# CERTIFICATION

## AOAC® *Performance Tested*SM

Certificate No.

**070801**

**The AOAC Research Institute hereby certifies that the method known as:**

## RapidChek® *E. coli* O157 (including H7) Lateral Flow Test Assay

manufactured by

**Romer Labs**
**130 Sandy Drive**
**Newark, DE 19713**
**USA**

This method has been evaluated in the AOAC® *Performance Tested Methods*SM Program and found to perform as stated by the manufacturer contingent to the comments contained in the manuscript. This certificate means that an AOAC® Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC *Performance Tested*SM certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER'S SPECIFICATIONS" - on the above-mentioned method for a period of one calendar year from the date of this certificate (November 20, 2021 – December 31, 2022). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Scott Coates

Scott Coates, Senior Director
Signature for AOAC Research Institute

November 20, 2021
Date

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**MODIFICATION MAY 2008: Strategic Diagnostics, Inc.**
**MODIFICATION OCTOBER 2009: Meredith Sutzko**

**SUBMITTING COMPANY**
**Strategic Diagnostics, Inc.**
**128 Sandy Drive**
**Newark, DE 19713**

**CURRENT SPONSOR**
**Romer Labs**
**130 Sandy Drive**
**Newark, DE 19713**

**KIT NAME(S)**
RapidChek® *E. coli* O157 (including H7) Lateral Flow Test Assay

**CATALOG NUMBERS**
**Original catalog numbers:** 3000037, 7000157, 7000157P, 7000157S, 7000158, 7000160, 7000161, 7000165
Updated catalog numbers: 10001179, 10001355, 10001686, 10001687, 10001688, 100001356, 10001359, 10001360

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**APPLICABILITY OF METHOD**
**Target organism – *E. coli* O157 (including H7)**

**Matrixes – (25 g) -Raw ground beef, boneless beef trim**

**MODIFICATION OCTOBER 2009 Modification: (375 g) - raw ground beef, beef trim samples**

**Performance claims - The immunochromatographic test strip-based RapidChek® *E. coli* O157 (including H7) (formerly RapidChek SELECT *E. coli* O157 method) was evaluated and shown to give 100% sensitivity (inclusivity) and 100% specificity (exclusivity) in this study**

**REFERENCE METHODS**
**USDA FSIS (2002) MLG. Chapter 5; revision 3; Detection, Isolation and Identification of *Escherichia coli* O157:H7 and *E. coli* O157:NM (Nonmotile) from Meat Products. (2)**
**Cray, W.C., Abbot, D.O., Beacorn, F.J. and Benson, S.T. (1998) Chapter 5; revision 2: Detection, isolation and identification of *Escherichia coli* O157:H7 and *E. coli* O157:NM from meat products. USDA/FSIS Microbiology Laboratory Guidebook, 3rd Edition, 1998, Volumes 1 & 2, U.S. Government Printing Office, Washington, D.C. (3)**

**ORIGINAL CERTIFICATION DATE**
**July 25, 2002**

**CERTIFICATION RENEWAL RECORD**
**Renewed annually through December 2022.**

**METHOD MODIFICATION RECORD**
1. **May 2008**
2. **October 2009**
3. **2009 – 2010**
4. **December 2012 Level 1**
5. **November 2018 Level 1**
6. **May 2019 Level 1**

**SUMMARY OF MODIFICATION**
1. **Filter pad component change**
2. **Matrix Extension**
3. **Certification not renewed in 2009. Reinstated 2010 with name change**
4. **Name change from Strategic Diagnostics to Romer**
5. **Editorial and formatting changes to insert.**
6. **Updated catalog numbers**

