Roche receives EUA for Cobas SARS-CoV-2 & Influenza A/B test

Sept. 4, 2020—Roche announced that the Cobas SARS-CoV-2 & Influenza A/B Test for use on the Cobas 6800/8800 systems has received emergency use authorization from the FDA. The test is an RT-PCR assay intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus in nasal or nasopharyngeal swab samples collected from individuals suspected of a respiratory infection. It is not intended for the detection of influenza C virus. Under FDA EUA, the test can be taken by individuals suspected of a respiratory viral infection consistent with COVID-19 by their health care provider.

The test runs on the Cobas 6800/8800 systems and has a full-process negative control, positive control, and internal control. The systems provide up to 96 results in about three hours; in an eight-hour shift, the Cobas 6800 provides 384 results and the Cobas 8800 provides 1,056 results.

This test is also available in markets accepting the CE mark.