

[b]BfR - German Federal Institute for Risk Assessment, Berlin, Germany. FLI – Friedrich Loeffler Institute, Federal Research Institute for Animal Health, Jena, Germany. HU - Institute for Hygiene and Environment, Hamburg, Germany. JLU – Justus Liebig University, Gießen, Germany. JMU – Julius Maximilians University, Würzburg, Germany. LGL - Bavarian Health and Food Safety Authority, Erlangen, Germany. MSU – Michigan State University, East Lansing, Michigan, USA. NCTC - National Collection of Type Cultures, culture collection of Public Health England, Salisbury, England, United Kingdom. PSU – Pennsylvania State University, State College, Pennsylvania, USA. Qlabs - Q Laboratories, Cincinnati, Ohio, USA. RKI – Robert-Koch-Institute, Berlin, Germany. RKI Wernigerode – Robert Koch Institute, Wernigerode, Germany. SSI - Statens Serum Institute, Copenhagen, Denmark. WWU – Westphalian Wilhelm University (Institute for Hygiene), Münster, Germany. UKE - University Medical Center Hamburg-Eppendorf, Germany. RIPAC – RIPAC-LABOR GmbH, Potsdam, Germany.

[c]"+" – Positive for the respective virulence gene (*stx1*, *stx2*, *eae*).

[d]"-" – Negative for the respective virulence gene (*stx1*, *stx2*, *eae)*.

[e]F – Female.

[f]y – Years.

[g]M – Male.

[h]n/s – not specified by the provider of the strain.

[i]HUS - Hemolytic–uremic syndrome.

[j]HC - Haemorrhagic colitis.

Table 9. Results of the internal Exclusivity Study- foodproof STEC Identification LyoKit **– *E. coli* and STEC strains of known serotypes other than O26, O45, O103, O104, O111, O121, O145, and O157 (1)**

