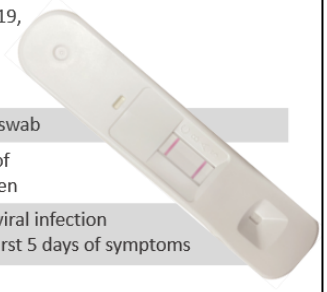
CLIAwaived™ Inc.
The Point-of-Care Marketplace

FAST FACTS

ViraDx™ SARS-COV-2/FLU A+B RAPID ANTIGEN TEST

FOR PROFESSIONAL USE ONLY

ViraDx Part Number	• CP0031
Why ViraDx?	• Detects and differentiates COVID-19, Flu A and Flu B with one sample • Results at 15 minutes • User-friendly test procedure
Sample Type	• Anterior nasal or nasopharyngeal swab
Detection Targets	• Nucleocapsid protein (N protein) of SARS-CoV-2, Flu A and Flu B antigen
Patient Population	• Patients suspected of respiratory viral infection consistent with COVID-19 within first 5 days of symptoms
Tests/Kit	• 25
External Controls	• 1 Positive control swab • 1 Negative control swab
Setting	• Testing sites that meet the requirements to perform point-of-care-testing
Method	• Lateral flow
Interpretation	• Visual read
Time To Result	• Read at 15 minutes
Clinical Performance	**COVID-19** (Anterior nasal swab): Sensitivity 93.8%; Specificity 100%
	COVID-19 (Nasopharyngeal): Sensitivity 93.1%; Specificity 100%
	Flu A: Sensitivity 92.2%; Specificity 94.2%
	Flu B: Sensitivity 90.0%; Specificity 94.3%
Storage	2 to 30° C (35 to 86°F)



1. ViraDx [package insert] PM-169.2 Carlsbad, CA: Lumos Diagnostics; 2023.

ViraDx Emergency Use Authorization Number (EUA): EUA220131

This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories

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

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

Refer to the Package Insert for complete instructions. Read the complete test procedure, including recommended Quality Control procedures, before performing the test.
For in vitro diagnostic use.
For Rx use only.

Distributed By:
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