Quidel gets EUA for Solana SARS molecular test

Dec. 29, 2020—Quidel received emergency use authorization from the FDA to market its Solana SARS-CoV-2 assay, an isothermal reverse transcriptase–helicase-dependent amplification (RT-HDA) assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and nasal swab specimens in viral transport media from patients suspected of having COVID-19 by their health care provider. Testing is limited to CLIA-certified laboratories that perform high- and moderate-complexity tests. The assay offers a 25-minute run time for up to 11 samples.

“With so many of our nation’s laboratories overwhelmed by demand for COVID-19 tests and under pressure to produce more timely results, there is a compelling societal need for the throughput and quick run time offered by our new Solana molecular testing technology,” Douglas Bryant, president and CEO of Quidel, said in a press statement. “Joining our Lyra and Lyra Direct assays for SARS-CoV-2, we now offer another molecular weapon in the fight against COVID-19 to quickly diagnose symptomatic patient populations.”

The assay consists of two main steps—specimen preparation, and amplification and detection of target sequences specific to SARS-CoV-2 using the company’s proprietary isothermal RT-HDA in the presence of target-specific fluorescence probes. The Solana instrument objectively measures and interprets a fluorescent signal, reports the test results to the user on its display screen, and can print out results via an integrated printer.