Qiagen gets EUA for NeuMoDx COVID-19 multiplex test

March 31, 2021—Qiagen announced FDA emergency use authorization for the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay, to help identify people suspected of respiratory viral infection consistent with COVID-19. The multiplex PCR test detects and differentiates influenzas A and B, respiratory syncytial virus, and SARS-CoV-2 infections within 80 minutes.

“The authorization of this new test will become a pivotal tool for the detection and differentiation of SARS-CoV-2 from influenza like illnesses, or ILIs,” Jean-Pascal Viola, senior VP and head of Qiagen’s molecular diagnostics business area and corporate business development, said in a press release. “This test will play an important role in differentiating between ILI’s while the burden of COVID-19 continues. With its ease of use and true random access, the NeuMoDx will help laboratories maintain throughput for this increased testing volume while continuing routine testing. Also, with the continued ramp up of our manufacturing capacity, the NeuMoDx will be ready to answer the needs of molecular diagnostic laboratories for 2021 and beyond.”

The company launched the test in November in the European Union and other markets that accept CE-IVD and will now begin commercialization of the test in the U.S.