**Performance of the Shiga Toxin Quik Chek Immunoassay, Enzyme Immunoassay, and E. coli 0157 Culture in Children**

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**Abstract**

Background: Shiga toxin-producing Enterohemorrhagic E. coli (EHEC) can cause serious clinical sequelae, particularly in children. In North America, outbreaks are frequent and rapid diagnosis is beneficial. Also, EHEC is a documented laboratory-acquired infection. Rapid, direct, Shiga toxin detection methods may reduce laboratory handling of infected stool, broth, and organism growing in culture. Our objective was to evaluate the performance of the Shiga Toxin Quik Chek test when performed directly on stool and after specimen incubation in GN broth.

Methods: 891 stool specimens (fresh and in Cary Blair medium) from patients ≤18 years of age were enrolled prospectively during two “high incidence” EHEC periods: July 1-Nov. 30, 2013, and May 1-Nov. 30, 2014. Duplicate specimens were removed from analysis. Shiga Toxin Quik Chek (STQC), a rapid enzyme immunoassay that detects STX1 and STX2, was performed directly on stool, and after specimen incubation on Remel GN broth after specimen incubation. The Premier EHEC enzyme immunoassay (EIA) and culture on CHROMagar 0157 were also performed after incubation in GN broth. A “true positive” (TP) was defined as positivity on CHROMagar 0157 but many other disease-causing serogroups are documented.

Objectives

1. To evaluate the performance of the Shiga Toxin Quik Chek test (Techlab, Blacksburg, VA) that detects STX1 and STX2.
2. EIA and PCR perform best after incubation of stool in broth.
3. EIA and PCR test both be performed on stool specimens.

**Results**

- Sensitivity of STQC was highest following specimen incubation in GN broth. A “true positive” (TP) was defined as positivity on CHROMagar 0157 but many other disease-causing serogroups are documented.
- EIA and PCR perform best after incubation of stool in broth.
- EIA and PCR test both be performed on stool specimens.

**Methods**

Specimens

- All stool samples submitted for culture to the Clinical Microbiology Laboratory at The Children’s Hospital of Philadelphia were considered for inclusion (fresh and in Cary Blair medium).
- Only first stool specimens submitted to the laboratory were included. Duplicate specimens were excluded.

Specimen processing

Routine procedures

- Stool specimens were inoculated on 5% sheep’s blood, MacConkey, XLD, CIN and Campylobacter blood media; and GN broth (Remel, Lenexa, KS) and incubated for 18-24 hours in O2 at 35-37°C.
- Stool specimens were also inoculated on to 0157 CHROMagar (BD Diagnostics, Sparks, MD) and examined after incubation for 18-24 hours in O2 at 35-37°C in a darkened incubator.
- Cultures were processed according to routine procedures on the stool broth.
- The Premier EHEC enzyme immunoassay (Meridian Biosciences, Cincinnati, OH) was performed according to manufacturer’s instructions on inoculated GN broth after incubation for 16-24 hours.

**Conclusions**

- The Shiga Toxin Quik Chek test was rapid, user-friendly, and appropriate for use in a clinical microbiology laboratory.
- The sensitivity of Shiga Toxin Quik Chek was superior from broth compared to direct testing on stool.
- In an outbreak setting, stool could be tested directly and specimens with negative tests could be reflexed to re-testing after broth incubation.
- Use of STQC after broth incubation would improve sensitivity over culture and EIA, and reduce labor.
- Culture was limited by poor sensitivity (70%), and its inability to detect non-0157 strains.

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