



CERTIFICATE OF COMPLIANCE

LRQA

hereby declares that the certification assessment has demonstrated that

foodproof® *Enterobacteriaceae* plus *Cronobacter* Detection Kits (Cat. No. R 310 15.1 or R 302 15.1), 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:
Hygiëna 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. The summary of the validation report is available on the MicroVal website: www.microval.org

Reference methods:

1. ISO 21528-1:2017 Microbiology of the food chain - Horizontal method for the detection and enumeration of *Enterobacteriaceae* - Part 1: Detection of *Enterobacteriaceae*
2. ISO 22964:2017 Microbiology of the food chain - Horizontal method for the detection of *Cronobacter* spp.

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

The validation and certification has been performed in accordance with EN ISO 16140-2:2016 and the MicroVal Rules and Certification Scheme version 8.

Certificate no.: 2007LR08091920

First approval date: 6 July 2010

Renewal date: 24 June 2022

Expiry date: 5 July 2026

ISSUED BY: LRQA Nederland B.V.
Rotterdam, The Netherlands



The overview on the claims for the current LR8/9/19/20 certificate is given in the Table below:

Detection of *Enterobacteriaceae* and/or detection of *Cronobacter* spp.

| | | | | | | | | | | | | |
|----------------------------------|---|--------|--|-----|----------|---------|--|--------|--|-----|----------|---------|
| Enrichment | Standard protocol: 100 g sample material* plus 900 ml BPW pre-warmed at 37 °C, 16 - 20 h at 37 °C ± 1 °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 µl of BPW culture in 900 µl BPW, 20 - 24 h at 37 °C ± 1 °C (shaking at 900 U/min) | | | | | | | | | | | |
| Reagent D treatment | A 500 02 | | | | | | | | | | | |
| DNA extraction | Manual protocol foodproof StarPrep One Kit | | | | | | Automated protocol foodproof MagPrep IV Kit | | | | | |
| | S 400 07 | | | | | | S 400 15 | | | | | |
| Real-time PCR | foodproof EBC detection kit, Hybridization probes | | foodproof EBC detection kit, 5'Nuclease | | | | foodproof EBC detection kit, Hybridization probes | | foodproof EBC detection kit, 5'Nuclease | | | |
| | R 310 15.1 | | R 302 15.1 | | | | R 310 15.1 | | R 302 15.1 | | | |
| Thermocyclers | LC 480 II | LC 2.0 | LC 480 II | IQ5 | ABI 7500 | Mx 3005 | LC 480 II | LC 2.0 | LC 480 II | IQ5 | ABI 7500 | Mx 3005 |
| Software version | 1.5.1 | 4.1 | 1.5.1 | 2.0 | 2.0.6 | MX4.1 d | 1.5.1 | 4.1 | 1.5.1 | 2.0 | 2.0.6 | MX4.1 d |
| Scope (including subcultivation) | Infant formula and infant cereals (P1) | X | X | X | X | X | X | X | X | X | X | X |
| | Probiotics containing products (P1) | X | X | X | X | X | X | X | X | X | X | X |
| | Probiotics containing products (P2) | X | X | X | X | X | X | X | X | X | X | X |
| | Ingredients (P1) | X | X | X | X | X | X | X | X | X | X | X |
| | Environmental samples (P1) | X | X | X | X | X | X | X | X | X | X | X |

*specific sample preparations: see detection kit inserts