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Multicenter clinical evaluation of the portrait toxigenic *C. difficile* assay for detection of toxigenic *Clostridium difficile* strains in clinical stool specimens.

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Abstract

We compared the Portrait Toxigenic *C. difficile* Assay, a new semiautomated sample-to-result molecular test, to a toxigenic bacterial culture/cell cytotoxin neutralization assay (TBC/CCNA) for the detection of toxigenic *Clostridium difficile* in 549 stool specimens. Stool specimens were also tested by one of three alternative FDA-cleared molecular tests for toxigenic *C. difficile* (Xpert *C. difficile*, Illumigene *C. difficile*, or GeneOhm Cdiff). The sensitivities and specificities of the molecular tests compared to TBC/CCNA were as follows: 98.2% and 92.8% for the Portrait assay, 100% and 91.7% for the Xpert assay, 93.3% and 95.1% for the Illumigene assay, and 97.4% and 98.5% for the GeneOhm assay, respectively. The majority of Portrait false-positive results (20/31; 64.5%) were also positive for *C. difficile* by an alternative molecular test, suggesting an increased sensitivity compared to the culture-based "gold standard" method. The Portrait test detected an assay input of 30 CFU in 100% of spiked samples and detected an input of 10 CFU in 96.7% of samples tested.

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