**Under this AOAC® *Performance Tested*SM License Number, 070801 this method is distributed by:**
**NONE**

**Under this AOAC® *Performance Tested*SM License Number, 070801 this method is distributed as:**
**NONE**

**PRINCIPLE OF THE METHOD (1)**
The Romer Labs RapidChek® *E. coli* O157 (including H7) Test Kit method is an immunoassay-based test that uses anti-*E. coli* O157 spp. antibodies (Abs) and colloidal gold-antibody conjugates incorporated into a lateral flow test strip. The method utilizes a proprietary enrichment broth (8 h, 42˚C).
Following enrichment, the test strip is placed into the tube containing the enrichment broth. The liquid sample flows through the test strip where it re-hydrates antibody-coated colloidal gold reagents specific to *E. coli* O157 spp impregnated in the strip. If antigens are present in the sample, they will bind to the antibody-gold conjugate to form an antigen/antibody complex. As this complex migrates through the nitrocellulose matrix, it passes a zone of anti-*E. coli* O157 antibody immobilized on the nitrocellulose membrane (the test line). If antigen is present, the complex is captured in this zone and is visualized by the formation of a red line. A second zone on the membrane (the control line) is designed to capture any antibody-gold complex not bound in the first zone. As a result, when *E. coli* O157 antigen is present, the formation of 2 red lines is observed, whereas when *E. coli* O157 is not present, only 1 line forms.
This validation report was prepared for claims to detect *E. coli* O157 (including H7) in raw ground beef and raw boneless beef trim using the SDI RapidChek® *E. coli* O157 (including H7) Test Kit method

**DISCUSSION OF THE VALIDATION STUDY (1)**

The RapidChek *E. coli* O157 (including H7) test method was shown to be highly effective in detecting *E. coli* O157 in raw ground beef and raw boneless beef. A total of 160 samples were tested internally using *E.* coli O157-inoculated food samples (target levels of 1 to 10 CFU/ 25g sample) in method comparison studies. The RapidChek and SELECT methods reported greater numbers of positive results than the reference method in both matrixes. Thirty-four (34) samples were confirmed positive with 225mL RapidChek media, thirty-six (36) samples were confirmed positive with 112.5mL RapidChek SELECT media, thirty-nine (39) samples were confirmed positive with 225mL RapidChek SELECT media, and only twenty-three (23) samples were confirmed positive by the reference method. All test method presumptive positive tested positive on BAX PCR validating the use of the proprietary enrichment media on the BAX PCR system. The total aerobic plate count ranged from $3.5 \times 10^3$ to $7.2 \times 10^3$ CFU/g. Seven false negatives were reported with the test methods. They were detected only after the immunomagnetic concentration step. Eight false negatives were evident by the BAX screen of reference method samples. The accuracy of the method was as follows: 225mL RapidChek test method was 148% accurate, 112.5mL RapidChek SELECT test method was 157% accurate, and 225mL RapidChek SELECT test method was 170% accurate. The RapidChek SELECT *E. coli* method was tested with 50 strains of *E. coli* O157 and 50 strains of non-*E. coli* O157 bacteria commonly found in food. The test method detected 50 of the *E. coli* O157 strains and none of the non-*E. coli* O157 bacteria, resulting in a sensitivity of 100% and specificity of 100%. The method was highly robust and stable under control (4 to 25°C) and accelerated stability conditions (37 to 45°C).

