

Validation of the Hygiena™ foodproof® *Salmonella* Genus plus Enteritidis & Typhimurium PCR Kit for Raw and Ready-to-Cook Meat and Poultry Products and Environmental Samples

Identification of the most relevant serovars for human and animal health, *S. Enteritidis* and *S. Typhimurium*, is critical when managing the food production chain from farm-to-fork to reduce consumer risk. Global regulations concerning these serovars require test methods to be robust in sensitivity and specificity to ensure reliable and accurate results.



Validation Methods

- The study comprises inclusivity of 75 *Salmonella* spp., 25 *S. Enteritidis*, 25 *S. Typhimurium* strains, and 30 exclusivity non-target strains, sensitivity, relative level of detection (RLOD) and collaborative studies.
- Validation of the alternative method was performed and compared to the cultural reference method for:
 - Raw Meat and Poultry (25 g)
 - Ready-to-Cook Meat and Poultry (25 g)
 - Environmental Samples
- Samples were enriched in:
 - Buffered Peptone Broth 1:10 at 37°C ± 1°C for 16 h - 20 h
- Following incubation, DNA extraction was performed with **foodproof®** StarPrep Three Kit (bulk or 8-strip), then lysates were analyzed by real-time PCR.



Bulk Extraction Option

8-Strip Extraction Option

Validation Results

- The validation study (NordVal No. 055) indicated that the alternative method performs equally compared to reference method EN ISO 6579-1:2017 and 6579-3:2014 and fulfills the validation criteria according to EN ISO 16140-2:2016.
- The specificity studies yielded:
 - 100% inclusivity of all target strains
 - 100% exclusivity of all non-target strains
- Additionally, the acceptability limits for the sensitivity and the Relative LOD studies for all categories and enrichment protocols were met.

Industry Significance

- This validation provides a multiplex real-time PCR assay that is a rapid and reliable alternative method for the detection of *Salmonella* spp., *Salmonella* Enteritidis and *Salmonella* Typhimurium in raw and ready-to-cook meat and poultry products and environmental samples.
- The **foodproof®** assays have a wide range of extraction options and compatible instruments like the ABI7500 and BAX® Q7 Systems.
- Ability to utilize a single assay to not only screen for *Salmonella*, but also to identify regulated strains using the same enrichment, lysate, and assay improves operational efficiencies throughout food production and environmental monitoring, as well as high throughput testing laboratories.