

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

K070691

**B. Purpose for Submission:**

Premarket notification

**C. Measurand:**

*Escherichia coli* 0157:H7

**D. Type of Test:**

Direct detection of *E. coli* 0157:H7 from fecal specimens using chromogenic substrate potassium tellurite, cefixime and cefsulodin - qualitative assay.

**E. Applicant:**

Becton, Dickinson and Company

**F. Proprietary and Established Names:**

BBL™ CHROMagar™ 0157:H7

**G. Regulatory Information:**

1. Regulation section:

866.2360 subjected to the limitation in 866.9 (c) (3)

2. Classification:

I

3. Product code:

JSI

4. Panel:

83 Microbiology

**H. Intended Use:**

1. Intended use(s):

BBL™ CHROMagar™ 0157:H7 is a selective medium for the isolation, differentiation and presumptive identification of *Escherichia coli* 0157:H7 from human clinical stool specimens.

2. Indication(s) for use:

BBL™ CHROMagar™ 0157:H7 is a selective medium for the isolation, differentiation and presumptive identification of *Escherichia coli* 0157:H7 from human clinical stool specimens.

3. Special conditions for use statement(s):

Prescription Use

4. Special instrument requirements:

Not Applicable

**I. Device Description:**

BBL™ CHROMagar™ 0157 is a prepared plated medium. The formulation incorporates chromogenic substrates, which allow colonies of *E. coli* 0157:H7 to produce a mauve color for presumptive identification from the primary isolation plate and differentiation from other organisms.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

BBL™ MacConkey II Agar with Sorbitol (SMAC)

2. Predicate 510(k) number(s):

K871855

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Intended Use	For detection of <i>E. coli</i> 0157	For detection of <i>E. coli</i> 0157
Reporting Results	<i>E. coli</i> 0157 (Presumptive)	<i>E. coli</i> 0157
Reading	Manual	Manual
Incubation	18 -24 hr	18-24 hr

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Inoculum	Direct fecal specimens	Isolated colonies from any source
Formula Differential Media	Uses a chromogenic mix as a differential media	Uses sorbitol and neutral red as a differential media
Formula Selective Media	Uses tellurite, cefixime and cefsulodin	Uses bile salts and crystal violet.

**K. Standard/Guidance Document Referenced (if applicable):**

Not Applicable

**L. Test Principle:**

BBL™ CHROMagar™ 0157 formulation incorporates chromogenic substrates, which allow colonies of *E. coli* 0157:H7 to produce a mauve color for presumptive identification from the primary isolation plate and differentiation from other organism. Specially selected Difco™ peptones are incorporated to supply nutrients. Potassium tellurite, cefixime and cefsulodin act as selective agents which reduce the number of bacteria other than *E. coli* 0157:H7 that grow on this medium. The chromogenic mix consists of artificial substrates (chromogens), which release an insoluble colored compound when hydrolyzed by a specific enzyme. *E. coli* 0157:H7 utilizes one of the chromogenic substrates which produce mauve colored colonies. The growth of mauve colored colonies is considered presumptive identification for *E. coli* 0157:H7 on BBL™ CHROMagar™ 0157. Non-*E. coli* 0157:H7 bacteria may utilize other chromogenic substrates resulting in blue to blue-green colored colonies or, if none of the chromogenic substrates are utilized, colonies may appear as a natural color.

## M. Performance Characteristics (if/when applicable):

### 1. Analytical performance:

#### a. *Precision/Reproducibility:*

Reproducibility studies were conducted in triplicates at 3 sites, 2 external and 1 internal, using expected *Escherichia coli* O157:H7 QC isolates and a variety of Non-*Escherichia coli* O157:H7 isolates (*Salmonella typhimurium*, *Escherichia coli* H7 (Non O157), *Shigella sonnei*, and additional *Escherichia coli*). The intra-site and inter-site reproducibility for BBL CHROMagar O157 was  $\geq 95\%$ .

#### b. *Linearity/assay reportable range:*

Not Applicable

#### c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Quality Control (QC) data was compiled across all three sites and all batches of BBL CHROMagar *Escherichia coli* O157:H7. The testing followed the recommendations of the QC strains listed in the package insert. This included the *Escherichia coli* O157:H7 ATCC™ 700728 as positive growth: light mauve to mauve colonies, *Escherichia coli* ATCC™ 25922: growth inhibition (partial to complete), and *Enterobacter cloacae* ATCC™ 13047 as growth: blue-green to blue colonies. All individual QC batches passed the acceptance criteria.