No.	BCD[a] ID	Strain ID	Species	Serogroup/ Serotype	*stx*1	*stx*2	*eae*	Source[b]	Origin	foodproof STEC Identification Result
1	BCD 5581	10407	*E. coli*	O78:H11	-[c]	-	-	BgVV Dessau	human	-[d]
2	BCD 5583	214/085	*E. coli*	O2:K1	-	+[e]	-	BgVV Dessau	chicken	-
3	BCD 5644	1236	*E. coli*	O128	+	+	+	JMU	unknown	-
4	BCD 5646	4014/95	*E. coli*	O69:H-	+	+	-	JMU	unknown	-
5	BCD 5647	GH VUB 60	*E. coli*	O101:H9	-	+	-	JMU	unknown	-
6	BCD 5850	H 282/89	*E. coli*	O22:H8	+	+	-	HU Hamburg	unknown	-
7	BCD 5852	H 509/95	*E. coli*	O48:H21	-	+	+	HU Hamburg	unknown	-
8	BCD 7833	18785	*E. coli*	O-rough:H-	+	+	-	LGL	unknown	-
9	BCD 7834	15818	*E. coli*	ONT:H-	+	-	-	LGL	unknown	-
10	BCD 7836	20393	*E. coli*	O57:H-	+	-	-	LGL	unknown	-
11	BCD 7837	18364	*E. coli*	ONT:H-	+	-	-	LGL	unknown	-
12	BCD 7841	21521	*E. coli*	O23:H-	+	+	-	LGL	unknown	-
13	BCD 7853	18997	*E. coli*	O5:H-	+	-	+	LGL	unknown	-
14	BCD 7859	15302	*E. coli*	ONT:H-	+	+	-	LGL	unknown	-
15	BCD 7870	19410	*E. coli*	O113:H-	-	+	-	LGL	unknown	-
16	BCD 7871	21761	*E. coli*	ONT:H-	-	+	-	LGL	unknown	-
17	BCD 7872	19271	*E. coli*	ONT:H-	+	-	-	LGL	unknown	-
18	BCD 7874	22095	*E. coli*	O-rough:H-	+	-	+	LGL	unknown	-
19	BCD 7877	18369	*E. coli*	O146:H21	-	+	-	LGL	unknown	-
20	BCD 8240	1576/96	*E. coli*	O148	-	-	-	HU Hamburg	unknown	-
21	BCD 8253	4608-58/Qrsn	*E. coli*	O143:K:H-	-	-	-	HU Hamburg	unknown	-
22	BCD 8262	145-46/Qrsn	*E. coli*	O164:K-:H-	-	-	-	HU Hamburg	unknown	-
23	BCD 8318	774-36/89	*E. coli*	O55:K1:H-	-	+	+	HU Hamburg	unknown	-
24	BCD 8332	815-36-88	*E. coli*	ONT	-	+	-	HU Hamburg	unknown	-
25	BCD 12502	LM 680	*E. coli*	O138:H8	-	+	-	JLU	milk	-
26	BCD 12504	LM 841	*E. coli*	O8:H27	-	+	-	JLU	beef	-
27	BCD 12505	LM 872	*E. coli*	O17:H-	-	+	-	JLU	raw milk	-
28	BCD 12506	LM 1046	*E. coli*	O22:H-	+	+	-	JLU	minced beef	-
29	BCD 12508	LM 1119	*E. coli*	O84:H21	+	+	+	JLU	lamb meat	-
30	BCD 12509	LM 1126	*E. coli*	O7:H-	+	+	-	JLU	lamb meat	-
31	BCD 12510	LM 1247	*E. coli*	ONT:H-	+	+	-	JLU	lamb meat	-
32	BCD 12511	LM 1328	*E. coli*	O23:H15	-	+	-	JLU	raw milk cheese	-
33	BCD 12512	LM 1364	*E. coli*	O8:H-	-	+	-	JLU	beef	-
34	BCD 12513	LM 1389	*E. coli*	O-rough:H23	+	+	-	JLU	beef	-
35	BCD 12514	LM 1394	*E. coli*	O46:H-	-	+	-	JLU	beef	-
36	BCD 12516	LM 1419	*E. coli*	O74:H-	-	+	-	JLU	minced beef	-
37	BCD 12517	LM 1436	*E. coli*	O64:H8	+	+	-	JLU	beef	-
38	BCD 12519	LM 1460	*E. coli*	O91:H-	-	+	-	JLU	minced beef	-
39	BCD 12520	LM 1541	*E. coli*	O22:H-	-	+	-	JLU	beef	-
40	BCD 12521	LM 1548	*E. coli*	O65:H-	+	-	-	JLU	pork sausage	-
41	BCD 12522	LM 1552	*E. coli*	O8:H-	-	+	-	JLU	minced beef	-
42	BCD 12533	Rd 15	*E. coli*	O136:H19	+	-	-	JLU	feces (cattle)	-
43	BCD 12534	Rd 28	*E. coli*	O3:H-	+	-	-	JLU	feces (cattle)	-
44	BCD 12541	Rd 53	*E. coli*	O105:H18	+	-	-	JLU	feces (cattle)	-
45	BCD 12549	Rd 1475	*E. coli*	O74:H29	-	+	-	JLU	feces (cattle)	-
46	BCD 12550	Rd 1479	*E. coli*	O129:H-	-	+	-	JLU	feces (cattle)	-
47	BCD 12551	Rd 1484	*E. coli*	O12:H-	-	+	-	JLU	feces (cattle)	-
48	BCD 14193	No. 1670	*E. coli*	O91:H21	+	+	+	JLU	raw milk	-
49	BCD 14194	No. 924	*E. coli*	O4:H-	+	+	-	JLU	lamb meat	-
50	BCD 14195	No. 1106	*E. coli*	O8:H-	+	-	-	JLU	lamb meat	-
51	BCD 14196	No. 1251	*E. coli*	ONT:H-	+	+	-	JLU	lamb meat	-
52	BCD 14197	No. 1555	*E. coli*	O9:H10	-	+	-	JLU	minced meat	-
53	BCD 14201	No. 1628	*E. coli*	ONT:H18	+	+	-	JLU	minced meat	-
54	BCD 14202	No. 1631	*E. coli*	O133:H21	-	+	-	JLU	minced meat	-
55	BCD 14203	No. 1633	*E. coli*	O146:H21	+	+	-	JLU	minced meat	-
56	BCD 14204	No. 1361	*E. coli*	O113:H-	+	+	-	JLU	beef	-
57	BCD 14205	No. 1459	*E. coli*	O7:H16	+	-	-	JLU	beef	-
58	BCD 14206	No. 1608	*E. coli*	O22:H8	+	+	-	JLU	beef	-
59	BCD 14207	No. 1614	*E. coli*	ONT:H19	+	+	-	JLU	beef	-

