DiaSorin gets additional BARDA funding

February 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 the variants VOC 202012/01 strain (lineage B.1.1.7) and the variant 20C/501Y.V2 (lineage B.1.351), recently isolated in the U.K. and South Africa, respectively. The test has been available in countries that accept the CE mark and in the U.S. through FDA EUA since last March 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 this year's flu season.

DiaSorin Molecular, 562-240-6500