CERTIFICATION

AOAC® *Performance Tested*SM

Certificate No.

070401

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

foodproof® *Listeria monocytogenes* Detection Kits (5'Nuclease and Hybridization Probes)
with **food**proof® ShortPrep II Kit

manufactured by

BIOTECON Diagnostics GmbH
Hermannswerder Haus 17
14473 Potsdam, Germany

This method has been evaluated in the AOAC® *Performance Tested Methods*SM Program, and found to perform as stated by the manufacturer contingent to the comments contained in the manuscript. This certificate means that an AOAC® Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC *Performance Tested*SM certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER'S SPECIFICATIONS" - on the above mentioned method for a period of one calendar year from the date of this certificate (December 06, 2016 – December 31, 2017). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Deborah McKenzie

Deborah McKenzie, Senior Director
Signature for AOAC Research Institute

December 06, 2016
Date

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SUBMITTING COMPANY
BIOTECON Diagnostics GmbH
Hermannswerder Haus 17
14473 Posdam, Germany

KIT NAME(S)
foodproof® *Listeria monocytogenes* Detection Kits (5'Nuclease and Hybridization Probes)
with **food**proof® ShortPrep II Kit

CATALOG NUMBERS
R 302 23, R 300 23, S400 02

INDEPENDENT LABORATORY
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APPLICABILITY OF METHOD
Target organism – Listeria monocytogenes
Matrices – (25 g) - died whole eggs, dry whole milk, vanilla ice cream, Harzer cheese, sausage, raw ground chicken, raw ground pork, ham, Graviax, Pollack fillet, Coal fish, melon cubes, white cabbage, bean sprouts, paprika emulsion dye, parsley flakes, dry pet food, peanut butter, milk chocolate, pizza, spaghetti
Performance claims - This advanced PCR-method has been designed to reduce the time taken to achieve results from PCR reactions and to enable the user to monitor the amplification of the PCR product simultaneously, in real-time.

REFERENCE METHODS
http://vm.cfsan.fda.gov/~ebam/bam-toc.html, Hitchins A, January 2003, BAM: Bacteriological Analytical Manual Online, Chapter 10: Detection and Enumeration of Listeria monocytogenes in Foods (5)
http://www.fsis.usda.gov/OPHS/microlab/mlgbook.htm, Sparling P, April 2002, USDA: Microbiology Laboratory Guidebook, Chapter 8.03: Isolation and Identification of Listeria monocytogenes from Red Meat, Poultry, Egg, and Environmental Samples (6)

ORIGINAL CERTIFICATION DATE
September 14, 2004

CERTIFICATION RENEWAL RECORD
Renewed Annually through December 2017

METHOD MODIFICATION RECORD
1. **February 2011**

SUMMARY OF MODIFICATION
1. **Change of probes**

Under this AOAC® *Performance Tested*SM License Number, 070401 this method is distributed by:
NONE

Under this AOAC® *Performance Tested*SM License Number, 070401 this method is distributed as:
NONE

PRINCIPLE OF THE METHOD (1)

The **food**proof *Listeria monocytogenes* Detection Kit provides a rapid detection method for the testing of enrichment cultures inoculated with food samples that are potentially contaminated with *Listeria monocytogenes*. The ability to obtain a rapid result is particularly important due to the perishable nature of the potentially contaminated foods. Beyond supplying a rapid result, the LightCycler® Carousel-Based System provides superior detection sensitivity and specificity to the food industry, and eliminates the need for time-consuming traditional detection methods. This type of organism detection also minimizes the risk of sample contamination and false-positive results. The **food**proof *Listeria monocytogenes* Detection Kit is used to qualitatively detect *Listeria monocytogenes* DNA in raw material and food samples. The kit provides primers and Hybridization Probes (for sequence-specific detection), ready-to-use amplification and detection reagents, and a control template to ensure accurate performance of PCR, using a hot start methodology on the LightCycler® Carousel-Based System. To ensure maximum reliability of the kit, an Internal Control (IC) has been added to the **food**proof *Listeria monocytogenes* Detection Mix (vial 1) that will prevent misinterpretation of false-negative results due to inhibition of the amplification. Hybridization Probes were designed to bind specifically to the IC, allowing detection in channel F3 (LightCycler® Software 3.5 and versions below) or 705 (LightCycler® Software 4.x), whereas the *Listeria monocytogenes* DNA is detected in channel F2 (LightCycler® Software 3.5 and versions below) or 640 (LightCycler® Software 4.x). In case of a negative result due to inhibition of amplification by the sample DNA of interest, the amplification of the IC is suppressed as well. Whereas, a negative result for the sample DNA of interest and amplification of the IC, clearly indicates the absence of *Listeria monocytogenes* DNA in the sample. The kit minimizes contamination risk and contains all reagents (except for template DNA) needed for detection of *Listeria monocytogenes* DNA. The **food**proof *Listeria monocytogenes* Detection Kit is specifically adapted for PCR in glass capillaries using the LightCycler® Carousel-Based System. Primers and Hybridization Probes provide specific detection of *Listeria monocytogenes* DNA in food preparations. The kit described in this Instruction Manual has been developed for the LightCycler® Carousel-Based System.

