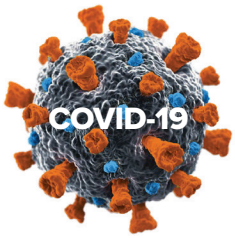
LUMOS DIAGNOSTICS

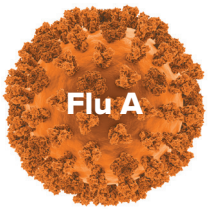
1 Sample – 3 Results

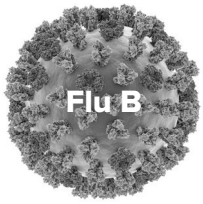
ViraDx™

ViraDx™ is a point-of-care test to detect and differentiate SARS-CoV-2, Flu A and Flu B from one sample.

FOR PROFESSIONAL USE ONLY







EFFICIENT: 3 results to aid in a differential diagnosis at the point of care

RAPID: actionable results in 15 minutes to help improve patient management decisions

HIGHLY CORRELATED TO PCR:[1]
COVID-19: Sensitivity (Anterior nasal swab) 93.8%; Specificity 100%
COVID-19: Sensitivity (Nasopharyngeal) 93.1%; Specificity 100%

Flu A: Sensitivity 92.2%; Specificity 94.2%
Flu B: Sensitivity 90.0%; Specificity 94.3%

INSTRUMENT-FREE: user-friendly test procedure for non-lab settings

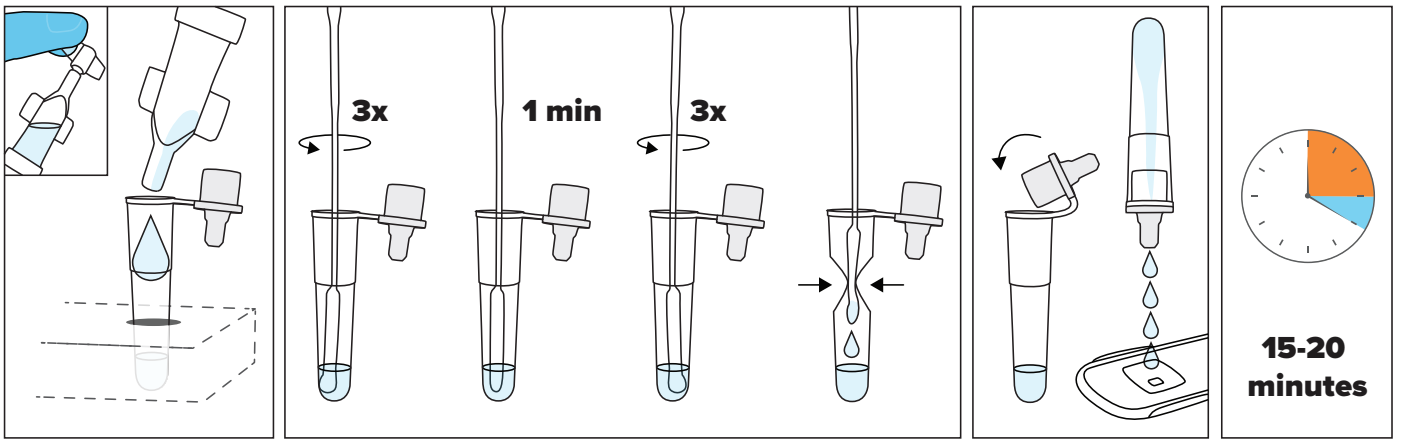
For in vitro diagnostic use

For Rx Use Only

ViraDx™

SIMPLE INSTRUMENT-FREE TEST PROCEDURE

PROCEDURE

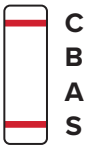


Read test results at 15 minutes.

NOTE: False positive or false negative results can occur if the test is not read between 15 and 20 minutes.

SIMPLE RESULT INTERPRETATION

INTERPRETATION OF RESULTS

A reddish purple S, A and/or B line(s) with C line is POSITIVE.	C line only **NEGATIVE (-)**	No C line **INVALID**
 **A line:** Influenza type A  **B line:** Influenza type B  **S line:** COVID-19 ***NOTE: Co-infection with influenza A, B and/or SARS-CoV-2 is rare. If results are positive for more than one antigen, i.e., influenza A, B and/or COVID-19, the patient specimens should be re-tested.**		 

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 the 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.

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

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PM-231.2 OCT 2023

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