60	BCD 14208	No. 1650	*E. coli*	O153:H25	-	+	-	JLU	beef	-
61	BCD 14209	No. 1657	*E. coli*	O133:H21	-	+	-	JLU	beef	-
62	BCD 14212	No. 1667	*E. coli*	O113:H4	+	+	-	JLU	hamburger	-
63	BCD 14213	No. 175	*E. coli*	O10:H4	+	-	+	JLU	carcass (lamb)	-
64	BCD 14214	No. 209	*E. coli*	O156:H25	+	-	+	JLU	carcass (lamb)	-
65	BCD 14216	No. 213	*E. coli*	O156:H25	+	-	+	JLU	carcass (lamb)	-
66	BCD 14217	No. 215	*E. coli*	O107:H11	+	-	+	JLU	carcass (lamb)	-
67	BCD 14218	No. 216	*E. coli*	O156:H25	+	-	+	JLU	carcass (lamb)	-
68	BCD 14219	No. 177	*E. coli*	O84:H31	+	-	+	JLU	feces (sheep)	-
69	BCD 14225	No. 207	*E. coli*	O156:H+ nt	+	-	+	JLU	feces (sheep)	-
70	BCD 14232	No. 668	*E. coli*	O146:H28	+	+	-	JLU	feces (cattle)	-
71	BCD 14235	No. 723	*E. coli*	O8:H21	+	-	-	JLU	feces (cattle)	-
72	BCD 14239	No. 994	*E. coli*	O74:H39	+	+	-	JLU	feces (cattle)	-
73	BCD 16194	C 420-09	*E. coli*	O8:K85ab:Hru	+	-	-	SSI	unknown	-
74	BCD 16195	C 837-09	*E. coli*	O174:K101:H8	+	+	-	SSI	unknown	-
75	BCD 16196	C 165-02	*E. coli*	O73:H18	-	+	-	SSI	unknown	-
76	BCD 16197	C 352-09	*E. coli*	O89:K+:H-	-	+	+	SSI	unknown	-
77	BCD 16198	C 351-09	*E. coli*	O2:K-:H25	-	+	-	SSI	unknown	-

[a]BCD – Biotecon Diagnostics GmbH culture collection.

[b] BgVV - Federal Institute for Consumer Health Protection and Veterinary Medicine, Dessau, Germany. HU - Institute for Hygiene and Environment, Hamburg, Germany. JLU – Justus Liebig University, Gießen, Germany. JMU – Julius Maximilians University, Würzburg, Germany. LGL - Bavarian Health and Food Safety Authority, Erlangen, Germany. SSI - Statens Serum Institute, Copenhagen, Denmark.

[c]"-" – Negative for the respective virulence gene (*stx1*, *stx2*, *eae*).

[d]"-" – Negative result with the **food**proof STEC Identification LyoKit

[e]"+" – Positive for the respective virulence gene (*stx1*, *stx2*, *eae)*.

Table 10. Results of the internal Exclusivity Study- foodproof **STEC Identification LyoKit -** Non-*E.coli* organisms (1)