**Table 1. Results from Inclusivity Study (1)**

| | Organism | Serotype | Code | Number | Source | Test Reactivity |
|---|---|---|---|---|---|---|
| 1 | *E. coli* | O157:H7 | ATCC | 51658 | Clinical Isolate | + |
| 2 | *E. coli* | O157:H7 | ATCC | 700728 | Unknown | + |
| 3 | *E. coli* | O157:H7 | ATCC | 43895 | Clinical Isolate | + |
| 4 | *E. coli* | O157:NM | ATCC | 700377 | Clinical Isolate | + |
| 5 | *E. coli* | O157:H7 | ATCC | 43890 | Clinical Isolate | + |
| 6 | *E. coli* | O157:H7 | ATCC | 700531 | Clinical Isolate | + |
| 7 | *E. coli* | O157:NM | ATCC | 700376 | Clinical Isolate | + |
| 8 | *E. coli* | O157:H7 | ATCC | 35150 | Clinical Isolate | + |
| 9 | *E. coli* | O157:H7 | ATCC | 43889 | Human feces | + |
| 10 | *E. coli* | O157:H7 | ATCC | 51657 | Human feces | + |
| 11 | *E. coli* | O157:H7 | CDC | A9218-C1 | Food | + |
| 12 | *E. coli* | O157 | PSU | 53 | Human feces | + |
| 13 | *E. coli* | O157 | PSU | 54 | Cow feces | + |
| 14 | *E. coli* | O157 | PSU | 59 | Pig intestine | + |
| 15 | *E. coli* | O157 | PSU | 61 | Cow Isolate | + |
| 16 | *E. coli* | O157 | PSU | 64 | Cow Isolate | + |
| 17 | *E. coli* | O157 | PSU | 66 | Food | + |
| 18 | *E. coli* | O157 | PSU | 68 | Human Isolate | + |
| 19 | *E. coli* | O157 | PSU | 69 | Cow Isolate | + |
| 20 | *E. coli* | O157 | PSU | 70 | Cow Isolate | + |
| 21 | *E. coli* | O157 | PSU | 71 | Human feces | + |
| 22 | *E. coli* | O157 | PSU | 79 | Chicken Isolate | + |
| 23 | *E. coli* | O157 | PSU | 80 | Human feces | + |
| 24 | *E. coli* | O157:H7 | R&F | 235 | Food | + |
| 25 | *E. coli* | O157:H7 | R&F | 225 | Food | + |
| 26 | *E. coli* | O157:H7 | R&F | 234 | Food | + |
| 27 | *E. coli* | O157:H7 | R&F | 223 | Clinical Isolate | + |
| 28 | *E. coli* | O157:H7 | R&F | 224 | Food | + |
| 29 | *E. coli* | O157:H7 | R&F | 219 | Apple Cider | + |
| 30 | *E. coli* | O157:H7 | R&F | 220 | Food | + |
| 31 | *E. coli* | O157:H7 | R&F | 221 | Beef Isolate | + |
| 32 | *E. coli* | O157:NM | R&F | 244 | Clinical, Iowa | + |
| 33 | *E. coli* | O157:H7 | R&F | 248 | Clinical, Iowa | + |
| 34 | *E. coli* | O157:H7 | R&F | 249 | Clinical, Iowa | + |
| 35 | *E. coli* | O157:H7 | R&F | 252 | Apple Cider | + |
| 36 | *E. coli* | O157:H7 | R&F | 377 | Ground Beef | + |
| 37 | *E. coli* | O157:H7 | R&F | 401 | Beef Isolate | + |
| 38 | *E. coli* | O157:H7 | Silliker | 1675 | Unknown | + |
| 39 | *E. coli* | O157: H - | TW | 6558 | Clinical Isolate | + |
| 40 | *E. coli* | O157:NM | USDA | 8302 | Clinical Isolate | + |
| 41 | *E. coli* | O157:H7 | USDA | C7927 | Clinical Isolate | + |
| 42 | *E. coli* | O157:H7 | USDA | C9490 | Clinical Isolate | + |
| 43 | *E. coli* | O157:H7 | USDA | 45753-32 | Food | + |
| 44 | *E. coli* | O157:H7 | USDA | A8959-C7 | Clinical Isolate | + |
| 45 | *E. coli* | O157:H7 | USDA | 3417-85 | Clinical Isolate | + |
| 46 | *E. coli* | O157:H7 | USDA | 505B | Beef Isolate | + |
| 47 | *E. coli* | O157:H7 | USDA | 413-95 | Food | + |
| 48 | *E. coli* | O157:H7 | USDA | 45750 | Food | + |
| 49 | *E. coli* | O157:H7 | USDA | 45753-35 | Food | + |
| 50 | *E. coli* | O157:H7 | USDA | 380-94 | Clinical Isolate | + |

