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The study was approved by the Hennepin County Medical Center Institutional Review Board (IRB; HSR #18-4498) and by the Ethical & Independent Review Board.

Samples were tested in singlicate by laboratory personnel on Clarity systems at both testing sites.

The performance of currently available toxin EIA tests, there is an unmet need for a toxin test with high sensitivity that, depending on the setting and patient population, could be used as a standalone test.

The Singulex Clarity® C. diff toxins A/B assay, for use on the CE-marked single-tube PCR system, is able to detect as little as 0.5 pg/mL of *C. difficile* toxin A and 0.2 pg/mL of *C. difficile* toxin B in stool, making for appropriate treatment and infection-control measures, and may prevent the propagation and spreading of *C. difficile* infection.

An unformed stool sample was submitted for routine testing within 72 hours of collection. Each residual stool sample was de-identified and stored at 2–8°C until being tested with each of the following tests:

- *C. difficile* toxin A/B EIA (Quik Chek Complete) (Trifolyt, Inc., Minneapolis, MN)
- PCR-"C. difficile* (Xpert *C. difficile*)
- PCR-"*E. coli* O157:H7* (Cepheid, Sunnyvale, CA)
- PCR-"*Salmonella* (Cepheid, Sunnyvale, CA)
- PCR-"*Shigella* (Cepheid, Sunnyvale, CA)
- PCR-"*C. perfringens* CDE (Cepheid, Sunnyvale, CA)

Methylotruncus (formerly *Clostridoides*) *dolichum* was stool samples submitted for routine testing within 72 hours of collection. Each residual stool sample was de-identified and stored at 2–8°C until being tested with each of the following tests:

- *C. difficile* toxin A/B EIA (Quik Chek Complete) (Trifolyt, Inc., Minneapolis, MN)
- PCR-"*C. difficile* (Xpert *C. difficile*)
- PCR-"*E. coli* O157:H7* (Cepheid, Sunnyvale, CA)
- PCR-"*Salmonella* (Cepheid, Sunnyvale, CA)
- PCR-"*Shigella* (Cepheid, Sunnyvale, CA)
- PCR-"*C. perfringens* CDE (Cepheid, Sunnyvale, CA)

The automated *Singles* C. diff toxins A/B assay, shows high sensitivity and specificity with equal good functional time.

- *Singles* C. diff toxins A/B assay is able to detect as little as 0.5 pg/mL of *C. difficile* toxin A and 0.2 pg/mL of *C. difficile* toxin B in stool, making for appropriate treatment and infection-control measures, and may prevent the propagation and spreading of *C. difficile* infection.

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