BioFire Defense BioFire COVID-19 test gets EUA

March 31, 2020—BioFire Defense, a subsidiary of BioMérieux, has received emergency use authorization by the U.S. Food and Drug Administration for its BioFire COVID-19 test for use in CLIA moderate and high-complexity clinical laboratories to detect SARS-CoV-2. The test detects SARS-CoV-2 in approximately 45 minutes from a nasopharyngeal swab in transport media and runs on the fully automated FilmArray 2.0 and FilmArray Torch platforms.

BioFire COVID-19 was developed with funding from the U.S. Department of Defense by leveraging an existing contract agreement with BioFire Defense. The initial test kits are committed to the DoD for redistribution. Test kits will be available for commercial distribution in the United States under the EUA as well as internationally where regulatory approval allows.

BioMérieux has also received authorization to sell the BioFire COVID-19 test External Control Kit. This positive control material may be used for quality control and laboratory verification of the test.