2357. Toxin Detection Using Single Molecule Counting Technology: The Best of Both Worlds?
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**Session:** 250. HAI: C. difficile - Diagnostic Testing
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**Background.** Accurate diagnosis of C. difficile remains challenging as there is no standalone laboratory test with adequate clinical sensitivity and specificity. Thus, many clinical laboratories currently employ a multistep algorithm incorporating a sensitive screening test followed by a specific toxin test. An automated ultrasensitive toxin immunosay (Singulex Clarity C. difficile toxins A/B assay) has demonstrated excellent performance compared with cell cytotoxicity neutralization assay (CCNA). In this study, the Clarity assay was evaluated relative to glutamate dehydrogenase (GDH), toxigenic C. difficile, toxin B gene PCR, multistep algorithms, and C. difficile culture with ribotyping.

**Methods.** Residual clinical stool samples (n = 293) were collected from patients with suspected C. difficile. The samples were tested on-site with GDH (C. difficile CHEK™-60), PCR (EntericBio realityte C. difficile assay), a membrane-type toxin EIAs (Tox A/B Quik Chek®), and culture and ribotyping. In total, 188 samples were tested with GDH and 239 samples were tested by PCR. All PCR-positive samples (n = 148) and prospectively tested GDH samples (n = 97) were tested with the toxin EIAs. Culture and ribotyping information were available for 205 samples.

**Results.** Three of the tests evaluated were toxin EIA result (23 positive, 21 negative). These specimens underwent five standard diagnostic assays: enzyme immunoassay for toxins A and B (EIAs), cytotoxin cell assay, bacterial culture isolation, and two different NAATs to determine presence of viable C. difficile cells, toxins, and toxin-encoding genes (Table 1). The concentration (fg/mL) of toxins A and B in all stool samples was then quantified using MSD® multiplexed immunosay (Table 1).

**Conclusion.** The Clarity assay had strong PPA compared with toxin EIAs and strong NPA compared with PCR. The low NPA and PPA compared with toxin EIAs and PCR, respectively, may reflect the poor sensitivity of current toxigenic EIAs and low specificity of PCR. The Clarity assay detected 30 different ribotype strains, and less than 70% of samples (by PCR) or strains (by ribotyping) had toxins present. The Clarity assay may be considered for use as a standalone test for CDI diagnosis.

Disclosures. All authors: No reported disclosures.

2359. Prospective Feasibility Study for Novel Ultrasensitive Multiplexed Immunosay for Clostridiodes difficile Toxins A and B
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**Background.** Infants have a high rate of asymptomatic Clostridiodes difficile colonization (up to 37%) but can rarely develop true CDI infection (CD). However, currently available polymerase chain reaction (PCR) and enzyme immunoassays (EIA) have suboptimal sensitivity/specifcity to distinguish CDI from colonization. Recent data from adults showed that lower cycle threshold (Ct) values of a semi-quantitative CD toxin B gene (tcdB) PCR assay in stool correlated with detection of free CD toxin in stool and poor clinical outcomes. We hypothesized that a tcdB PCR assay may be utilized to distinguish CDI from colonization in patients < 3 years old.

**Methods.** Symptomatic patients < 3 years old with CD detected by the BioFire FilmArray Gastrointestinal Panel (FGP) were enrolled 2/2018-3/2019. We performed CD tcdB PCR and toxin A/B/GDH EIA on frozen aliquots of stool in Cary Blair. CDI was defined among those that were tcdB PCR positive as (1) a consistent clinical syndrome (diarrhea + no current laxative use), (2) CD EIA toxin+, (3) symptomatic improvement with CDI-directed treatment, and (4) no alternative etiology of diarrhea identified. Patients who did not meet criteria for CDI were considered colonized. We compared median tcdB PCR Ct values between the CDI and colonized groups using the Mann-Whitney test.

**Results.** Of 193 FGP CD+ patient samples with charts available for review, 37 (19%) samples were EIA GDH+/toxin+, 121 (63%) were GDH+/toxin− and 35 (18%) were EIA−. 150 (78%) samples had detectable tcdB by PCR. Six (4%) patients met criteria for CDI and 144 (96%) for colonization. Median (interquartile range) tcdB PCR Ct values were 23.8 (22.0–29.5) and 30.5 (26.3–35.8) in patients with CDI and colonization, respectively (P = 0.03).

**Conclusion.** Using a strict clinical and laboratory definition, 4% of evaluable patients < 3 years old met criteria for CDI and had significantly lower tcdB PCR Ct values than colonized patients. A combination of clinical and laboratory criteria, including semi-quantitative tcdB PCR, may help differentiate colonization from CDI in this patient population.

Disclosures. All authors: No reported disclosures.
Disclosures. All authors: No reported disclosures.

2360. Impact of a Two-Step Antimicrobial Stewardship Intervention on C. difficile Infection Diagnosis at an Urban Veteran’s Affairs Medical Center
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Background. C. difficile infection (CDI) is a common healthcare-associated infection and quality measure for hospitals. Diagnosis of CDI is challenging as testing modalities, i.e., nucleic acid amplification test (NAAT), are highly sensitive but cannot differentiate between colonization and infection. Therefore, judicious use of testing is critical to avoid unnecessary diagnosis and treatments.

