Clinical Evaluation of the Singulex Clarity C. diff Toxins A/B Assay, Currently in Development, for Ultrasensitive Detection of Clostridium difficile Toxins A and B

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INTRODUCTION
Clostridium difficile is an emerging pathogen, and the number of cases has increased rapidly in recent years. The clinical manifestations of the disease range from mild diarrheal illness to sepsis, and the associated healthcare costs are high. As a result, there is a need for a simple, rapid, and sensitive test for the detection of C. difficile toxins. Existing tests, such as enzyme immunoassays (EIAs) and nucleic acid amplification tests (NAATs), have limitations in terms of sensitivity and specificity. The Singulex Clarity C. diff toxins A/B assay is an automated, rapid, and ultrasensitive immunoassay for the detection of C. difficile toxins A and B.

METHODS
The Singulex Clarity C. diff toxins A/B assay was performed on 311 stool samples from patients with suspected Clostridium difficile infection (CDI) at Stanford Hospital, Stanford, CA, USA. The assay was compared with the gold standard, the Xpert® C. difficile assay. The results were analyzed using the McNemar test.

RESULTS
The Singulex Clarity C. diff toxins A/B assay detected 96.8% of samples with positive results on the Xpert® C. difficile assay. The assay had a sensitivity of 93.3% and a specificity of 98.6%.

CONCLUSIONS
The Singulex Clarity C. diff toxins A/B assay is a rapid, ultrasensitive, and highly specific test that can be used in the clinical setting to detect C. difficile toxins A and B.

REFERENCES