DISCUSSION OF THE ORIGINAL VALIDATION STUDY (1)

Highest detection sensitivity is very important for pathogens like *Listeria monocytogenes* because smallest contamination can cause the most fatal consequences for all involved persons and also for the involved food company. Real-time PCR delivers highest degrees of accuracy because by specific DNA amplification detection of very low cell copy numbers is possible. This could be confirmed by comparing the **food**proof *Listeria monocytogenes* Detection Kit with the official BAM/FDA and USDA/FSIS reference methods. After 48 hours of enrichment inall 15 *Listeria monocytogenes* relevant food groups inoculations with higher and lower amounts of *Listeria monocytogenes* were detectable in an equal manner (sometimes even better but this was not confirmed by the reference method) with the LightCycler method than with the reference methods. Some food groups are generally more problematic than others. They show a high background flora that can overgrow the *Listeria monocytogenes* colonies on selective microbial agars and makes PCR analysis difficult because of the low amount of specific cells. The here described performance of the alternative method shows that also these food types are safely detectable with the **food**proof *Listeria monocytogenes* Detection Kit.

By excluding more than 59 related bacteria strains, the exclusivity of the method was underlined (60 isolates tested as DNA extracts and 30 as pure cultures). Also the inclusivity of the **food**proof *Listeria monocytogenes* Detection Kit was proven. There was no failure by testing more than 100 *Listeria monocytogenes* strains of all serotypes (102 isolates tested as DNA extracts and 50 as pure cultures enriched in the appropriate USDA and BAM media).

Ruggedness and applicability for routine use were demonstrated by a wide set of different tests. The ruggedness test showed that there was no nameable influence by variation of main kit components, apparatuses, testers and other, nor for the ShortPrep **food**proof II sample preparation kit neither for the *Listeria monocytogenes* LC-Detection kit. Different lots were tested and showed comparable good results. To confirm the kit stability the whole system underwent a series of tests, including a 13 month long term study, a stress test at higher storage temperatures and a freeze-thaw test. Altogether the influence of this storage times and temperature variations was negligible for the quality of the **food**proof *Listeria monocytogenes* Detection Kit.

Table 15.10a: Total number of 50 cultured *Listeria monocytogenes* strains tested for Inclusivity (1)

***Listeria monocytogenes* isolates**	**Sources**	**Test frequency**	**Test result**
Listeria monocytogenes 1/2a	SLCC 4955 SLCC 6204 SLCC 7053 SLCC 7149 SLCC 7150 SLCC 7163 ATCC 19111	7	**all isolates were positive tested**
Listeria monocytogenes 1/2b	SLCC 6031 SLCC 7059 SLCC 7151	3	
Listeria monocytogenes 1/2c	SLCC 4950 SLCC 6793 ATCC 19112	3	
Listeria monocytogenes 3a	SLCC 4949 ATCC 19113	2	
Listeria monocytogenes 3b	SLCC 2540 SLCC 7140 SLCC 7381	3	
Listeria monocytogenes 3c	SLCC 2479	1	
Listeria monocytogenes 4a	SLCC 5069 SLCC 5070 ATCC 19114	3	
Listeria monocytogenes 4ab	SLCC 7065 SLCC 7069 SLCC 7083	3	
Listeria monocytogenes 4b	ATCC 19115 SLCC 4013 SLCC 7056 SLCC 7060 SLCC 7061 SLCC 7067 SLCC 7070 SLCC 7071 SLCC 7073 SLCC 7074 SLCC 7075 SLCC 7194 SLCC 7370 SLCC 7372	14	
Listeria monocytogenes 4c	ATCC 19116 SLCC 4925 SLCC 4954	3	
Listeria monocytogenes 4d	SLCC 2375 SLCC 4926 ATTC 19117	3	
Listeria monocytogenes 4e	ATTC 19118	1	
Listeria monocytogenes 7	SLCC 2482	1	
Listeria monocytogenes unknown	EgDSLCC 5 SLCC 53 DSM 20600	3	

