FDA clears Simplexa flu A/B, RSV assay

November 2020—DiaSorin Molecular received FDA clearance for its Simplexa Flu A/B & RSV Direct Gen II kit. The assay can be run alone or alongside the Simplexa COVID-19 Direct kit, allowing for differential diagnosis of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus.

"With COVID-19 set to play a major role in the upcoming flu season, it was critical for us to have the Simplexa Flu A/B & RSV Direct Gen II assay available in time for patient samples to be tested, when needed, alongside the Simplexa COVID-19 Direct assay," Michelle Tabb, chief scientific officer of DiaSorin Molecular, said in a press statement. "Detection and differential diagnosis between influenza, RSV, and COVID-19 will be vital this year, and we are pleased to contribute to this solution."

The Simplexa Flu A/B & RSV Direct Gen II assay is designed for use with the Liaison MDX instrument.

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