**Table 2. Results from the Exclusivity Study (1)**

| | Organism | | Code | Number | Serotype | Test Reactivity |
|---|---|---|---|---|---|---|
| 1 | *Aeromonas* | *hydrophila* | ATCC | 35654 | not applicable (na) | - |
| 2 | *Aeromonas* | *hydrophila* | ATCC | 49140 | na | - |
| 3 | *Aeromonas* | *veronii* | ATCC | 9071 | na | - |
| 4 | *Aeromonas* | *veronii* | ATCC | 51106 | na | - |
| 5 | *Bacillus* | *brevis* | SDI | 87a | na | - |
| 6 | *Bacillus* | *cereus* | ATCC | 11778 | na | - |
| 7 | *Bacillus* | *cereus* | ATCC | 12826 | na | - |
| 8 | *Bacillus* | *subtilis* | ATCC | 27370 | na | - |
| 9 | *Citrobacter* | *amalonaticus* | ATCC | 25405 | na | - |
| 10 | *Citrobacter* | *amalonaticus* | ATCC | 25406 | na | - |
| 11 | *Citrobacter* | *braakii* | ATCC | 12012 | na | - |
| 12 | *Citrobacter* | *braakii* | ATCC | 43162 | na | - |
| 13 | *Citrobacter* | *braakii* | ATCC | 51113 | na | - |
| 14 | *Citrobacter* | *farmeri* | ATCC | 51112 | na | - |
| 15 | *Citrobacter* | *freundii* | ATCC | 8090 | na | - |
| 16 | *Citrobacter* | *freundii* | ATCC | 43864 | na | - |
| 17 | *Citrobacter* | *koseri* | ATCC | 27026 | na | - |
| 18 | *Citrobacter* | *sedlakii* | ATCC | 51115 | na | - |
| 19 | *Citrobacter* | *werkmanii* | ATCC | 51114 | na | - |
| 20 | *Citrobacter* | *youngae* | ATCC | 11102 | na | - |
| 21 | *Citrobacter* | *youngae* | ATCC | 11606 | na | - |
| 22 | *Enterobacter* | *aerogenes* | ATCC | 15038 | na | - |
| 23 | *Enterobacter* | *cloacae* | ATCC | 13047 | na | - |
| 24 | *Enterobacter* | *cloacae* | ATCC | 23355 | na | - |
| 25 | *Enterobacter* | *cloacae* | ATCC | 27508 | na | - |
| 26 | *Escherichia* | *blattae* | ATCC | 33430 | na | - |
| 27 | *Escherichia* | *coli* | ATCC | 4157 | unknown | - |
| 28 | *Escherichia* | *coli* | ATCC | 8739 | unknown | - |
| 29 | *Escherichia* | *coli* | ATCC | 12014 | O55:K59(B5):H- | - |
| 30 | *Escherichia* | *coli* | USDA | 12795 | O26:K60(B6) | - |
| 31 | *Escherichia* | *coli* | ATCC | 23316 | unknown | - |
| 32 | *Escherichia* | *coli* | ATCC | 23980 | O91:K.:NM | - |
| 33 | *Escherichia* | *coli* | ATCC | 51446 | unknown | - |
| 34 | *Escherichia* | *coli* | | 95.0122 | O111 | - |
| 35 | *Escherichia* | *coli* | | 96.154 | O113 | - |
| 36 | *Escherichia* | *coli* | | 99.0849 | O26 | - |
| 37 | *Escherichia* | *hermanii* | ATCC | 33650 | na | - |
| 38 | *Escherichia* | *vulneris* | ATCC | 33821 | na | - |
| 39 | *Hafnia* | *alvei* | ATCC | 25927 | na | - |
| 40 | *Klebsiella* | *oxytoca* | ATCC | 8724 | na | - |
| 41 | *Klebsiella* | *oxytoca* | ATCC | 43165 | na | - |
| 42 | *Klebsiella* | *oxytoca* | ATCC | 43863 | na | - |
| 43 | *Klebsiella* | *pneumoniae* | ATCC | 4352 | na | - |
| 44 | *Klebsiella* | *pneumoniae* | ATCC | 8308 | na | - |
| 45 | *Klebsiella* | *pneumoniae* | ATCC | 27736 | na | - |
| 46 | *Proteus* | *mirabilis* | ATCC | 4630 | na | - |
| 47 | *Proteus* | *mirabilis* | ATCC | 14153 | na | - |
| 48 | *Proteus* | *vulgaris* | ATCC | 6380 | na | - |
| 49 | *Proteus* | *vulgaris* | ATCC | 8427 | na | - |
| 50 | *Salmonella* | *anatum* | ATCC | 9270 | na | - |
| 51 | *Salmonella* | *dublin* | ATCC | 15480 | na | - |
| 52 | *Salmonella* | *enteritidis* | ATCC | 8391 | na | - |
| 53 | *Salmonella* | *enteritidis* | ATCC | 130776 | na | - |
| 54 | *Salmonella* | *enteritidis* | Tyson | T22 | na | - |
| 55 | *Salmonella* | *gallinarum* | ATCC | 9184 | na | - |
| 56 | *Salmonella* | *heidelberg* | ATCC | 8326 | na | - |
| 57 | *Salmonella* | *infantis* | ATCC | 51741 | na | - |
| 58 | *Salmonella* | *kentucky* | ATCC | 9263 | na | - |
| 59 | *Salmonella* | *maarsen* | ATCC | 15793 | na | - |
| 60 | *Salmonella* | *newport* | ATCC | 6962 | na | - |
| 61 | *Salmonella* | *seftenberg* | ATCC | 43845 | na | - |
| 62 | *Salmonella* | *typhimurium* | ATCC | 14028 | na | - |

