Quidel gets EUA for QuickVue SARS rapid antigen test

Dec. 22, 2020 —Quidel announced it received emergency use authorization from the FDA to market its QuickVue SARS Antigen test, a point-of-care assay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nares swab specimens from people who are suspected of having COVID-19 by their health care provider within the first five days of symptom onset.

The test offers excellent performance for the detection of SARS-CoV-2—96.6 percent positive percent agreement and 99.3 percent negative percent agreement versus PCR—with test results available in 10 minutes.

“The flexibility of QuickVue for meeting the urgent testing needs of everyone from school systems to rural areas and even locations without electricity gives us the opportunity to do enormous good in communities across our nation and the world,” Douglas Bryant, president and CEO of Quidel, said in a press release. “We will scale immediately to supply the more than 30,000 QuickVue professional market customers we serve today and look forward to extending the benefits of this technology as broadly and rapidly as possible in the months and years ahead.”

The company plans to reach a production run rate of 600 million QuickVue tests per year by the end of 2021.