

Singulex assay development, 9/17

September 2017—Singulex is developing an ultra-sensitive *Clostridium difficile* toxin A/B assay for use on its Sgx Clarity system, a fully automated, in vitro diagnostics platform powered by single-molecule counting technology.

In initial pilot studies, the Sgx Clarity *C. difficile* assay demonstrated the ability to detect the disease-causing toxins at concentrations up to 100 times lower than commercially available immunoassay methods. The turnaround time for the Sgx Clarity *C. difficile* toxin A/B assay was shown to be less than one hour, allowing for rapid detection and rule out of suspected *C. difficile* infections.

The assay aims to be the first ultra-sensitive test to offer physicians and laboratorians the specificity intrinsic to toxin tests but at a sensitivity level that rivals molecular methods. The clinical goal is to help clinicians safely to rule out *C. difficile* infection with greater confidence and provide clinically actionable toxin detection in less than an hour.

The Sgx Clarity system is CE marked and currently available in the European market.

The company also announced it received the CE mark for its ultra-sensitive troponin I assay. The Singulex Sgx Clarity cTnI Assay quantitatively measures the biomarker troponin at levels far lower than existing technologies, according to the company. The test is first offered for the Sgx Clarity system.

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