**Table 7. Results from the Method Comparison Studies (1)**

| Matrix | Analyte | Method | Number of Samples | Inoculation Level, MPN/25g | Presumptive Positives | BAX | Confirmed Positives | Reference Method | | Chi square | Sensitivity Rate | False Negative Rate | Specificity Rate | False Positive Rate |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | BAX | Cultural | | | | | |
| Ground Beef | *E. coli* O157:H7 ATCC 35150 | 225mL RapidChek SELECT | 5 | 0 | 0 | - | 0 | 0 | 0 | 9.9 | - | - | 100 | 0 |
| | | | 20 | 0.95 | 19 | 19 | 20 | 10 | 10 | | 95 | 5 | - | - |
| | | 112.5 mL RapidChek SELECT | 5 | 0 | 0 | - | 0 | - | - | 3.86 | - | - | 100 | 0 |
| | | | 20 | 0.95 | 16 | 16 | 18 | - | - | | 89 | 11 | - | - |
| | | 225mL RapidChek | 5 | 0 | 0 | - | 0 | - | - | 7.43 | - | - | 100 | 0 |
| | | | 20 | 0.95 | 18 | 18 | 18 | - | - | | 100 | 0 | - | - |
| Boneless Beef | *E. coli* O157:H7 ATCC 51657 | 225mL RapidChek SELECT | 5 | 0 | 0 | - | 0 | 0 | 0 | 5.48 | - | - | 100 | 0 |
| | | | 20 | 2.32 | 19 | 19 | 19 | 5 | 13 | | 100 | 0 | - | - |
| | | 112.5 mL RapidChek SELECT | 5 | 0 | 0 | - | 0 | - | - | 0.46 | - | - | 100 | 0 |
| | | | 20 | 2.32 | 15 | 15 | 18 | - | - | | 83 | 17 | - | - |
| | | 225mL RapidChek | 5 | 0 | 0 | - | 0 | - | - | 0.46 | - | - | 100 | 0 |
| | | | 20 | 2.32 | 15 | 15 | 16 | - | - | | 94 | 6 | - | - |
| Boneless Beef | *E. coli* O157:H7 PSU 93.0134 | 225mL RapidChek SELECT | 5 | 0 | 0 | - | 0 | 0 | 0 | 0.43 | - | - | 100 | 0 |
| | | | 20 | 0.38 | 12 | 12 | 14 | 11 | 14 | | 86 | 14 | - | - |
| | | 112.5 mL RapidChek SELECT | 5 | 0 | 0 | - | 0 | - | - | 2.49 | - | - | 100 | 0 |
| | | | 20 | 0.38 | 10 | 10 | 12 | - | - | | 83 | 17 | - | - |
| | | 225mL RapidChek | 5 | 0 | 0 | - | 0 | - | - | 0.11 | - | - | 100 | 0 |
| | | | 20 | 0.38 | 13 | 13 | 13 | - | - | | 100 | 0 | - | - |

