

CE mark for Singulex IVD platform, 6/17

June 2017—Singulex announced it received the CE mark for the Sgx Clarity system, a fully automated in vitro diagnostics platform powered by single-molecule counting technology. Up to 1,000 times more sensitive than existing technologies, single-molecule counting technology measures biomarkers at the lowest levels, revealing the presence, or absence, of disease so clinicians can provide the right treatment at the right time.

Singulex plans to obtain CE marking for a cardiac troponin I assay in Europe and will submit data for regulatory clearance of the Sgx Clarity system in the U.S., anticipating FDA clearance in 2018. The company is also developing a point-of-care platform for its single-molecule counting technology and is exploring additional applications beyond the clinical setting.

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