(SLCC = Seeliger's Listeria Culture Collection, c/o Klinikum der Stadt Mannheim, Fakultät für Klinische Medizin der Universität Heidelberg, Institut für Medizinische Mikrobiologie und Hygiene, Mannheim, Germany)

Table 15.10b: Total number of 102 *Listeria monocytogenes* DNA extracts tested for Inclusivity (1)

***Listeria monocytogenes* isolates**	**Sources**	**Test frequency**	**Test result**
Listeria monocytogenes 1/2a	SLCC 4955 SLCC 6204 SLCC 7149 SLCC 7150 SLCC 7153 SLCC 7163 SLCC 7165 SLCC 7195 SLCC 7196 SLCC 7197 SLCC 7198 SLCC 7973 SLCC 7053 SLCC 7054 SLCC 7055 ATCC 19111	16	**all isolates were positive tested**
Listeria monocytogenes 1/2b	SLCC 6031 SLCC 7151 SLCC 7152 SLCC 7163 SLCC 7354 SLCC 7367 SLCC 7059	7	
Listeria monocytogenes 1/2c	SLCC 4950 SLCC 6793 SLCC 7154 SLCC 7290 SLCC 7352 SLCC 7355 ATCC 19112	7	
Listeria monocytogenes 3a	SLCC 4949 SLCC 7135 SLCC 7179 ATCC 19113	4	
Listeria monocytogenes 3b	SLCC 2540 SLCC 7140 SLCC 7381	3	
Listeria monocytogenes 3c	SLCC 2479	1	
Listeria monocytogenes 4a	SLCC 5069 SLCC 5070 ATCC 19114	3	
Listeria monocytogenes 4ab	SLCC 7083 SLCC 7065 SLCC 7069	3	
Listeria monocytogenes 4b	ATCC 19115 SLCC 788 SLCC 4013 SLCC 7056 SLCC 7057 SLCC 7058 SLCC 7060 SLCC 7061 SLCC 7062 SLCC 7063 SLCC 7064 SLCC 7066 SLCC 7067 SLCC 7068 SLCC 7070 SLCC 7071 SLCC 7072 SLCC 7073 SLCC 7074 SLCC 7075 SLCC 7076 SLCC 7077 SLCC 7078 SLCC 7079 SLCC 7080	42	

	SLCC 7081 SLCC 7082 SLCC 7084 SLCC 7085 SLCC 7086 SLCC 7087 SLCC 7089 SLCC 7090 SLCC 7091 SLCC 7092 SLCC 7139 SLCC 7194 SLCC 7356 SLCC 7370 SLCC 7371 SLCC 7372 SLCC 7374		
Listeria monocytogenes 4c	ATCC 19116 SLCC 4925 SLCC 4954 SLCC 6277 SLCC 6813 SLCC 6821 SLCC 6823	7	
Listeria monocytogenes 4d	SLCC 2375 SLCC 4926 SLCC 4952 ATTC 19117	4	
Listeria monocytogenes 4e	ATTC 19118	1	
Listeria monocytogenes 7	SLCC 2482	1	
Listeria monocytogenes unknown	EgDSLCC 5835 SLCC 53 NCTC 10528	3	

(SLCC = Seeliger's Listeria Culture Collection, c/o Klinikum der Stadt Mannheim, Fakultät für Klinische Medizin der Universität Heidelberg, Institut für Medizinische Mikrobiologie und Hygiene, Mannheim, Germany)