**DISCUSSION OF THE MODIFICATION STUDY Approved October 2009 (4)**

The RapidChek *E. coli* O157 test method was shown to be highly effective in detecting *E. coli* O157 in 375 gram samples of raw ground beef and boneless beef trim. A total of 100 samples were tested using *E.* coli O157-inoculated food samples (target level of 1 to 10 CFU/ 375g sample) in method comparison studies. Thirty-seven (37) samples tested positive with the RapidChek method at 8h, forty-nine (49) samples tested positive after 10h, and fifty-one (51) samples tested positive with the RapidChek method after 12 and 18 h of incubation. Fifty-one (51) RapidChek samples confirmed positive while fifty-seven (57) samples were confirmed positive by the reference method. All test method potential positives tested positive on PCR validating the use of the proprietary enrichment media on the two PCR systems tested (BAX and GDS). The total aerobic plate count ranged from 397 CFU/g in boneless beef trim to 1447 CFU/g in ground beef. The accuracy of the method was 89%.

**Table 1. Results from Inclusivity Study (4)**

| | Organism | Serotype | Code | Number | Source | Test Reactivity |
|---|---|---|---|---|---|---|
| 1 | *E. coli* | O157:H7 | ATCC | 51658 | Clinical Isolate | + |
| 2 | *E. coli* | O157:H7 | ATCC | 700728 | Unknown | + |
| 3 | *E. coli* | O157:H7 | ATCC | 43895 | Clinical Isolate | + |
| 4 | *E. coli* | O157:NM | ATCC | 700377 | Clinical Isolate | + |
| 5 | *E. coli* | O157:H7 | ATCC | 43890 | Clinical Isolate | + |
| 6 | *E. coli* | O157:H7 | ATCC | 700531 | Clinical Isolate | + |
| 7 | *E. coli* | O157:NM | ATCC | 700376 | Clinical Isolate | + |
| 8 | *E. coli* | O157:H7 | ATCC | 35150 | Clinical Isolate | + |
| 9 | *E. coli* | O157:H7 | ATCC | 43889 | Human feces | + |
| 10 | *E. coli* | O157:H7 | ATCC | 51657 | Human feces | + |
| 11 | *E. coli* | O157:H7 | CDC | A9218-C1 | Food | + |
| 12 | *E. coli* | O157 | PSU | 53 | Human feces | + |
| 13 | *E. coli* | O157 | PSU | 54 | Cow feces | + |
| 14 | *E. coli* | O157 | PSU | 59 | Pig intestine | + |
| 15 | *E. coli* | O157 | PSU | 61 | Cow Isolate | + |
| 16 | *E. coli* | O157 | PSU | 64 | Cow Isolate | + |
| 17 | *E. coli* | O157 | PSU | 66 | Food | + |
| 18 | *E. coli* | O157 | PSU | 68 | Human Isolate | + |
| 19 | *E. coli* | O157 | PSU | 69 | Cow Isolate | + |
| 20 | *E. coli* | O157 | PSU | 70 | Cow Isolate | + |
| 21 | *E. coli* | O157 | PSU | 71 | Human feces | + |
| 22 | *E. coli* | O157 | PSU | 79 | Chicken Isolate | + |
| 23 | *E. coli* | O157 | PSU | 80 | Human feces | + |
| 24 | *E. coli* | O157:H7 | R&F | 235 | Food | + |
| 25 | *E. coli* | O157:H7 | R&F | 225 | Food | + |
| 26 | *E. coli* | O157:H7 | R&F | 234 | Food | + |
| 27 | *E. coli* | O157:H7 | R&F | 223 | Clinical Isolate | + |
| 28 | *E. coli* | O157:H7 | R&F | 224 | Food | + |
| 29 | *E. coli* | O157:H7 | R&F | 219 | Apple Cider | + |
| 30 | *E. coli* | O157:H7 | R&F | 220 | Food | + |
| 31 | *E. coli* | O157:H7 | R&F | 221 | Beef Isolate | + |
| 32 | *E. coli* | O157:NM | R&F | 244 | Clinical, Iowa | + |
| 33 | *E. coli* | O157:H7 | R&F | 248 | Clinical, Iowa | + |
| 34 | *E. coli* | O157:H7 | R&F | 249 | Clinical, Iowa | + |
| 35 | *E. coli* | O157:H7 | R&F | 252 | Apple Cider | + |
| 36 | *E. coli* | O157:H7 | R&F | 377 | Ground Beef | + |
| 37 | *E. coli* | O157:H7 | R&F | 401 | Beef Isolate | + |
| 38 | *E. coli* | O157:H7 | Silliker | 1675 | Unknown | + |
| 39 | *E. coli* | O157: H - | TW | 6558 | Clinical Isolate | + |
| 40 | *E. coli* | O157:NM | USDA | 8302 | Clinical Isolate | + |
| 41 | *E. coli* | O157:H7 | USDA | C7927 | Clinical Isolate | + |
| 42 | *E. coli* | O157:H7 | USDA | C9490 | Clinical Isolate | + |
| 43 | *E. coli* | O157:H7 | USDA | 45753-32 | Food | + |
| 44 | *E. coli* | O157:H7 | USDA | A8959-C7 | Clinical Isolate | + |
| 45 | *E. coli* | O157:H7 | USDA | 3417-85 | Clinical Isolate | + |
| 46 | *E. coli* | O157:H7 | USDA | 505B | Beef Isolate | + |
| 47 | *E. coli* | O157:H7 | USDA | 413-95 | Food | + |
| 48 | *E. coli* | O157:H7 | USDA | 45750 | Food | + |
| 49 | *E. coli* | O157:H7 | USDA | 45753-35 | Food | + |
| 50 | *E. coli* | O157:H7 | USDA | 380-94 | Clinical Isolate | + |

