ViraDx™

SARS-COV-2 FLU A+B RAPID ANTIGEN TEST

FOR PROFESSIONAL USE ONLY*

What does the ViraDx™ test target?

The ViraDx test targets the nucleocapsid antigen SARS-CoV-2, influenza A and influenza B.

What are the storage requirements for ViraDx?

The ViraDx test should be stored at 2-30°C (35-86°F) in the original sealed pouch, away from direct sunlight.

What patient samples can be used on the ViraDx test?

The ViraDx test should be used with freshly collected anterior nasal or nasopharyngeal swab specimens. Samples must not be placed in any viral transport media.

Can the patient swabs be stored frozen for retrospective testing?

Freshly collected specimens should be tested immediately. If necessary, swab samples can be stored for up to 4 hours at room temperature or up to 8 hours at 2-8°C.

Can I use a different type of swab to collect the sample?

No. Only the swabs provided in the kit are to be used for collecting specimens. Other swabs may not work properly.

When can the ViraDx results be interpreted?

The test results should be read at 15 minutes. Do not read the results after 20 minutes.

***Note:** To ensure proper test performance, it is important to read results at 15 minutes. False positive or false negative results can occur if the test is not read between 15 and 20 minutes.*

The Test line is quite weak. Does this affect the interpretation of results?

The test line may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen detected. Even if the test line is light or faint, the test must be interpreted as a positive result.

The Test line is visible, but the control line is absent. Can I still report the results?

A reddish-purple line should always appear at the Control line position (C position). If a line does not form at the Control line position in 15 minutes, the test result is invalid, and the test should be repeated with a new ViraDx test.

How sensitive and specific is the ViraDx test?

The ViraDx test demonstrated the following clinical performance characteristics:[1]

- **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%

Does a negative ViraDx test result rule out COVID-19, influenza A and influenza B?

A negative test result does not exclude infection with SARS-CoV-2, influenza A or B. Negative test results are presumptive and may need to be confirmed with a molecular test. Therefore, results obtained with the ViraDx test should be used in conjunction with clinical findings to make an accurate diagnosis.

1. ViraDx [package insert] PM-169.2. Carlsbad, CA: Lumos Diagnostics; 2022.

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

Wilburn Medical USA™

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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.
Rx only.

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