Table 15.11a: Total number of cultured bacteria strains tested for exclusivity (1)

No.	Strain	Source	Test result
1	*Acetobacter pasteurianus*	DSM 3509	negative
2	*Achromobacter (Alcaligenes) xylosoxidans subsp. denitrificans*	DSM 30026	negative
3	*Acinetobacter calcoaceticus*	DSM 1139	negative
4	*Bacillus cereus*	own isolate	negative
5	*Brochothrix campestris*	DSM 4712	negative
6	*Brochothrix thermospacta*	DSM 20171	negative
7	*Corneybacterium pisciola*	DSM 20730	negative
8	*Citrobacter freundii*	own isolate	negative
9	*Corynebacterium glutamicum*	DSM 20300	negative
10	*Enterococcus faecalis*	DSM 20478	negative
11	*Kurthia zopfii*	DSM 20580	negative
12	*Listeria grayi*	SLCC 20596	negative
13	*Listeria grayi*	DSM 20601	negative
14	*Listeria innocua*	DSM 20649	negative
15	*Listeria innocua*	NCTC 10528	negative
16	*Listeria ivanovii subsp. ivanovii*	DSM 20750	negative
17	*Listeria ivanovii*	SLCC 2028	negative
18	*Listeria seeligeri*	SLCC 7307	negative
19	*Listeria welshimeri*	SLCC 5877	negative
20	*Listeria welshimeri*	SLCC 768	negative
21	*Megasphaera elsdenii*	ATCC 17753	negative
22	*Micrococcus luteus*	own isolate	negative
23	*Moraxella catarrhalis*	DSM 9143	negative
24	*Planococcus kocurii*	DSM 20474	negative
25	*Plesiomonoas shigelloides*	DSM 8224	negative
26	*Proteus vulgaris*	DSM 5140	negative
27	*Pseudomonas aeruginosa*	ATCC 10145	negative
28	*Serratia marcescens*	DSM 1636	negative
29	*Sporosarcina ureae*	DSM 2281	negative
30	*Staphylococcus aureus subsp. aureus*	DSM 20231	negative

(DSM = German Collection of Microorganisms, ATCC = American Type Culture Collection, NCTC = National Collection of Type Cultures)

Table 15.11b: Total number of bacterial DNA extracts tested for exclusivity (1)

No.	Strain	Source	Test result
1	*Acetobacter pasteurianus*	DSM 3509	negative
2	*Achromobacter (Alcaligenes) xylosoxidans subsp. denitrificans*	DSM 30026	negative
3	*Acinetobacter calcoaceticus*	DSM 1139	negative
4	*Aeromonas hydrophila subsp. anaerogenes*	DSM 30188	negative
5	*Bacillus alcalophilus*	DSM 485	negative
6	*Bacillus badius*	own isolate	negative
7	*Bacillus cereus*	own isolate	negative
8	*Bacillus firmus*	DSM 12	negative
9	*Bacillus stearothermophilus*	DSM 456	negative
10	*Brevundimonas vesicularis*	DSM 7226	negative
11	*Brochothrix campestris*	DSM 4712	negative
12	*Brochothrix thermospacta*	DSM 20171	negative
13	*Brochothrix thermospacta*	DSM 20599	negative
14	*Carnobacterium piscicola*	DSM 20730	negative
15	*Citrobacter freundii*	own isolate	negative
16	*Clostridium perfringens*	own isolate	negative
17	*Corynebacterium glutamicum*	DSM 20300	negative
18	*Delftia (Comamonas) acidovorans*	DSM 39	negative
19	*Enterobacter cloacae*	DSM 30054	negative
20	*Enterococcus faecalis*	DSM 20478	negative
21	*Erysipelothrix rhusiopathiae*	DSM 5055	negative
22	*Escherichia coli*	NCTC 12790	negative
23	*Escherichia coli (O157:H7)*	ATCC 43895	negative
24	*Jonesia denitrificans*	DSM 20603	negative
25	*Klebsiella pneumoniae subsp. pneumoniae*	ATCC 13883	negative
26	*Kurthia zopfii*	DSM 20580	negative
27	*Lactobacillus casei*	DSM 20011	negative
28	*Lactobacillus delbrueckii subsp. lactis*	DSM 20072	negative
29	*Lactobacillus hilgardii*	DSM 20051	negative
30	*Lactobacillus kefiri*	DSM 20588	negative
31	*Lactobacillus sakei*	DSM 20494	negative
32	*Lactococcus lactis subsp. lactis*	DSM 20729	negative
33	*Leuconostoc mesenteroides subs. mesenteroides*	DSM 20241	negative
34	*Listeria grayi*	DSM 20596	negative
35	*Listeria grayi*	DSM 20601	negative
36	*Listeria innocua*	DSM 20649	negative
37	*Listeria innocua*	NCTC 10528	negative
38	*Listeria ivanovii subsp. ivanovii*	DSM 20750	negative
39	*Listeria ivanovii*	SLCC 2028	negative
40	*Listeria seeligeri*	DSM 20751	negative
41	*Listeria seeligeri*	SLCC 7307	negative
42	*Listeria welshimeri*	SLCC 768	negative
43	*Listeria welshimeri*	SLCC 5877	negative

