DiaSorin gets BARDA funding for 510(k) clearance

Jan. 14, 2021–DiaSorin Molecular received additional federal funding from the Biomedical Advanced Research and Development Authority for the validation and submission of the Simplexa COVID-19 Direct kit and the Simplexa COVID-19 & Flu A/B Direct kit for FDA 510(k) clearance. The company initially received BARDA funding in March 2020 to test, validate, and submit the Simplexa COVID-19 Direct kit for FDA emergency use authorization.

The Simplexa COVID-19 Direct kit detects the presence of the RNA of SARS-CoV-2, including VUI 202012/01 (lineage B.1.1.7) and the variant 20C/501Y.V2 (B.1.351 lineage), recently isolated in the U.K. and South Africa, respectively. The test has been available in countries accepting the CE mark and in the U.S. through FDA EUA since March 2020 and is designed for use on the Liaison MDX.

The Simplexa COVID-19 & Flu A/B Direct kit is expected to be finalized and available for the this year's flu season.