No.	Strain ID[a]	Genus	Species	Subspecies/ Serovar	Source[b]	Origin	**food**proof **STEC Identification Result**
1	DSM 1530	*Bacillus*	*firmus*	Not applicable	DSMZ	unknown	-[c]
2	DSM 4689	*Campylobacter*	*coli*	Not applicable	DSMZ	pig feces	-
3	BCD 4696	*Citrobacter*	*freundii*	Not applicable	TU Berlin	unknown	-
4	DSM 4596	*Citrobacter*	*koseri*	Not applicable	DSMZ	throat	-
5	LMG 2790	*Cronobacter*	*sakazakii*	Not applicable	LMG	human clinical material	-
6	DSM 12409	*Enterobacter*	*hormaechei*	Not applicable	DSMZ	sputum of a male patient	-
7	DSM 6629	*Lactobacillus*	*intestinalis*	Not applicable	DSMZ	intestine of rat	-
8	DSM 20750	*Listeria*	*ivanovii*	5	DSMZ	sheep	-
9	DSM 20600	*Listeria*	*monocytogenes*	Not applicable	DSMZ	rabbit	-
10	DSM 3493	*Pantoea*	*agglomerans*	Not applicable	DSMZ	knee laceration	-
11	DSM 20331	*Pediococcus*	*damnosus*	Not applicable	DSMZ	lager beer yeast	-
12	DSM 2140	*Proteus*	*vulgaris*	Not applicable	DSMZ	inner ear infection	-
13	DSM 30120	*Providencia*	*alcalifaciens*	Not applicable	DSMZ	feces	-
14	BCD 4940	*Pseudomonas*	*stutzeri*	Not applicable	University of Bielefeld	unknown	-
15	DSM 4594	*Rahnella*	*aquatilis*	Not applicable	DSMZ	unknown	-
16	DSM 4617	*Raoultella*	*planticola*	Not applicable	DSMZ	air	-
17	BCD 5692	*Salmonella*	*bongori*	40:z35:-	HU Hamburg	unknown	-
18	BCD 14407	*Salmonella*	*bongori*	Malawi	BgVV Berlin	unknown	-
19	DSM 4224	*Salmonella*	*enterica*	Abony	DSMZ	unknown	-
20	BCD 5199	*Salmonella*	*enterica arizonae*	63:g,z51:-	HU Hamburg	unknown	-
21	BCD 5205	*Salmonella*	*enterica arizonae*	62:z36:-	HU Hamburg	unknown	-
22	BCD 5208	*Salmonella*	*enterica arizonae*	51:g,z51:-	HU Hamburg	unknown	-
23	BCD 16065	*Salmonella*	*enterica arizonae*	56:z4, z23:-	BfR	lance-head viper	-
24	BCD 5685	*Salmonella*	*enterica diarizonae*	53:l,k:z	HU Hamburg	unknown	-
25	BCD 5686	*Salmonella*	*enterica diarizonae*	61:i:z	HU Hamburg	unknown	-
26	BCD 6078	*Salmonella*	*enterica diarizonae*	60:z52:z53	BgVV Berlin	unknown	-
27	BCD 14402	*Salmonella*	*enterica diarizonae*	47:l,v:z	BgVV Berlin	reptile, feces	-
28	BCD 14403	*Salmonella*	*enterica diarizonae*	50:z:z52	BgVV Berlin	pig, organ	-
29	BCD 16063	*Salmonella*	*enterica diarizonae*	52:k:z35	BfR	snake	-
30	BCD 16066	*Salmonella*	*enterica diarizonae*	57:c:z	BfR	snake	-

31	BCD 16067	*Salmonella*	*enterica diarizonae*	59:z52:z53	BfR	snake	-
32	BCD 16068	*Salmonella*	*enterica diarizonae*	65:l, v:z	BfR	snake	-
33	BCD 6124	*Salmonella*	*enterica enterica*	Thetford	BgVV Berlin	unknown	-
34	BCD 6149	*Salmonella*	*enterica enterica*	Wedding	BgVV Berlin	unknown	-
35	BCD 6162	*Salmonella*	*enterica enterica*	Plymouth	BgVV Berlin	unknown	-
36	BCD 6179	*Salmonella*	*enterica enterica*	Koketime	BgVV Berlin	unknown	-
37	BCD 6180	*Salmonella*	*enterica enterica*	Roan	BgVV Berlin	unknown	-
38	BCD 6191	*Salmonella*	*enterica enterica*	Ealing	BgVV Berlin	unknown	-
39	BCD 7934	*Salmonella*	*enterica enterica*	Havana	BgVV Berlin	meat	-
40	BCD 15698	*Salmonella*	*enterica enterica*	Litchfield	BfR	crustaceans	-
41	BCD 16061	*Salmonella*	*enterica enterica*	Paratyphi A	BfR	human, Turkey	-
42	BCD 16064	*Salmonella*	*enterica enterica*	Winnipeg	BfR	Peking duck	-
43	BCD 16077	*Salmonella*	*enterica enterica*	Crossness	HPA	unknown	-
44	BCD 14404	*Salmonella*	*enterica houtenae*	16:z4,z32:-	BgVV Berlin	reptile, organ	-
45	BCD 14405	*Salmonella*	*enterica houtenae*	48:g,z51:-	BgVV Berlin	reptile, feces	-
46	BCD 14406	*Salmonella*	*enterica houtenae*	11:z4,z23:-	BgVV Berlin	pig	-
47	BCD 7956	*Salmonella*	*enterica indica*	41:b:1,7	BgVV Berlin	unknown	-
48	BCD 14410	*Salmonella*	*enterica indica*	45:a:e,n,x	BgVV Berlin	reptile	-
49	BCD 14411	*Salmonella*	*enterica indica*	Ferlac	BgVV Berlin	unknown	-
50	BCD 2431	*Salmonella*	*enterica salamae*	58:l,z13,z28:z6	BGA Berlin	unknown	-
51	BCD 6100	*Salmonella*	*enterica salamae*	21:z10:-	BgVV Berlin	unknown	-
52	BCD 13311	*Salmonella*	*enterica salamae*	55:k:z39	unknown	unknown	-
53	BCD 14398	*Salmonella*	*enterica salamae*	42:r:-	BgVV Berlin	fish (perch)	-
54	BCD 14414	*Salmonella*	*enterica salamae*	30:l,z28:z6	BgVV Berlin	reptile, feces	-
55	BCD 16062	*Salmonella*	*enterica salamae*	9,12,46,27:c:z39	BfR	snake	-
56	DSM 7532	*Shigella*	*boydii*	Not applicable	DSMZ	unknown	-
57	BCD 7566	*Shigella*	*dysenteriae*	Not applicable	HU Hamburg	unknown	-
58	DSM 4782	*Shigella*	*flexneri*	2a	DSMZ	unknown	-
59	DSM 4569	*Serratia*	*ficaria*	0:1	DSMZ	fig	-
60	BCD 13767	*Yersinia*	*frederiksenii*	Not applicable	unknown	unknown	-

