

FDA approves Bio-Rad's multi-target reliance SARS-CoV-2/FluA/FluB RT-PCR assay kits

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Designed to target the nucleocapsid gene, the assays are not affected by known coronavirus variants as determined by in-silico analysis



Bio-Rad Laboratories, Inc., a global leader of life science research and clinical diagnostic products has announced that its Reliance SARS-CoV-2/FluA/FluB RT-PCR and Reliance SARS-CoV-2 RT-PCR Assay Kits were granted Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA).

The multi-target Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit simultaneously detects and differentiates SARS-CoV-2 (the virus associated with COVID-19), influenza A, and influenza B in a single multiplex reaction. The highly sensitive respiratory pathogen panel is intended for use with nasopharyngeal swabs and anterior nasal swabs. The assay kit includes Bio-Rad positive and negative molecular controls and is validated to run on Bio-Rad's CFX Opus 96, CFX96 Touch, and CFX96 Dx qPCR Systems as well as qPCR systems offered by other manufacturers.

Bio-Rad's Reliance SARS-CoV-2 RT-PCR Assay Kit is a multiplex test that targets two separate regions in the nucleocapsid gene (N1 and N2 regions) to ensure greater sensitivity and tolerance to potential mutations, which may occur within the viral genome over time, in the detection of SAR-CoV-2. The assay kit contains the company's standard and negative molecular controls and is validated to run on the CFX Opus 96, CFX96 Touch, and CFX96 Dx qPCR Systems, the CFX Opus 384 and CFX384 Touch Systems for higher throughput testing and is validated to run on qPCR systems offered by other manufacturers.