



CERTIFICATE OF COMPLIANCE LRQA

hereby declares that the certification assessment has demonstrated that

foodproof Salmonella Detection Kits (Cat. No. R 310 27 or R 302 27), combined with Reagent D (Cat. No. A500 02 and foodproof StarPrep One Kit (Cat. No. S 400 07) or foodproof Magnetic Preparation Kit IV (Cat. No. S 400 15) for DNA extraction

Manufactured and supplied by: Hygiena Diagnostics GmbH Hermannswerder 17 14473 Potsdam Germany

has been validated and revealed to be at least equivalent to the reference method as demonstrated by the validation study report, which has been prepared by a MicroVal Expert Laboratory and approved by the MicroVal Technical Committee. The above-mentioned production facility complies to the QMS requirements as mentioned in the MicroVal Rules. The summary of the validation report is available on the MicroVal website: www.microval.org

Reference method: ISO 6579-1:2017; Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of *Salmonella* – Part 1: Detection of *Salmonella* spp.

Scope: Infant formula and infant cereals, Probiotics containing products, Ingredients, and Environmental samples

The validation and certification has been performed in accordance with EN ISO 16140-2:2016 and the MicroVal Rules.

Certificate no.: 2011LR39 First approval date: 22 October 2012

Surveillance date: 11 October 2024 Expiry date: 21 October 2028

ISSUED BY: LRQA Nederland B.V.

Rotterdam, The Netherlands

Certificate no.: 2011LR39 11-10-2024 Page 1 of 2



The overview on the claims for the current LR39 certificate is given in the Table below:

Detection of Salmonella

	Enrichment	Standard protocol: 100 g sample material* plus 900 ml BPW pre-warmed at 37 °C, $16 - 20 \text{ h}$ at 37 °C $\pm 1 \text{ °C}$									
	Subcultivation	Standard protocol P1: 100 μl of BPW culture in 900 μl BPW, 3 - 4 h at 37 °C ±1 °C (shaking at 900 U/min)									
		Specific protocol P2: 100 μ l of BPW culture in 900 μ l BPW, 20 - 24 h at 37 °C ± 1 °C (shaking at 900 U/min)									
	Reagent D treatment	A 500 02									
	DNA extraction	Manua		odproof StarPrep One Kit			Automated protocol food proof MagPrep IV Kit S 400 15				
	Real-time PCR, pre-screening on EB	food proof EBC detection kit, Hybridization probes		foodproof EBC detection kit, 5'Nuclease			food proof EBC detection kit, Hybridization probes		food proof EBC detection kit, 5'Nuclease		
		R 310 15.1		R 302 15.1			R 310 15.1		R 302 15.1		
	Real-time PCR, Salmonella detection	food proof S detection kit, Hybridization probes		food proof S detection kit, 5'Nuclease			food proof S detection kit, Hybridization probes		food proof S detection kit, 5'Nuclease		
		R 310 27		R 302 27			R 310 27		R 302 27		
	Thermocyclers	LC 480 II	LC 2.0	LC 480 II	IQ5	Mx 3005	LC 480 II	LC 2.0	LC 480 II	IQ5	Mx 3005
	Software version	1.5.1	4.1	1.5.1	2.0	MX4.1d	1.5.1	4.1	1.5.1	2.0	MX4.1d
uo	Infant formula and infant cereals (P1)	Х	Х	Х	Х	Х	х	Х	Х	Х	Х
bcultivati	Probiotics containing products (P1)	х	Х	х	х	Х					
Scope (including subcultivation	Probiotics containing products (P2)	х	Х	х	х	Х	х	х	х	х	Х
ope (in	Ingredients (P1)	Х	Х	Х	Х	Х					
Sc	Environmental samples (P1)	Х	Х	х	х	Х					

^{*}specific sample preparations: see EBC detection kit inserts

Certificate no.: 2011LR39 11-10-2024 Page 2 of 2