[a]BCD – Biotecon Diagnostics GmbH culture collection.
[b] BfR - German Federal Institute for Risk Assessment, Berlin, Germany. BGA Berlin – (former) Federal Health Agency, Berlin, Germany. BgVV - Federal Institute for Consumer Health Protection and Veterinary Medicine, Berlin, Germany. DSMZ - German Collection of Microorganisms and Cell Cultures, Braunschweig, Germany. HPA – (former) Health Protection Agency, London, England, United Kingdom. HU - Institute for Hygiene and Environment, Hamburg, Germany. LMG – Laboratory of Microbiology Gent Bacteria Collection, Ghent, Belgium. TU Berlin - Technical University of Berlin, Germany. University of Bielefeld – Bielefeld, Germany.
[c]"-" - Negative result with the **food**proof STEC Identification LyoKit

Table 11. BIOTECON Diagnostics STEC Method Results for Fresh Raw Ground Beef: Presumptive vs. Confirmed (1)

Matrix	Strain	MPN[a] /test portion	N[b]	Incubation Time (h)	BIOTECON Diagnostics STEC presumptive			Confirmed[e](15-24 h)			dPOD$_{CP}$[g]	95% CI[h]
					x[c]	POD$_{CP}$[d]	95% CI	x	POD$_{CC}$[f]	95% CI		
Fresh Raw Ground Beef (25 g)	*E. coli* O157:H7 JLU[j] No. 1433	N/A[i]	5	8	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
				22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.13 (0.59, 2.16)	20	8	8	0.40	0.22, 0.61	7	0.35	0.18, 0.57	0.05	-0.11, 0.21
				22 ± 2	8	0.40	0.22, 0.61	7	0.35	0.18, 0.57	0.05	-0.11, 0.21
		3.46 (1.75, 6.83)	5	8	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
				22 ± 2	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Fresh Raw Ground Beef (375 g)	*E. coli* O157:H7 JLU No. 1433	N/A[i]	5	12	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
				22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.13 (0.59, 2.16)	20	12	7	0.35	0.18, 0.57	6	0.30	0.15, 0.52	0.05	-0.11, 0.21
				22 ± 2	7	0.35	0.18, 0.57	6	0.30	0.15, 0.52	0.05	-0.11, 0.21
		3.46 (1.75, 6.83)	5	12	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
				22 ± 2	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47

All results were identical on the three real-time PCR instruments used (LightCycler® 480 Instrument II, LightCycler® 96 System, Agilent AriaMx Real-Time PCR System).
[a]MPN = Most Probable Number is calculated using the LCF MPN calculator ver. 1.6 provided by AOAC RI, with 95% confidence interval.
[b]N = Number of test potions.
[c]x = Number of positive test portions.
[d]POD$_{CP}$ = Candidate method presumptive positive outcomes divided by the total number of trials.
[e]25 g test portions were confirmed using the candidate confirmation method and 375 g test portions were confirmed using the candidate confirmation method and the reference confirmation method. Results obtained following the candidate method confirmation were identical to results obtained from confirmation by the modified USDA/FSIS-MLG 5C.00 reference method.
[f]POD$_{CC}$ = Candidate method confirmed (375 g, 25 g) or reference method confirmed (375 g) positive outcomes divided by the total number of trials.
[g]dPOD$_{CP}$ = Difference between the candidate method presumptive result and candidate method confirmed (375 g, 25 g) or reference method confirmed (375 g) result POD values.
[h]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[i]N/A = Not applicable.
[j]JLU = Justus Liebig University, Gießen, Germany.

