

Wondfo USA Receives 510(k) Clearance for WELLlife™ COVID-19 Test

Enabling rapid detection of the SARS-CoV-2 in Professional settings.

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Wondfo USA Co., Ltd. (Wondfo USA), a wholly owned subsidiary of Guangzhou Wondfo Biotech Co., Ltd., is pleased to announce that its WELLlife™ COVID-19 Antigen Test Rx has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for prescription use.

This clearance marks an important expansion of the WELLlife™ COVID-19 testing portfolio, which previously included authorization for over-the-counter (OTC) use. With the addition of the prescription-use indication, healthcare providers now have more flexibility to utilize the WELLlife™ COVID-19 Antigen Test in diverse clinical settings, supporting timely and accurate diagnosis of SARS-CoV-2 infection.

The WELLlife™ COVID-19 Antigen Test Rx offers rapid results in just 10 minutes, helping clinicians make informed decisions for patient management and infection control. The test detects active COVID-19 infection with high sensitivity and specificity and can be easily implemented in point-of-care environments such as clinics, urgent care centers, and doctor's offices.

Speaking from Wondfo USA's headquarters in Illinois, Brian Drake, VP of Sales and Downstream Marketing, commented "The FDA's clearance of the WELLlife™ COVID-19 Antigen Test Rx for prescription use further broadens the accessibility of our testing solutions across healthcare channels. This milestone reinforces Wondfo's commitment to equipping healthcare professionals with reliable, rapid diagnostics to support effective patient care and rapid response to public health issues."

About Wondfo USA Co., Ltd.

Wondfo USA Co., Ltd. is a leading provider of point-of care testing (POCT) products. Wondfo USA distributes rapid products in four major categories including Toxicology Testing, Infectious Disease, Women's Reproductive Health, and Veterinary Diagnostics. Wondfo's diagnostic products are sold globally, and are widely used in various settings, including clinical testing, critical care medicine, primary care, epidemic monitoring, on-site law enforcement, and family health management. With a strong commitment to innovation and quality, Wondfo's mission is to make significant contributions to the global healthcare industry. Wondfo USA has established an R&D and manufacturing facility in San Diego, CA as well as a dedicated distribution center in Bolingbrook, IL, ensuring a reliable supply of tests to meet the country's needs.

To learn more about Wondfo USA or the WELL life portfolio visit wondfousa.com.

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