FDA clears Simplexa COVID-19, flu A/B assay

April 2023—DiaSorin has received FDA 510(k) clearance for its Simplexa COVID-19 and Flu A/B Direct assay. The test is a real-time RT-PCR assay that detects and differentiates influenza A, influenza B, and SARS-CoV-2 viruses and is performed using nasopharyngeal swab samples. Results are available in a little more than an hour on the Liaison MDX instrument.

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