Table 12. BIOTECON Diagnostics STEC Method Results for Fresh Raw Beef Trim: Presumptive vs. Confirmed (1)

Matrix	Strain	MPN[a] /test portion	N[b]	Incubation Time (h)	BIOTECON Diagnostics STEC presumptive			Confirmed[e] (15-24 h)			dPOD$_{CP}$[g]	95% CI[h]
					x[c]	POD$_{CP}$[d]	95% CI	x	POD$_{CC}$[f]	95% CI		
Samples analyzed by BIOTECON Diagnostics GmbH												
Fresh Raw Beef Trim (25 g)	*E. coli* O26 JLU[j] 413/89 - 1	N/A[i]	5	8	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
				22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.83 (0.94, 3.55)	20	8	7	0.35	0.18, 0.57	8	0.40	0.22, 0.61	-0.05	-0.21, 0.11
				22 ± 2	8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.13, 0.13
		2.91 (1.54, 5.50)	5	8	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
				22 ± 2	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Fresh Raw Beef Trim (375 g)	*E. coli* O26 JLU 413/89 - 1	N/A	5	12	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
				22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.83 (0.94, 3.55)	20	12	5	0.25	0.11, 047	5	0.25	0.11, 047	0.00	-0.13, 0.13
				22 ± 2	5	0.25	0.11, 047	5	0.25	0.11, 047	0.00	-0.13, 0.13
		2.91 (1.54, 5.50)	5	12	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
				22 ± 2	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Samples analyzed by Q Laboratories (independent laboratory)												
Fresh Raw Beef Trim (25 g)	*E. coli* O26 ATCC[k] BAA-1653	N/A	5	8 and 22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.61 (0.33, 1.02)	20		9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	0.00	-0.13, 0.13
		1.97 (0.91, 4.27)	5		5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Fresh Raw Beef Trim (375 g)	*E. coli* O26 ATCC BAA-1653	N/A	5	12 and 22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.61 (0.33, 1.02)	20		8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.13, 0.13
		1.97 (0.91, 4.27)	5		5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47

All used PCR devices provided identical results. Samples analyzed by BIOTECON Diagnostics GmbH were tested on the LightCycler® 480 Instrument II, the LightCycler® 96 System, and the Agilent AriaMx Real-Time PCR System. Samples analyzed by the independent laboratory were tested on the ABI 7500 Fast and the CFX96 Touch Real-Time PCR System.
[a]MPN = Most Probable Number is calculated using the LCF MPN calculator ver. 1.6 provided by AOAC RI, with 95% confidence interval.
[b]N = Number of test potions.
[c]x = Number of positive test portions.
[d]POD$_{CP}$ = Candidate method presumptive positive outcomes divided by the total number of trials.
[e]25 g test portions were confirmed using the candidate confirmation method and 375 g test portions were confirmed using the candidate confirmation method and the reference confirmation method. Results obtained following the candidate method confirmation were identical to results obtained from confirmation by the modified USDA/FSIS-MLG 5C.00 reference method.
[f]POD$_{CC}$ = Candidate method confirmed (375 g, 25 g) or reference method confirmed (375 g) positive outcomes divided by the total number of trials.
[g]dPOD$_{CP}$ = Difference between the candidate method presumptive result and candidate method confirmed (375 g, 25 g) or reference method confirmed (375 g) result POD values.
[h]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[i]N/A = Not applicable.
[j]JLU = Justus Liebig University, Gießen, Germany.
[k]ATCC = American Type Culture Collection, Manassas, VA.

Table 13. Method Comparison Results for 25 g test portions: BIOTECON Diagnostics STEC Method vs. MLG 5C.00 Reference Method (1)

Matrix	Strain	MPN[a] /test portion	N[b]	Incubation Time (h)	BIOTECON Diagnostics STEC presumptive			Reference method[e]			dPOD$_{CP}$[g]	95% CI[h]
					x[c]	POD$_{CP}$[d]	95% CI	x	POD$_{R}$[f]	95% CI		
Samples analyzed by BIOTECON Diagnostics GmbH												
Fresh Raw Ground Beef (25 g)	*E. coli* O157 JLU[j] No. 1433	N/A[i]	5	8	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
				22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.13 (0.59, 2.16)	20	8	7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13
				22 ± 2	7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13
		3.46 (1.75, 6.83)	5	8	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
				22 ± 2	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Fresh Raw Beef Trim (25 g)	*E. coli* O26 JLU 413/89 - 1	N/A	5	8	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
				22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		1.83 (0.94, 3.55)	20	8	8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.13, 0.13
				22 ± 2	8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.13, 0.13
		2.91 (1.54, 5.50)	5	8	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
				22 ± 2	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Samples analyzed by Q Laboratories (independent laboratory)												
Fresh Raw Beef Trim (25 g)	*E. coli* O26 ATCC[k] BAA-1653	N/A	5	8 and 22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.61 (0.33, 1.02)	20		9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	0.00	-0.13, 0.13
		1.97 (0.91, 4.27)	5		5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47