44	*Macrococcus caseolyticus*	DSM 20597	negative
45	*Micrococcus luteus*	own isolate	negative
46	*Moraxella catarrhalis*	DSM 9143	negative
47	*Pantoea agglomerans*	own isolate	negative
48	*Planococcus kocurii*	DSM 20474	negative
49	*Plesiomonoas shigelloides*	DSM 8224	negative
50	*Proteus vulgaris*	DSM 2140	negative
51	*Pseudomonas aeruginosa*	ATCC 10145	negative
52	*Salmonella enterica subsp. enterica (Enteritidis)*	own isolate	negative
53	*Serratia marcescens*	DSM 1636	negative
54	*Shewanella putrefaciens*	DSM 6067	negative
55	*Shigella sonnei*	own isolate	negative
56	*Sporosarcina ureae*	DSM 2281	negative
57	*Staphylococcus aureus subsp. aureus*	DSM 20231	negative
58	*Streptococcus uberis*	DSM 20569	negative
59	*Weissella confusa*	DSM 20196	negative
60	*Yersinia enterocolitica subsp. enterocolitica*	DSM 4780	negative

(DSM = German Collection of Microorganisms, ATCC = American Type Culture Collection, NCTC = National Collection of Type Cultures

Table 15.8: In-house repeatability study summary of 20 food samples tested with PCR and microbiologically according to FDA-BAM or USDA/FSIS. (1)

Food	No. of Samples	Inoculation Level (MPN) cells per 25 gram	Inoculation Level cells per 1 gram	No. of positive tested samples				Chi Square Values 48h
				PCR 24h	PCR 48h	Cultural method 24h	Cultural method 48h	
Raw ground chicken[1]	20	5,75	0,23	3	17	8	15	0.5
	20	23,25	0,93	6	20	12	17	1.333
	5	-	-	0	0	0	0	0
Raw ground pork[1]	20	< 0,75	< 0,03	19	19	19	19	0
	20	275	11	18	20	20	20	0
	5	-	-	0	0	0	0	0
Gravlax[2] (low inoculation level repeated)	20	0,9	0,036	14	16	20	16	0
	20	10,75	0,43	20	20	20	20	0
	5	-	-	0	0	0	0	0
	20	5,75	0,23	17	17	17	17	0
	5	-	-	0	0	0	0	0
Bean sprouts[2]	20	5,75	0,23	15	18	16	18	0
	20	2,75	0,11	1	20	9	19	0
	5	-	-	0	0	0	0	0
Peanut butter[2]	20	2,3	0,092	17	17	17	17	0
	20	10,75	0,43	20	20	20	20	0
	5	-	-	0	0	0	0	0
Dried whole eggs[2]	20	10,75	0,43	16	16	16	16	0
	20	60	2,40	20	20	20	20	0
	5	-	-	0	0	0	0	0
Dry whole milk[2]	20	5,75	0,23	18	18	18	18	0
	20	5,75	0,23	20	20	20	20	0
	5	-	-	0	0	0	0	0
Dry pet food[2]	20	5,75	0,23	19	19	19	19	0
	20	115	4,6	20	20	20	20	0
	5	-	-	0	0	0	0	0
Milk chocolate[2]	20	0,9	0,036	14	14	14	14	0
	20	23,25	0,93	20	20	20	20	0

