



The right outcome starts with the right test.

One system with multiple assays delivering reliable results for SARS-CoV-2,* Flu A, Flu B, RSV, and Group A Strep within 15 minutes at the point-of-care.

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* In the USA, this product has not been FDA cleared or approved but has been authorized by the FDA under an Emergency Use Authorization for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high, or waived complexity tests. The product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens; and, in the USA, the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID 19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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