**Table 2. Results from the Exclusivity Study (4)**

| | Organism | | Code | Number | Test Reactivity |
|---|---|---|---|---|---|
| 1 | *Aeromonas* | *hydrophila* | ATCC | 35654 | - |
| 2 | *Aeromonas* | *hydrophila* | ATCC | 49140 | - |
| 3 | *Aeromonas* | *veronii* | ATCC | 9071 | - |
| 4 | *Aeromonas* | *veronii* | ATCC | 51106 | - |
| 5 | *Citrobacter* | *amalonaticus* | ATCC | 25405 | - |
| 6 | *Citrobacter* | *amalonaticus* | ATCC | 25406 | - |
| 7 | *Citrobacter* | *braakii* | ATCC | 12012 | - |
| 8 | *Citrobacter* | *braakii* | ATCC | 43162 | - |
| 9 | *Citrobacter* | *braakii* | ATCC | 51113 | - |
| 10 | *Citrobacter* | *farmeri* | ATCC | 51112 | - |
| 11 | *Citrobacter* | *freundii* | ATCC | 8090 | - |
| 12 | *Citrobacter* | *freundii* | ATCC | 43864 | - |
| 13 | *Citrobacter* | *koseri* | ATCC | 27026 | - |
| 14 | *Citrobacter* | *werkmanii* | ATCC | 51114 | - |
| 15 | *Citrobacter* | *youngae* | ATCC | 11102 | - |
| 16 | *Citrobacter* | *youngae* | ATCC | 11606 | - |
| 17 | *Enterobacter* | *cloacae* | ATCC | 13047 | - |
| 18 | *Enterobacter* | *cloacae* | ATCC | 23355 | - |
| 19 | *Enterobacter* | *cloacae* | ATCC | 27508 | - |
| 20 | *Escherichia* | *coli* | ATCC | 4157 | - |
| 21 | *Escherichia* | *coli* | ATCC | 8739 | - |
| 22 | *Escherichia* | *coli* | ATCC | 12014 | - |
| 23 | *Escherichia* | *coli* | USDA | 12795 | - |
| 24 | *Escherichia* | *coli* | ATCC | 23316 | - |
| 25 | *Escherichia* | *coli* | ATCC | 23980 | - |
| 26 | *Escherichia* | *coli* | ATCC | 51446 | - |
| 27 | *Hafnia* | *alvei* | ATCC | 25927 | - |
| 28 | *Klebsiella* | *oxytoca* | ATCC | 8724 | - |
| 29 | *Klebsiella* | *oxytoca* | ATCC | 43165 | - |
| 30 | *Klebsiella* | *oxytoca* | ATCC | 43863 | - |
| 31 | *Klebsiella* | *pneumoniae* | ATCC | 4352 | - |
| 32 | *Klebsiella* | *pneumoniae* | ATCC | 8308 | - |
| 33 | *Klebsiella* | *pneumoniae* | ATCC | 27736 | - |
| 34 | *Proteus* | *mirabilis* | ATCC | 4630 | - |
| 35 | *Proteus* | *mirabilis* | ATCC | 14153 | - |
| 36 | *Proteus* | *vulgaris* | ATCC | 6380 | - |
| 37 | *Proteus* | *vulgaris* | ATCC | 8427 | - |
| 38 | *Salmonella* | *anatum* | ATCC | 9270 | - |
| 39 | *Salmonella* | *dublin* | ATCC | 15480 | - |
| 40 | *Salmonella* | *enteritidis* | ATCC | 8391 | - |
| 41 | *Salmonella* | *enteritidis* | ATCC | 130776 | - |
| 42 | *Salmonella* | *enteritidis* | Tyson | T22 | - |
| 43 | *Salmonella* | *gallinarum* | ATCC | 9184 | - |
| 44 | *Salmonella* | *heidelberg* | ATCC | 8326 | - |
| 45 | *Salmonella* | *infantis* | ATCC | 51741 | - |
| 46 | *Salmonella* | *kentucky* | ATCC | 9263 | - |
| 47 | *Salmonella* | *maarsen* | ATCC | 15793 | - |
| 48 | *Salmonella* | *newport* | ATCC | 6962 | - |
| 49 | *Salmonella* | *seftenberg* | ATCC | 43845 | - |
| 50 | *Salmonella* | *typhimurium* | ATCC | 14028 | - |

