

E. COLI O157:H7



Protect your brand with the most robust detection tools in the food industry

Accuracy. Ease of use. Zero compromise.

THE CHALLENGE

HIGH STAKES IN FOOD PROTECTION CALLS FOR FASTER, MORE ROBUST TOOLS

New regulations, harsher penalties and numerous brand-threatening recalls have placed substantial pressures on food manufacturers. These market conditions require a paradigm change in food safety and quality monitoring programs.

VERIFLOW TECHNOLOGY

PROVEN PLATFORM DELIVERS ACCURACY, SPEED AND SENSITIVITY

Veriflow technology is proven to provide rapid, accurate, actionable detection of pathogen and spoilage indicators – with no compromises on ease of use and affordability. The technology is easily deployed on-site allowing you to identify microbial risks, take corrective action, and prevent large-scale contamination.

- ▶ Unsurpassed specificity across a wide spectrum of microbes
- ▶ Robust detection in both simple and complex matrices
- ▶ Sensitive and accurate to ensure confidence in your processes
- ▶ Reduces hold times and eliminates the need to ship at risk
- ▶ Saves money and resources throughout your process
- ▶ Meets the changing needs of the industry and allows you to protect your brand

VERIFLOW *E. COLI* O157:H7

Offers accurate detection with highest degree of confidence

Veriflow *E. coli* O157:H7 provides robust specificity and sensitivity across an extensive variety of environmental surfaces and multiple food and beverage matrices, without complex and time consuming sample preparation.

Unmatched specificity

- ▶ Broad inclusivity of 50 *E. coli* O157:H7 strains with 100% detection rate
- ▶ Correctly excludes all 35 closely related strains tested

Unrivaled sensitivity

- ▶ Target amplification of a conserved gene marker for *E. coli* O157:H7
- ▶ Reliable results in even the most challenging matrices

Unsurpassed ease of use

- ▶ Results in 18 hours versus 3-4 days with traditional methods
- ▶ Streamlines your quality management processes
- ▶ Easily implemented on site with existing resources
- ▶ Eliminates the need for proprietary media, two-step enrichment, and DNA extraction sample preparation

PRODUCT OVERVIEW

Veriflow® *E. coli* O157:H7 is a molecular based assay for the presumptive detection of *E. coli* O157:H7. The Veriflow system utilizes a game-changing technology that combines proven diagnostic principles for microbial detection with innovative, first-in-class scientific approaches. The robust platform performs at the highest levels of accuracy in even the most challenging matrices, with vastly simplified sample preparation. The Veriflow system eliminates the need for sample purification, gel electrophoresis, or fluorophore-based detection of target amplification. Results are visual immediately on a hand-held cassette with not need for complex data analysis.

PRODUCT PERFORMANCE VALIDATION

AOAC Certification

AOAC Performance Tested MethodsSM Program was utilized for validation and verification of assay performance. Replicate samples of raw meats, dairy and vegetables were inoculated and sampled according to directions outlined in either the USDA/FSIS MLG 5.08 or BAM chapter 4A reference methods. Replicate samples were inoculated at a low and high levels with an additional un-inoculated control set.

Synopsis of the Results

The results of this study demonstrated the specificity, accuracy and reliability of the Veriflow *E. coli* O157:H7 assay as compared to the traditional FDA BAM Chapter 4A and USDA/FSIS MLG 5.08 culture based reference methods for the detection of *E. coli* O157:H7 in raw ground beef (80% lean), 2% milk, leafy spinach and Whey powder. POD statistical analysis of all matrices tested indicate that there is no significant difference in performance between the methods at specific time points as assayed in this study, and importantly, no false positive or false negative results were observed in the entirety of the study. The successful validation of the assay is further supported by the results of the inclusivity and exclusivity testing, indicating that the Veriflow *E. coli* O157:H7 assay was able to accurately detect 50 strains of *E. coli* O157:H7 while correctly excluding all closely related strains tested.

Conclusion

Extensive testing was conducted to validate the sensitivity of the Veriflow *E. coli* O157:H7 assay. Over 160 samples were tested across a wide variety of challenging matrices without complex samples preparation after enrichment. The Veriflow *E. coli* O157:H7 assay provides flexibility and ease of use for the end user while delivering accurate results across a variety of food matrices, without complex sample preparation after enrichment. The Veriflow system also offers significant time savings by producing accurate presumptive results after a standard enrichment time of only 18 hours.

SPECIFICITY			
Assay	Strains	Results	
Inclusivity	50 <i>E. coli</i> O157:H7 strains	100 % Detection Rate	Correctly identified all strains tested
Exclusivity	35 Non- <i>E. coli</i> O157:H7 strains	100 % Exclusion Rate	Correctly excluded all strains tested

SENSITIVITY			
Matrix	Demonstrated equivalence to USDA MLG or FDA BAM reference method	External Validation	Client References
Ground Beef	YES	YES	YES
Dairy Products (i.e. milk)	YES	YES	YES
Leafy Spinach	YES	YES	YES
Whey Protein Powder	YES	NO	YES

VERIFLOW *E. COLI* O157:H7 SPECIES TECHNICAL SPECIFICATIONS

Specificity	50 strains of <i>E. coli</i> O157:H7
Time to Results	18 hours enrichment + 2 hour assay time
Matrix Compatibility	Wide variety of matrices
Sensitivity	Zero tolerance detection
Assay Format	Qualitative
Test Stability	1 year expiration with proper storage
Enrichment	Single step enrichment in mTSB or mBPWp for media No selective supplements required
Sample Preparation	Simple liquid transfer, no need for DNA extraction or purification
Work Flow	Simple 3 step procedure
Results Interpretation	Immediate visualization of results on hand-held cassette

For more information or to place an order, please contact Invisible Sentinel at 215.966.6118 or www.invisiblesentinel.com



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