

Performance Summary

iQ-Check *Campylobacter* Method



Introduction

The iQ-Check *Campylobacter* PCR Detection Kit is a test based on gene amplification and detection by real-time PCR after food and environmental samples are enriched in Bolton Broth or double-strength blood-free Bolton Enrichment Broth (2x BF-BEB). Ready-to-use PCR reagents contain oligonucleotides (primers and probes) highly specific for *Campylobacter jejuni*, *C. coli*, and *C. lari*. A synthetic DNA internal control is included in the reaction mix. An internal control is critical in any reaction to monitor for inhibitors and allows for the validation of any negative result. The iQ-Check *Campylobacter* method has been rigorously tested and validated by an internationally recognized validation agency (Table 1).

Table 1. Validation for the iQ-Check *Campylobacter* method.

Validation	Certificate Number
AOAC	PTM 031209

Inclusivity/Exclusivity Testing

Inclusivity testing is performed to verify that the method can detect *C. jejuni*, *C. coli*, and *C. lari* while exclusivity studies test non-*Campylobacter* strains to ensure there is no cross-reactivity. Exclusivity strains were enriched in nonselective broth for 24 hr at $37 \pm 1^\circ\text{C}$ and were tested at high levels. A single colony of each *Campylobacter* inclusivity strain was cultured in Bolton Broth under microaerobic atmospheric conditions for 24 hr at $41.5 \pm 1^\circ\text{C}$ and diluted to a low level ($\sim 10^3$) before testing. Results are shown in Table 2.

Table 2. Results of inclusivity/exclusivity testing.

Strains Tested	Positives Detected	Results
50 <i>Campylobacter</i>	100/100	100% inclusivity
35 non- <i>Campylobacter</i>	0/50	100% exclusivity

Limit of Detection

Limit of detection (LOD_{50}) is an estimation of the contamination level required to achieve positive detection in 50% of cases. This is measured by inoculating food matrices with *Campylobacter* strains and carrying out the validated enrichment, extraction, and detection protocols (Table 3).

Table 3. LOD_{50} for the iQ-Check *Campylobacter* method.

Matrix/Strain Pair	Enrichment	LOD_{50}^* CFU/sample size (range)
Raw ground chicken/ <i>C. lari</i>	Bolton Broth	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 *Campylobacter* method has 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 4).

Table 4. Matrices tested with the iQ-Check *Campylobacter* method.

Category	Matrices Tested
Meat products	Chicken carcass rinses, turkey carcass swabs, raw ground chicken
Primary production	Boot socks, neck skin, caecum

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