Methods. This single-center, retrospective chart review evaluated the impact of a two-step diagnostic stewardship intervention on C. difficile diagnosis and use of oral vancomycin in the inpatient setting. For the first step of the intervention, providers were educated on appropriate diagnosis and treatment, and given access to an optional electronic CDI clinical decision support system (CDSS). For the second step of the intervention, the CDI NAAT stand-alone testing option was removed from the lab ordering menu and providers were required to use the CDSS to order testing. Clinical data describing use of a multistep algorithm for diagnosis of Clostridioides difficile infection (CDI) is limited. In June 2018 we implemented a 2-step testing algorithm in which PCR testing (Ares® assay) is performed for all specimens followed by EIA toxin testing (TOX A/B QUIK CHEK® assay) when PCR is positive. We sought to describe outcomes for patients with PCR+/EIA− vs. PCR−/EIA− results. Outcomes evaluated included frequency of CDI treatment, retesting and retreatment within 3 months, and investigator determined categorization of C. difficile results by an investigator blinded to the EIA result.

Results. During the first 6 months of a 2-step testing algorithm, we found that patients with EIA+ test results were frequently treated for CDI and that 72% of EIA- patients were classified as probable, possible, unlikely and indeterminate cases of symptomatic CDI. For the EIA+ patients, 70%, 19%, 7%, and 4% were classified as probable, possible, unlikely and indeterminate cases of symptomatic CDI when compared with 38%, 34%, 22%, and 5% for EIA- patients.

Conclusion. During the first 6 months of a 2-step testing algorithm, we found that patients with EIA- test results were frequently treated for CDI and that 72% of EIA- cases were classified as probable or possibly having symptomatic CDI. Further study is needed to determine whether patients with EIA- results categorized with probable or possible symptomatic CDI would improve without CDI treatment. Disclosures. All authors: No reported disclosures.

2361. Evaluation of a 2-Step Testing Algorithm for Clostridioides difficile Infection
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Session: 250. HAI: C. difficile - Diagnostic Testing
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Background. Clinical data describing use of a multistep algorithm for diagnosis of Clostridioides difficile infection (CDI) is limited. In June 2018 we implemented a 2-step testing algorithm in which PCR testing (Ares® assay) is performed for all specimens followed by EIA toxin testing (TOX A/B QUIK CHEK® assay) when PCR is positive. We sought to describe outcomes for patients with PCR+/EIA+ vs. PCR−/EIA− results. Outcomes evaluated included frequency of CDI treatment, retesting and retreatment within 3 months, and investigator determined categorization of C. difficile results by an investigator blinded to the EIA result.

Methods. This retrospective cohort study was performed on a random sample of 85 unique patients with a PCR+ stool sample from July 2018 through December 2018. Demographic and clinical data were abstracted from the medical record during the index encounter and for 3 months thereafter. Based on predetermined criteria, index encounter results were categorized as representing probable, possible, unlikely, or indeterminate cases of symptomatic CDI.

Results. For the 85 study patients, 42%, 27%, and 31% were tested in the inpatient, outpatient, and ED/urgent care settings. Twenty-seven patients (32%) were EIA+, all of whom received CDI treatment. Fifty-eight (68%) were EIA−, of which 79% received treatment. Of the 12 EIA+ patients who did not receive treatment two had retesting within 3 months; one of whom subsequently tested EIA+ and was treated and the other tested PCR+. At least 1 C. difficile test was repeated within 3 months in 48% of EIA+ and 33% of EIA− patients. Based on repeat testing CDI treatment was prescribed for 12% of EIA+ subjects and for 11% of EIA− subjects. For the EIA+ patients, 70%, 19%, 7%, and 4% were classified as probable, possible, unlikely and indeterminate cases of symptomatic CDI compared with 38%, 34%, 22%, and 5% for EIA− patients.

Conclusion. During the first 6 months of a 2-step testing algorithm, we found that patients with EIA- test results were frequently treated for CDI and that 72% of EIA- cases were classified as probable or possibly having symptomatic CDI. Further study is needed to determine whether patients with EIA- results categorized with probable or possible symptomatic CDI would improve without CDI treatment. Disclosures. All authors: No reported disclosures.

2362. Back to the Future: The Impact of Multi-Step Algorithm C. difficile Testing at a Large Tertiary Medical Center
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Session: 250. HAI: C. difficile - Diagnostic Testing
Saturday, October 5, 2019: 12:15 PM

Background. Antibiotic stewardship and infection control programs rely on C. difficile infection (CDI) test results to measure CDI incidence in the hospital setting. C. difficile carriage is common and distinguishing infection from colonization is difficult with the highly sensitive nucleic acid amplification testing (NAAT) commonly used. Current guidelines recommend a multi-step algorithm for testing. The impact on patient outcomes and CDI metrics are largely unknown.

2363. Of the mandatory CDSS for CDI testing was shown to significantly decrease the number of tests ordered, the number of positive tests, and the use of oral vancomycin.

Disclosures. All authors: No reported disclosures.