High Agreement Between the Singulex Clarity C. diff Toxins A/B Assay and a C. difficile Laboratory Algorithm Utilizing GDH- and Toxin EIAs and Cytotoxin Testing

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ABSTRACT

Background: In this study, the performance of the Singulex Clarity C. difficile Toxin A/B (Clarity) assay was evaluated. The sample was tested onsite (within 2 to 12 hours of collection) with a rapid

Methods: A total of 124 GDH+/toxin- samples were tested with the Clarity assay (12.0 pg/mL).

RESULTS

Table 1. The semiquantitative PCR (CMC/PC) was performed by testing serial dilutions (1:10, 1:100, 1:1,000, 1:10,000, and 1:100,000) of 30% adult stool samples. Among the 124 GDH+/toxin- samples, 99 were CMC+/PC-. GDH+/toxin-/CCNA- samples had 96% negative agreement both with GDH-/toxin- samples and the standard-of-care algorithm, and 97% positive agreement with GDH+/toxin+ samples. Clarity had 96% negative agreement both with GDH-/toxin- samples and the standard-of-care algorithm, and 97% positive agreement with GDH+/toxin+ samples. Clarity had 96% negative agreement both with GDH-/toxin- samples and the standard-of-care algorithm, and 97% positive agreement with GDH+/toxin+ samples. Clarity had 96% negative agreement both with GDH-/toxin- samples and the standard-of-care algorithm, and 97% positive agreement with GDH+/toxin+ samples. Clarity had 96% negative agreement both with GDH-/toxin- samples and the standard-of-care algorithm, and 97% positive agreement with GDH+/toxin+ samples. Clarity had 96% negative agreement both with GDH-/toxin- samples and the standard-of-care algorithm, and 97% positive agreement with GDH+/toxin+ samples.