

Simplexa COVID-19, flu A/B assay gets CE mark

Sept. 21, 2021—[DiaSorin Molecular](#) announced it has CE marked its Simplexa COVID-19 and Flu A/B Direct kit. The multiplex test allows for the in vitro qualitative detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, and influenza B from a patient sample in one reaction well. The assay is designed for use on the Liaison MDX and is run directly from nasopharyngeal swabs.

“We are excited to expand our product offering with the launch of this combination kit for detection of SARS-CoV-2 and influenza that can help address concerns in anticipation of this upcoming flu season,” said Michelle Tabb, chief scientific officer of DiaSorin Molecular. “We are committed to providing flexible testing options with the new combo kit in addition to our standalone COVID-19 assay as well as the triplex for flu A, flu B, and RSV in order to meet laboratory’s evolving needs as the world comes back to a new normal.”

The kit will be submitted to the FDA for 510(k) review.