	5	-	-	0	0	0	0	0
Melon cubes[2]	20	0,75	0,03	14	14	14	14	0
	20	18,75	0,75	20	20	20	20	0
	5	-	-	0	0	0	0	0
White cabbage[2]	20	10,75	0,43	19	19	19	19	0
	20	37,5	1,5	20	20	20	20	0
	5	-	-	0	0	0	0	0
Pizza[2]	20	5,75	0,23	17	17	17	17	0
	20	23,25	0,93	20	20	20	20	0
	5	-	-	0	0	0	0	0
Parsley flakes[2]	20	2,75	0,11	0	8	1	6	0.5
	20	23,25	0,93	20	20	20	20	0
	5	-	-	0	0	0	0	0
Vanilla ice cream[2]	20	0,9	0,036	14	14	14	14	0
	20	5,75	0,23	19	19	19	19	0
	5	-	-	0	0	0	0	0
"Harzer" cheese[2] (low inocu-lation level repeated)	20	10,75	0,43	12	20	20	20	0
	20	18,75	0,75	19	20	20	20	0
	5	-	-	0	0	0	0	0
	20	2,3	0,092	16	16	16	16	0
	5	-	-	0	0	0	0	0
Pollack filet[2]	20	5,75	0,23	20	20	18	18	0.5
	20	10,75	0,43	20	20	17	17	1.333
	5	-	-	0	0	0	0	0
Paprika emulsion dye[2]	20	1,85	0,074	16	16	16	16	0
	20	23,25	0,93	20	20	20	20	0
	5	-	-	0	0	0	0	0
Spaghetti[2]	20	0,9	0,036	11	11	11	11	0
	20	2,3	0,092	19	19	19	19	0
	5	-	-	0	0	0	0	0
Ham[2]	20	2,75	0,11	0	5	5	5	0
	20	10,75	0,43	3	20	13	19	0
	5	-	-	0	0	0	0	0
Sausage[2]	20	5,75	0,23	18	18	18	18	0
	20	23,25	0,93	20	20	20	20	0
	5			0	0	0	0	0

1: food samples tested according to the USDA/FSIS method
2: food samples tested according to the FDA-BAM method

DISCUSSION OF MODIFICATION VALDATION APPROVED FEBRUARY 2011 (7)

For this method extension a repeatability study/method comparison with three different food matrices was accomplished. Moreover the in- and exclusivity of the real-time PCR system have been examined with a wide spectrum of different isolates. Therefore the **food**proof *Listeria monocytogenes* Detection Kit (formerly BIOTECON Diagnostics **food**proof® *Listeria monocytogenes* Detection Kit in combination with the **food**proof® ShortPrep II Kit were tested on two different real-time PCR instruments, the LightCycler® 480 System from Roche Diagnostics and the Mx3005P from Agilent/Stratagene. The repeatability study and the inclusivity and exclusivity studies gave the expected results. No deviations occurred all results were within the expected range.

Inclusivity (7)

StrainID	Serotype	Year	Country	Continent	Source	SourceDetails
SLCC5835	1/2a	1983	Canada	North America		
SLCC6204	1/2a	1985	Norway	Europe	animal	sheep
SLCC7053	1/2a	1986	Switzerland	Europe		
SLCC7054	1/2a	1986	Switzerland	Europe		
SLCC7055	1/2a	1986	Switzerland	Europe		
SLCC7149	1/2a	1986	Austria	Europe	food	cheese
SLCC7150	1/2a	1986	Austria	Europe	food	cheese
SLCC7163	1/2a	1986	Switzerland	Europe		
SLCC7165	1/2a	1986	Switzerland	Europe		
SLCC7195	1/2a	1986	Switzerland	Europe	human	new born
SLCC7196	1/2a	1986	France	Europe		
SLCC7197	1/2a	1986	Austria	Europe	food	cheese
SLCC7198	1/2a	1986	Austria	Europe	food	cheese
SLCC7973	1/2a					
SLCC6031	1/2b	1984	France	Europe	animal	mouse
SLCC7059	1/2b	1986	Switzerland	Europe		
SLCC7151	1/2b	1986	Austria	Europe	animal	roe
SLCC7152	1/2b	1986	Austria	Europe	animal	roe
SLCC7354	1/2b	1986	Austria	Europe	food	cheese/meat
SLCC7367	1/2b	1986	Switzerland	Europe	human	
SLCC6793	1/2c	1986	UK	Europe	human	
SLCC7154	1/2c	1986	Switzerland	Europe		
SLCC7290	1/2c	1986	Germany	Europe	human	
SLCC7352	1/2c	1986	Switzerland	Europe	animal	chicken
SLCC7355	1/2c	1986	Austria	Europe	food	cheese/meat
SLCC4949	3a					
SLCC7135	3a	1986	Austria	Europe	food	cheese
SLCC7179	3a	1986	Austria	Europe	food	cheese
SLCC2540	3b	1956	USA	North America	human	new born

