

Non-Confidential Description - PSU No. 3863
**“Rapid, Specific and Sensitive Immunoassay for the Detection
of Highly Variable Gram Negative Bacterial Antigens”**

Field of Invention/Keywords:

Food Testing, E. coli testing, Enzyme linked immunosorbant assays (ELISAs), Bacterial antigens

Links:

[Inventor website](#)

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Background

The Centers for Disease Control and Prevention (CDC) has estimated that non-O157 shiga toxin producing *Escherichia coli* (*E. coli*) [STEC] are responsible for 36,000 illnesses each year in the United States. The majority of these infections have been associated with six serogroups. Assays utilizing PCR are available but are not suitable for high volume, time sensitive food processing conditions. USDA Food Safety Inspection Services has mandated testing for both domestic and imported processed beef for these six serogroups.

Invention Description

The invention covers an ELISA test for the rapid, sensitive and specific identification and quantification of gram-negative *E. coli* containing the top six non-O157 STEC O groups. The assays were tested against a total of 174 reference *E. coli* O groups, 60 *E. coli* clinical isolates, and ten (10) other bacterial species. The results showed that the assays are highly specific (98%-100%) with a limit of detection of 10-20 CFU of bacteria following enrichment and an analytical sensitivity comparable to extant commercially available immunoassays. Importantly, the newly developed assays enabled a reduction in time from more than five (5) days using current protocols to less than two (2) days. The qualitative assay is colorimetric and does not require sophisticated equipment.

Status of the Invention

The inventors have reduced the invention to practice, utilized it in laboratory settings and conducted blind studies with third party meat samples to demonstrate the assay's utility and versatility. The inventors have modified their assay so that it may be manufactured as a kit using a 96-well plate (or greater) at point source food manufacturing locations. The inventors have also optimized the enrichment media to promote growth of the target *E. coli* over other bacterial strains.

Commercial Applications:

These rapid assays have considerable utility for detecting STEC O groups in food and in other sources such as serum and biopsies.

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