LumiraDx COVID-19 antigen test gets expanded EUA

December 2021—LumiraDx announced that the FDA's emergency use authorization for its SARS-CoV-2 antigen test has been expanded to include screening of asymptomatic individuals. This claim builds on its existing claim that covers use of the test in individuals suspected of having COVID-19 by their health care provider within 12 days of symptom onset. The test received EUA in August 2020.

The FDA authorized the expanded EUA after reviewing company data on the performance of the SARS-CoV-2 antigen test in individual asymptomatic subjects collected between June 2020 and March 2021. Results indicated high sensitivity and specificity in asymptomatic individuals with the LumiraDx SARS-CoV-2 Ag test, demonstrating an 82.1 percent positive agreement and 100 percent negative agreement with the RT-PCR test in 222 subjects.

LumiraDx, 888-586-4721