StrainID	Serotype	Year	Country	Continent	Source	SourceDetails
SLCC7140	3b	1986	Austria	Europe	food	cheese
SLCC7381	3b	1987	Switzerland	Europe		
SLCC2479	3c	1966				
SLCC5069	4a	1977	Germany GDR	Europe		
SLCC5070	4a	1977	Germany GDR	Europe		
SLCC788	4a	1958			animal	hare
SLCC7064	4ab	1986	Denmark	Europe		
SLCC7069	4ab	1986	Denmark	Europe		
SLCC7083	4ab	1986	Denmark	Europe		
SLCC2375	4b	1953	Germany	Europe	human	
SLCC4013	4b	1973	Germany	Europe	human	

SLCC7056	4b	1986	Switzerland	Europe		
SLCC7057	4b	1986	Switzerland	Europe		
SLCC7058	4b	1986	Switzerland	Europe		
SLCC7060	4b	1986	Switzerland	Europe		
SLCC7061	4b	1986	Denmark	Europe		
SLCC7062	4b	1986	Denmark	Europe		
SLCC7063	4b	1986	Denmark	Europe		
SLCC7064	4b	1986	Denmark	Europe		
SLCC7066	4b	1986	Denmark	Europe		
SLCC7067	4b	1986	Denmark	Europe		
SLCC7068	4b	1986	Denmark	Europe		
SLCC7070	4b	1986	Denmark	Europe		
SLCC7071	4b	1986	Denmark	Europe		
SLCC7072	4b	1986	Denmark	Europe		
SLCC7073	4b	1986	Denmark	Europe		
SLCC7074	4b	1986	Denmark	Europe		
SLCC7075	4b	1986	Denmark	Europe		
SLCC7076	4b	1986	Denmark	Europe		
SLCC7077	4b	1986	Denmark	Europe		
SLCC7078	4b	1986	Denmark	Europe		
SLCC7079	4b	1986	Denmark	Europe		
SLCC7080	4b	1986	Denmark	Europe		
SLCC7081	4b	1986	Denmark	Europe		
SLCC7082	4b	1986	Denmark	Europe		
SLCC7084	4b	1986	Denmark	Europe		
SLCC7085	4b	1986	Denmark	Europe		
SLCC7086	4b	1986	Denmark	Europe		
SLCC7087	4b	1986	Denmark	Europe		
SLCC7088	4b	1986	Denmark	Europe		
SLCC7089	4b	1986	Denmark	Europe		
SLCC7090	4b	1986	Denmark	Europe		
SLCC7091	4b	1986	Denmark	Europe		
SLCC7092	4b	1986	Denmark	Europe		
SLCC7139	4b	1986	Germany	Europe	human	
SLCC7194	4b	1986	Switzerland	Europe	human	new born
SLCC7356	4b	1986	Austria	Europe	food	cheese/meat
SLCC7370	4b	1986	Switzerland	Europe	human	
SLCC7372	4b	1986	Switzerland	Europe	human	
SLCC7373	4b	1986	Switzerland	Europe		
SLCC7374	4b	1986	Switzerland	Europe		
SLCC4925	4c	1964			animal	chicken

StrainID	Serotype	Year	Country	Continent	Source	SourceDetails
SLCC6277	4c	1985	Norway	Europe	animal	sheep
SLCC6813	4c	1986	UK	Europe	human	
SLCC6821	4c	1986	UK	Europe	human	
SLCC6823	4c	1986	UK	Europe	human	
SLCC4926	4e	1964			animal	chicken
SLCC2482	7	1966				

The **food**proof *Listeria monocytogenes* Detection Kit detected various isolates of the species *Listeria monocytogenes*, no false negative results occurred.