All used PCR devices provided identical results. Samples analyzed by BIOTECON Diagnostics GmbH were tested on the LightCycler® 480 Instrument II, the LightCycler® 96 System, and the Agilent AriaMx Real-Time PCR System. Samples analyzed by the independent laboratory were tested on the ABI 7500 Fast and the CFX96 Touch Real-Time PCR System.
[a]MPN = Most Probable Number is calculated using the LCF MPN calculator ver. 1.6 provided by AOAC RI, with 95% confidence interval.
[b]N = Number of test potions.
[c]x = Number of positive test portions.
[d]POD$_{CP}$ = Candidate method presumptive positive outcomes divided by the total number of trials.
[e]Reference method = MLG 5C.00. Reference method portions were tested at 25 g.
[f]POD$_{R}$ = Reference method positive outcomes divided by the total number of trials.
[g]dPOD$_{CP}$ = Difference between the candidate method presumptive POD values and reference method POD values.
[h]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[i]N/A = Not applicable.
[j]JLU = Justus Liebig University, Gießen, Germany.
[k]ATCC = American Type Culture Collection, Manassas, VA.

Table 14. Method Comparison Results for 375 g test portions: BIOTECON Diagnostics STEC Method vs. MLG 5C.00 Reference Method (1)

Matrix	Strain	MPN[a] /test portion	N[b]	Incubation Time (h)	BIOTECON Diagnostics STEC method			Reference method[e]			dPOD$_C$[g]		95% CI[h]
					x[c]	POD$_C$[d]	95% CI	x	POD$_R$[f]	95% CI			
	Samples analyzed by BIOTECON Diagnostics GmbH												
Fresh Raw Ground Beef (375 g)	*E. coli* O157 JLU[j] No. 1433	N/A[i]	5	12	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00		-0.43, 0.43
				22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00		-0.43, 0.43
		1.13 (0.59, 2.16)	20	12	6	0.30	0.15, 0.52	7	0.35	0.18, 0.57	-0.05		-0.32, 0.23
				22 ± 2	6	0.30	0.15, 0.52	7	0.35	0.18, 0.57	-0.05		-0.32, 0.23
		3.46 (1.75, 6.83)	5	12	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00		-0.43, 0.43
				22 ± 2	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00		-0.43, 0.43
Fresh Raw Beef Trim (375 g)	*E. coli* O26 JLU 413/89 - 1	N/A	5	12	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00		-0.43, 0.43
				22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00		-0.43, 0.43
		1.83 (0.94, 3.55)	20	12	5	0.25	0.11, 0.47	8	0.40	0.22, 0.61	-0.15		-0.40, 0.13
				22 ± 2	5	0.25	0.11, 0.47	8	0.40	0.22, 0.61	-0.15		-0.40, 0.13
		2.91 (1.54, 5.50)	5	12	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00		-0.43, 0.43
				22 ± 2	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00		-0.43, 0.43
	Samples analyzed by Q Laboratories (independent laboratory)												
Fresh Raw Beef Trim (375 g)	*E. coli* O26 ATCC[k] BAA-1653	N/A	5	12 and 22 ± 2	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00		-0.43, 0.43
		0.61 (0.33, 1.02)	20		8	0.40	0.22, 0.61	9	0.45	0.26, 0.66	-0.05		-0.33, 0.24
		1.97 (0.91, 4.27)	5		5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00		-0.43, 0.43

All used PCR devices provided identical results. Samples analyzed by BIOTECON Diagnostics GmbH were tested on the LightCycler® 480 Instrument II, the LightCycler® 96 System, and the Agilent AriaMx Real-Time PCR System. Samples analyzed by the independent laboratory were tested on the ABI 7500 Fast and the CFX96 Touch Real-Time PCR System.

[a]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.

[b]N = Number of test potions.

[c]x = Number of positive test portions.

[d]POD$_C$ = Candidate method presumptive positive outcomes confirmed positive divided by the total number of trials.

[e]Reference method = MLG 5C.00. Reference method portions were tested at 25 g.