**Table 3. Results from the Internal Laboratory Method Comparison Study: Ground Beef (4)**

| Matrix | Analyte | Method | Number of Samples | Inoculation Level, MPN/25g | Presumptive Positives | Confirmed Positives | Reference Method | Chi square | Sensitivity Rate | False Negative Rate | Specificity Rate | False Positive Rate |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ground Beef | *E. coli* O157:H7 ATCC 35150 | 225mL RapidChek | 5 | 0 | 0 | 0 | 0 | 9.9 | - | - | 100 | 0 |
| | | SELECT | 20 | 0.95 | 19 | 20 | 10 | | 95 | 5 | - | - |
| | | 112.5 mL RapidChek | 5 | 0 | 0 | 0 | 0 | 3.86 | - | - | 100 | 0 |
| | | SELECT | 20 | 0.95 | 16 | 18 | 10 | | 89 | 11 | - | - |
| | | 225mL RapidChek | 5 | 0 | 0 | 0 | 0 | 7.43 | - | - | 100 | 0 |
| | | | 20 | 0.95 | 18 | 18 | 10 | | 100 | 0 | - | - |

**Table 4. Results from the Internal Laboratory Method Comparison Study: Boneless Beef (4)**

| Matrix | Strain | Method | Number of Samples | Inoculation Level, MPN/25g | Presumptive Positives | Confirmed Positives | Reference Method | Chi square | Sensitivity Rate | False Negative Rate | Specificity Rate | False Positive Rate |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Boneless Beef | *E. coli* O157:H7 ATCC 51657 | 225mL RapidChek SELECT | 5 | 0 | 0 | 0 | 0 | 5.48 | - | - | 100 | 0 |
| | | | 20 | 2.32 | 19 | 19 | 13 | | 100 | 0 | - | - |
| | | 112.5 mL RapidChek SELECT | 5 | 0 | 0 | 0 | 0 | 0.46 | - | - | 100 | 0 |
| | | | 20 | 2.32 | 15 | 18 | 13 | | 83 | 17 | - | - |
| | | 225mL RapidChek | 5 | 0 | 0 | 0 | 0 | 0.46 | - | - | 100 | 0 |
| | | | 20 | 2.32 | 15 | 16 | 13 | | 94 | 6 | - | - |

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