



## 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
<b>Positive Percent Agreement (PPA)</b>	87.5%	85.9%	86.8%
<b>Negative Percent Agreement (NPA)</b>	99.7%	99.7%	99.7%
<b>Limit of Detection (TCID<sub>50</sub>/mL) *</b>	7.90 x10 <sup>2</sup>	1.01 x10 <sup>2</sup>	5.85 x10 <sup>1</sup>

\* 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.