

Performance Summary

iQ-Check *E. coli* O157:H7 Method



Introduction

The iQ-Check *E. coli* O157:H7 PCR Detection Kit is a test based on gene amplification and detection by real-time PCR after food and environmental samples are enriched in buffered peptone water (BPW). Ready-to-use PCR reagents contain oligonucleotides (primers and probes) highly specific for *Escherichia coli* O157:H7. 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 *E. coli* O157:H7 method has been rigorously tested and validated by internationally recognized validation agencies (Table 1).

Table 1. Validations for the iQ-Check *E. coli* O157:H7 method.

Validation	Certificate Number
AOAC	PTM 020801
NF Validation	BRD 07/15-06/08
USDA FSIS MLG	Chapter 5C.00

Inclusivity/Exclusivity Testing

Inclusivity testing is performed to verify that the method can detect *E. coli* O157:H7 while exclusivity studies test non-*E. coli* O157:H7 organisms, including other *E. coli* strains, to ensure there is no cross-reactivity. Exclusivity strains were enriched in nonselective broth for 24 hr at $41.5 \pm 1^\circ\text{C}$ and were tested at high levels. A target of 10–100 colony forming units (CFU) of each *E. coli* O157:H7 inclusivity strain was cultured in BPW for 8 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/Identified	Results
100 <i>E. coli</i> O157:H7 strains tested	100/100	100% inclusivity
84 non- <i>E. coli</i> O157:H7 strains tested	0	100% exclusivity

Limit of Detection

Limit of detection (LOD_{50}) is an estimate of the contamination level required to achieve positive detection in 50% of cases. This is measured by inoculating food matrices with *E. coli* O157:H7 strains and carrying out the validated enrichment, extraction, and detection protocols (Table 3).

The average LOD_{50} of the iQ-Check *E. coli* O157:H7 method was determined to be 0.6 (range: 0.4–0.9).

Table 3. LOD_{50} for the iQ-Check *E. coli* O157:H7 method.

Matrix/Sample Pair	LOD_{50} , CFU/sample size (range)
Veal (25 g)/ <i>E. coli</i> O157:H7	0.5 (0.3–1.0)
Ground beef (375 g)/ <i>E. coli</i> O157:H7	0.7 (0.4–1.2)

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 *E. coli* O157:H7 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 *E. coli* O157:H7 method.

Category	Matrices Tested
Meat products Raw and RTC, RTE and RTRH	Raw and RTC: Ground beef, beef trim, beef sampling cloth (4 x 4"), chicken breast, chicken thigh, mechanically separated chicken, ground pork, pork trim, lamb, veal RTE and RTRH: Sausage
Diary products Raw milk and products	Raw milk and products: Raw milk (cow, sheep, goat), raw milk cheese (cow, sheep, goat)
Produce Fresh, processed	Fresh: Spinach Processed: Apple cider

RTC, ready to cook; RTE, ready to eat; RTRH, ready to reheat.

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