Exclusivity (7)

Nr.	Organism	Strain-Nr. (internal)	Strain-Nr. (external)	Source
1	*Brochothrix campestris*	13915	DSM 4712	Soil
2	*Brochothrix thermospacta*	13918	DSM 20171	Fresh pork sausage
3	*Carnobacterium maltaromaticum*	7639	DSM 20730	Diseased rainbow trout
4	*Enterococcus faecalis*	7640	DSM 20478	Urine
5	*Erysipelothrix rhusiopathiae*	14464	DSM 5055	Spleen of pig with endocarditis
6	*Escherichia coli*	7883	NCTC 12790	Unknown
7	*Geobacillus stearothermophilus*	4924	DSM 456	Sugar beet juice from extraction installations
8	*Jonesia denitrificans*	14465	DSM 20603	Boiled ox blood
9	*Lactobacillus casei*	2471	DSM 20011	Cheese
10	*Listeria grayi*	7308		Standing corn stalks and leaves
11	*Listeria grayi*	2828	DSM 20601	Faeces of chinchilla
12	*Listeria grayi*	13948	SLCC 7211	Unknown
13	*Listeria innocua*	2829	DSM 20649	Brain of cow
14	*Listeria innocua*	3903	NCTC 10528	Unknown
Nr.	**Organism**	**Strain-Nr. (internal)**	**Strain-Nr. (external)**	**Source**
15	*Listeria innocua*	13962	SLCC 6362	Sheep
16	*Listeria ivanovii* subsp. *ivanovii*	2831	DSM 20750	Sheep
17	*Listeria ivanovii*	7299	SLCC 2028	Food
18	*Listeria ivanovii*	7303	SLCC 4121	Leaves
19	*Listeria seeligeri*	2832	DSM 20751	Unknown
20	*Listeria seeligeri*	6920	SLCC 7307	Cheese
21	*Listeria seeligeri*	6923	SLCC 3954	Soil
22	*Listeria welshimeri*	2830	DSM 20650	Decaying plant material
23	*Listeria welshimeri*	6914	SLCC 767	Unknown
24	*Listeria welshimeri*	6918	SLCC 6199	Human
25	*Macrococcus caseolyticus*	14431	DSM 20597	Skin of irish thoroughbred horse
26	*Pseudomonas aeruginosa*	5592	ATCC 10145	Water
27	*Salmonella enterica* subsp. *enterica* (Enteritidis)	14151	2627/00	Human stool
28	*Staphylococcus haemolyticus*	8740	DSM 20264	Human skin
29	*Staphylococcus hominis*	15362		Human skin
30	*Weissella confusa*	10501	DSM 20196	Sugar cane

The **food**proof® *Listeria monocytogenes* Detection Kit was specific for *Listeria monocytogenes* on both real-time PCR instruments, no false positive results occurred.

Table 3: Results of the repeatability study with 3 food matrices tested and microbiologically according to the FDA-BAM or USDA/FSIS methods (7)

Food	No. of Samples	Inoculation Level (Determination via MPN) cells per 25 gram	Inoculation Level cells per 1 gram	PCR 24 h	PCR 48 h	Cultural Con-firmation	FDA-BAM or USDA/FSIS 24 h	FDA-BAM or USDA/FSIS 48 h	total
Soft Cheese*	20	0.5	0.02	2	5	5	1	5	5
	20	4	0.16	10	13	13	8	13	13
	5	-	-	0	0	0	0	0	0
Coal Fish*	20	0.75	0.03	4	9	9	7	5	8
	20	5.25	0.21	12	16	16	15	16	16
	5	-	-	0	0	0	0	0	0
Smoked Ham**	20	1.75	0.07	3	7	7	3	5	5
	20	2.75	0.11	8	11	10	11	9	11
	5	-	-	0	0	0	0	0	0

* Food matrix tested according to the FDA-BAM method

** Food matrices tested according to the USDA/FSIS method

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