[f]POD$_R$ = Reference method confirmed positive outcomes divided by the total number of trials.

[g]dPOD$_C$ = Difference between the candidate method and reference method POD values.

[h]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

[i]N/A = Not applicable.

[j]JLU = Justus Liebig University, Gießen, Germany.

[k]ATCC = American Type Culture Collection, Manassas, VA.

Table 19. Results of the external Inclusivity Study- foodproof STEC Identification LyoKit (1)

No.	Strain ID	Species	Serogroup/ Serotype	*stx1*	*stx2*	*eae*	Source[a]	Origin	foodproof STEC Identification Result[b]
1	TW08101	*E. coli*	O103	+[c]	-[d]	+	MSU	human	positive for O103
2	TW04162	*E. coli*	O103	+	-	+	MSU	human	positive for O103
3	DEC 8D	*E. coli*	O111	-	-	+	MSU	human (infant)	positive for O111
4	DEC 15A	*E. coli*	O111	n/s[e]	n/s	n/s	MSU	human	positive for O111
5	TW07614	*E. coli*	O121	-	+	n/s	MSU	human	positive for O121
6	TW07931	*E. coli*	O121	-	+	+	MSU	human	positive for O121
7	TW07596	*E. coli*	O145	+	-	+	MSU	human	positive for O145
8	TW09356	*E. coli*	O145	+	-	n/s	MSU	human	positive for O145
9	DEC 10B	*E. coli*	O26	+	-	+	MSU	human	positive for O26
10	DEC 9F	*E. coli*	O26	-	-	+	MSU	human	positive for O26
11	TW07862	*E. coli*	O26	+	-	+	MSU	calf, cow	positive for O26
12	1.2622	*E. coli*	O45	+	-	-	PSU	not available	positive for O45
13	DEC 11C	*E. coli*	O45	n/s	n/s	n/s	MSU	human	positive for O45
14	TW07947	*E. coli*	O45	+	-	+	MSU	human	positive for O45
15	700599	*E. coli*	O157:H7	n/s	n/s	n/s	ATCC	salami	positive for O157
16	43895	*E. coli*	O157:H7	+	+	n/s	ATCC	raw hamburger	positive for O157
17	1398	*E. coli*	O104:H12	+	-	-	JLU	not available	positive for O104
18	17614	*E. coli*	O104:H[7]	+	-	-	BfR	not available	positive for O104

[a]Michigan State University Culture Collection (MSU)- East Lansing, MI, USA; Pennsylvania State University Culture Collection (PSU)- Middletown, PA, USA; American Type Culture Collection (ATCC)- Manassas, VA, USA; JLU – Justus Liebig University, Gießen, Germany; BfR - German Federal Institute for Risk Assessment, Berlin, Germany.

[b]Results on both real-time PCR platforms the ABI 7500 Real-Time PCR System and the CFX96 Touch Real-Time PCR Detection System.

[c]"+" - Positive for the respective virulence gene (*stx1*, *stx2*, *eae)*.

[d]"-" – Negative for the respective virulence gene (*stx1*, *stx2*, *eae)*.

Table 20. Results of the external Exclusivity Study- foodproof STEC Identification LyoKit (1)

No.	Strain ID	Genus	Species	Subspecies/ Serovar	Source[a]	Origin	foodproof STEC Identification Result[b]
1	8739	*Escherichia*	*coli*	Not applicable	ATCC	Feces	-[c]
2	9113	*Escherichia*	*coli*	O113	NCTC	Not Available	-
3	10444	*Escherichia*	*coli*	O115	NCTC	Mammal, Calf	-
4	9117	*Escherichia*	*coli*	O117	NCTC	Not Available	-
5	9118	*Escherichia*	*coli*	O118	NCTC	Not Available	-
6	10089	*Escherichia*	*coli*	O142	NCTC	Not Available	-
7	10677	*Escherichia*	*coli*	O146	MSU	Not Available	-
8	9207	*Shigella*	*boydii*	Not applicable	ATCC	Pork Liver	-

[a]American Type Culture Collection (ATCC)- Manassas, VA, USA; National Collection of Type Cultures (NCTC)- Proton Down, Salisbury, UK; Michigan State University Culture Collection (MSU)- East Lansing, MI, USA.

[b]Results on both real-time PCR platforms the ABI 7500 Real-Time PCR System and the CFX96 Touch Real-Time PCR Detection System.

[c]"-" - Negative result with the STEC Identification LyoKit

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