Evaluation of Diagnostic Tests for Clostridium difficile Infection

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**Abstract:** We evaluated toxigenic *Clostridium difficile* detection by a lateral flow assay for antigen and toxin, an enzyme immunoassay, and two commercial PCR methods. Compared to the cell cytotoxicity neutralization assay and toxigenic culture, both toxin detection methods lacked sensitivity. PCR, following combined antigen and toxin detection provided the most useful diagnostic information.

150 sample study utilizing VIDAS Toxin A/B EIA (Biomerieux), GeneOhm *C. difficile* PCR (BD), GeneXpert *C. difficile* PCR (Cepheid), *C. DIFF QUIK CHEK COMPLETE*, (Techlab), Cell Cytotoxicity Neutralization Assay (CCNA), Toxigenic Culture (TC)

**Results and Discussion**

- *C. difficile* was cultured from 19 specimens and the *C. DIFF QUIK CHEK COMPLETE*, GDH was positive for all of these samples
- The VIDAS Toxin A/B EIA was 53.3% sensitive, *C. DIFF QUIK CHEK COMPLETE* Toxin A/B was 73.3% sensitive
- Future mutations in the Toxin B gene may reduce the sensitivity of PCR based assays
- We propose a two-step algorithm using *C. DIFF QUIK CHEK COMPLETE* to screen followed by GeneXpert PCR (Cepheid):

- Results with *C. DIFF QUIK CHEK COMPLETE* can be reported rapidly for samples if they are GDH negative (85.3% in our study) or positive for both GDH and CDT (7.3% in our study). For samples with discordant results, PCR testing can then exclude the presence of toxigenic *C. difficile* strains