#### d. *Detection limit:*

Not Applicable

#### e. *Analytical specificity:*

A total of 59 organisms, representing several genera of stool pathogens and 5 *E. coli* O157:H7 were included in a cross reactivity testing. The stool pathogens included *Salmonella* spp., *Shigella* spp., *Campylobacter* spp., *Yersinia* spp., *Plesiomonas* spp., *Aeromonas* spp., *Vibrio* spp., and *E. coli* non-O157:H7. The identification of the microorganisms was blinded from the sites. The sites tested the organisms in three different lots and interpreted the results. The *E. coli* O157:H7 strains grew mauve colonies 15/15 times (100%). The non-*E. coli* O157:H7 strains showed non-mauve colonies 58/59 times per each lot for a total of 174/177 times (98.3%). *Campylobacter fetus*, BD645, which was frozen, did not grow on the original subculture media; therefore, this isolate was removed from the testing procedure. Additionally, one *Salmonella* spp. strain (*S. Heidelberg*) produced mauve colonies

resembling *E. coli* O157:H7. Therefore, a limitation statement indicating the possibility of false positive results with this particular strain was added to the package insert.

#### Interference Study

An interference study was independently conducted in replicates five times using a variety of substances that may be present in stool or rectal specimens. Among the substances used were blood, water, K-Y Jelly, Vaseline, Hydrocortisone ointment, tucks pad, soap, Metamucil, Milk of Magnesia, Senna, Fleet Glycerin Suppository, and Dulcolax Suppository. The results showed that *E. coli* O157 grew on CHROMagar media within the claimed range of time in the presence of all of these substances.

*f. Assay cut-off:*

Not Applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

Two external studies and one internal study were conducted on BBL™ CHROMagar O157.

*i.* A user-based retrospective study: A collection of 3136 stool specimens were cultured, of which 2855 specimens provided acceptable results for this study. BBL CHROMagar O157:H7 were compared to SMAC media. Final results of the isolate identification were determined by additionally testing (biochemical, serology, or ID system) as recommended in the Package insert. Results produced a positive percent agreement of *Escherichia coli* O157:H7 of 86.4% (19/22) and a negative percent agreement of Non-*Escherichia coli* O157:H7 of 99.8% (2828/2833). However, for 281 isolates the sponsor reported “Not Available (NA)” data because a confirmation protocol was not followed as stated in the package insert.

*ii.* BBL™ CHROMagar™ O157 Field Trial in a regional hospital.

A collection of 110 frozen fecal isolates, 6 archived, frozen stools, and 10 fresh stool specimens were compared to SMAC, SMAC-CT and TSA II. Among the frozen and archived fecal isolates, 56 were Shiga toxin positive *E. coli* O157:H7 and the additional 60 were comprised of Shiga Toxin-positive *E. coli* Non-O157 (8), Shiga toxin-Negative *E. coli* (15), *Pseudomonas aeruginosa* (5), *Klebsiella* spp. (10), *Enterobacter* spp. (10), *Serratia* spp. (4), and *Proteus* spp. (8). Results produced a positive percent agreement of 98% (55/56) *E. coli* O157:H7 on CHROMagar O157:H7 and a negative percent agreement of 100% (60/60) for the non-*E. coli* O157:H7 strains. Additionally, CHROMagar O157 test results demonstrated that 1/10

fresh stools were positive for *E. coli* O157:H7 and the remaining 9/10 were negative for *E. coli* O157:H7. These latter results were confirmed using biochemical tests, latex agglutination, and Premier EHEC.

*b. Matrix comparison:*

Not Applicable

3. Clinical studies:

*a. Clinical Sensitivity:*

Not Applicable

*b. Clinical specificity:*

Not Applicable

*c. Other clinical supportive data (when a. and b. are not applicable):*

As described in the package insert, interpretation of plate results must be completed within 18-24 hours after inoculation of the BBL CHROMagar O157:H7 plate. A separate time detection study measuring growth in 18-24 hours range of time was independently conducted. All organisms grew within the expected range of time.

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

Not Applicable

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.