Preliminary Performance Evaluation of the Automated Singulex Clarity C. diff Toxins A/B Assay and Comparison to PCR and Multi-Step Algorithms

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RESULTS

Figure 1. The automated Clarity C. diff assays are powered by Single Molecule Counting technology, shown for the detection of GDH and C. difficile toxins A/B. The Toxins A/B assay uses cellulose acetate as an absorbent/collector plate for purified GDH, which is captured by antibodies on a microparticle-based immunoassay using Single Molecule Counting technology based on single-photon fluorescence detection. The Singulex Clarity system uses confocal optics and an avalanche photodiode detector to yield digital fluorescence continuous measurement for diagnostic guidance document for C. difficile Infection in the Molecular Test Era.

CONCLUSIONS

The Singulex Clarity C. diff toxins A/B assay (in development) provided ultra-sensitive detection of Tox A and Tox B, with higher sensitivity than other EIA and higher specificity than PCR.

Testing with PCR alone had poor sensitivity, and testing with EIA alone had poor specificity; Singulex Clarity C. diff toxins A/B assay detected 68.4% (15/22) more CCNA-positive samples than EIA alone.

Testing with EIA resulted in discordance in 41.1% (39/95) of the samples, and the percent of PCR in the discordant sample set was only 48.0% (12/25).

Testing with a PCR-plus-toxin algorithm had poor sensitivity and specificity and reported 27.4% PCR/CAI samples.

Measurements of Tox A and Tox B concentrations may have the potential to guide treatment by distinguishing between colonized individuals and CDI patients.

Singulex Clarity C. diff toxins A/B assay outperformed EIA, PCR, and two multiplex algorithms, and may offer a standalone solution for CDI diagnostics.

REFERENCES


