COVID-19 / Influenza A&B Test

The WELLlife™ COVID-19 / Influenza A&B Test differentiates between SARS-COV-2, influenza A and influenza B antigens with a single test.

Features and Benefits

• Cost-effective

Differentiate between SARS-COV-2, influenza A, and influenza B antigens with a single test using an anterior nasal swab specimen.

• Rapid

Results available in 10 minutes allow for testing and treatment decision-making during the same office visit.

•Quality Assurance

The outstanding clinical performance, including built-in kit controls for external quality testing, enables physicians to make quicker and more confident decisions.

•Extended Detection Window

Offers a broader detection window for differentiation of SARS-COV-2, influenza A, and influenza B antigens within five (5) days of symptom onset.

•Wide Storage Temperature

36°F-86°F(2°C-30°C) allows for easier product storage.

Product Performance

	SARS-COV-2	Influenza A	Influenza B
Positive Percent Agreement (PPA)	87.5%	85.9%	86.8%
Negative Percent Agreement (NPA)	99.7%	99.7%	99.7%
Limit of Detection (TCID50/mL) *	7.90 x102	1.01 x102	5.85 x101

* LOD for Influenza A A/Victoria/4897/2022(H1N1), LOD for Influenza B B/Florida/4/2006(Yamagata). Please refer to PI for more detailed information.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. 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.

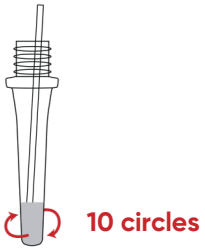
Authorized Distributor
Global Supply Exchange, LLC
6900 Tavistock Lakes Blvd, Suite 400
Orlando, Florida 32827

Ana Viruel
786-436-7320
ana.viruel@globalsupplyexchange.com

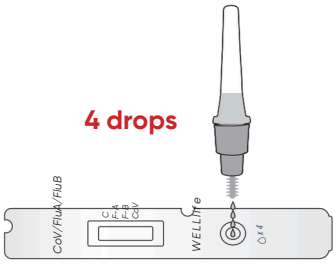
WELLlife™

Quick 3-Step Test Protocol

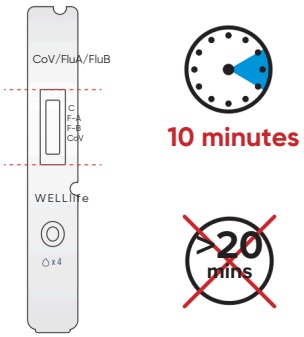
1. Immerse the swab into the buffer tube and swirl the swab in the buffer. Ensure the sample is mixed thoroughly by making at least 10 circles.



2. Invert the buffer tube and squeeze 4 drops of test sample into the sample well on the test cassette.

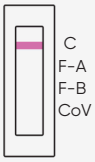


3. Start timer. Read results at 10 minutes.

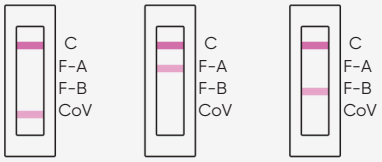


Clear Interpretation

Negative



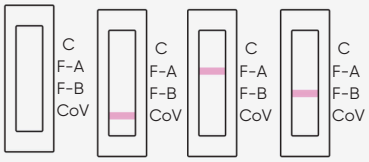
Positive



COVID-19 Positive | Influenza A Positive | Influenza B Positive

If the control line at "C" is visible and any other line or multiple lines at 'F-A', 'F-B" and/or 'CoV' appear, the test is positive for that virus.

Invalid



If a line is not visible at 'C', even if any other line is visible in the results window, the result is considered invalid.

* Please refer to QRI for detailed results interpretation.

Ordering Information

Item Code	Description	Size
WV01P0002	WELLlife™ COVID-19 / Influenza A&B Test	25T/Kit
WV01P0003	WELLlife™ COVID-19 / Influenza A&B Test Control Kit	5T/Kit

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