

Performance Summary

iQ-Check *S. Enteritidis* and *S. Typhimurium* Methods



Introduction

The iQ-Check *S. Enteritidis* and *S. Typhimurium* PCR Detection Kits are tests based on gene amplification and detection by real-time PCR after food and environmental samples are enriched in buffered peptone water (BPW) or supplemented BPW, depending on the matrix being tested. Ready-to-use PCR reagents contain oligonucleotides (primers and probes) highly specific for *Salmonella* Enteritidis or *S. Typhimurium*. A synthetic DNA internal control is included in the reaction mix. An internal control is critical in any reaction to monitor for inhibitors and allow for the validation of any negative result. The iQ-Check *S. Enteritidis* and *S. Typhimurium* methods have been rigorously tested and validated by an internationally recognized validation agency for direct screening of samples and as part of the confirmation process (Table 1).

Table 1. Validations for the iQ-Check *S. Enteritidis* and *S. Typhimurium* methods.

Validation	Certificate Number
AOAC for <i>S. Enteritidis</i>	PTM 081903
AOAC for <i>S. Typhimurium</i>	PTM 081904

Inclusivity/Exclusivity Testing

Inclusivity testing is performed to verify that the method can detect *S. Enteritidis* or *S. Typhimurium*, while exclusivity studies test non-*S. Enteritidis* and non-*S. Typhimurium* strains to ensure there is no cross-reactivity for the strains tested.* Exclusivity strains were enriched in BPW and supplemented BPW for 18–24 hr at 37 ± 2°C and were tested at high levels. A single colony of each *S. Enteritidis* and *S. Typhimurium* inclusivity strain was cultured in BPW and supplemented BPW for 18–24 hr at 37 ± 2°C and diluted to a low level (~10³) before testing. Results are shown in Table 2.

Table 2. Results of inclusivity/exclusivity testing.

Strains Tested	Positives Detected	Results
50 <i>S. Enteritidis</i> strains tested	50/50	100% inclusivity
50 <i>S. Typhimurium</i> strains tested	50/50	100% inclusivity
154 non- <i>S. Enteritidis</i> strains tested†	0/154	100% exclusivity
165 non- <i>S. Typhimurium</i> strains tested††	0/165	100% exclusivity

† Including 97 non-*Enteritidis* *Salmonella* strains.

†† Including 106 non-*Typhimurium* *Salmonella* strains.

* Variability of *Salmonella* serotypes occurs often, especially in wild-type strains. Therefore, complete serotyping with a *Salmonella* antisera method is recommended in a confirmation process.

Limit of Detection

Limit of detection (LOD₅₀) is an estimation of the contamination level required to achieve positive detection in 50% of cases. This is measured by inoculating food matrices with *S. Enteritidis* or *S. Typhimurium* strains and carrying out the validated enrichment, extraction, and detection protocols (Tables 3 and 4).

The average LOD₅₀ of the iQ-Check *S. Enteritidis* method was determined to be 0.6 (range: 0.3–1.2). The average LOD₅₀ of the iQ-Check *S. Typhimurium* method was determined to be 0.6 (range: 0.3–1.3).

Table 3. LOD₅₀ for the iQ-Check *S. Enteritidis* method.

Matrix/Strain Pair	Enrichment	LOD ₅₀ , CFU/ sample size (range)
Skinless raw chicken breast/ <i>S. Enteritidis</i>	BPW	0.6 (0.3–1.1)
Raw chicken breast with skin/ <i>S. Enteritidis</i>	BPW	0.5 (0.3–0.8)
Skinless raw chicken breast 2% w/w salt/ <i>S. Enteritidis</i>	BPW	0.7 (0.4–1.2)
Skinless raw chicken thigh/ <i>S. Enteritidis</i>	BPW	0.6 (0.3–1.1)
Raw chicken thigh with skin/ <i>S. Enteritidis</i>	BPW	0.7 (0.4–1.2)

Table 4. LOD₅₀ for the iQ-Check *S. Typhimurium* method.

Matrix/Strain Pair	Enrichment	LOD ₅₀ , CFU/ sample size (range)
Skinless raw chicken breast/ <i>S. Typhimurium</i>	BPW	0.6 (0.4–1.2)
Raw chicken breast with skin/ <i>S. Typhimurium</i>	BPW	0.6 (0.4–1.1)
Skinless raw chicken breast 2% w/w salt/ <i>S. Typhimurium</i>	BPW	0.7 (0.3–1.2)
Skinless raw chicken thigh/ <i>S. Typhimurium</i>	BPW	0.6 (0.4–1.1)
Raw chicken thigh with skin/ <i>S. Typhimurium</i>	BPW	0.7 (0.4–1.3)

Method Comparison/Matrix Studies

Matrix testing is critical to demonstrating the performance of a method compared to the reference method with real-world food samples. The iQ-Check S. Enteritidis and S. Typhimurium methods have been verified with external and internal testing on a wide variety of foods. No significant difference was found between the reference method and alternative method for all matrices tested (Table 5).

Table 5. Matrices tested with the iQ-Check S. Enteritidis and S. Typhimurium methods.

Category	Matrices Tested
Meat products	Skinless raw chicken breast, raw chicken breast with skin, skinless raw chicken breast 2% w/w salt, skinless raw chicken thigh, raw chicken thigh with skin
Primary production	Boot/drag swab

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