COVID-19 / Influenza A&B Test Control Kit

INSTRUCTIONS FOR USE

REF WV01P0003

IVD **℞ ONLY**

For *in vitro* diagnostic use
For prescription use only
For use under an Emergency Use Authorization (EUA) only

Please read instructions carefully before you perform the test.

INTENDED USE

The WELLlife™ COVID-19 / Influenza A&B Test Control Kit is intended for *in vitro* diagnostic use in quality control testing with the WELLlife™ COVID-19 / Influenza A&B Test.

SUMMARY

The WELLlife™ COVID-19 / Influenza A&B Test Control Kit includes five (5) Flu A/Flu B/SARS-CoV-2 Positive Control Swabs and five (5) Flu A/Flu B/SARS-CoV-2 Negative Control Swabs for external quality control testing. Use the WELLlife™ COVID-19 / Influenza A&B Test Control Kit to help ensure that the WELLlife™ COVID-19 / Influenza A&B Test is functioning properly and to demonstrate proper performance by the test operator. External controls are intended to monitor substantial device failure.

If External Quality Control testing fails, repeat the testing of the failed control or contact Wondfo Product Support at +1-888-444-3657 or at ***https://wondfousa.com/.*** before running patient samples.

External quality control requirements should be established in accordance with local, state, and federal regulations or accreditation requirements. Minimally, Wondfo recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator.

KIT CONTENTS

5- WELLlife™ COVID-19 / Influenza A&B Test Positive Control Swab (packaged in individual pouches) and coated with recombinant influenza A antigens, recombinant influenza B antigens and SARS-CoV-2 antigens and 0.05% ProClin 300
5- WELLlife™ COVID-19 / Influenza A&B Test Negative Control Swab (packaged in individual pouches) and coated with inactivated Streptococcus A antigen and 0.05% ProClin 300
1- WELLlife™ COVID-19 / Influenza A&B Test Control Kit Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- WELLlife™ COVID-19 / Influenza A&B Test (REF No. WV01P0001)
- Timer or watch

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. 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.
3. Caution: Federal law restricts this device to sale by or on the order of a physician.
4. DO NOT use kit contents beyond the expiration date printed on the outside of the box.
5. Not for patient use.
6. Follow Good Laboratory Practices, wear protective clothing, use disposable gloves, do not eat, drink or smoke in the area.
7. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
8. The control swabs and test device should be discarded in a proper biohazardous container after testing.
9. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
10. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
11. This product is provided for quality assurance purposes and must not be used for calibration or as primary reference preparations in any test procedure.

KIT STORAGE AND STABILITY

Store the WELLlife™ COVID-19 / Influenza A&B Test Control Kit at 35.6-86°F (2-30°C). Kit materials are stable until expiration date printed on the outer box label.

RUNNING AN EXTERNAL QUALITY CONTROL TEST PROCEDURE

To perform a positive or negative control test, complete the steps in the Test Procedure section of the assay Instructions for Use treating the control swab in the same manner as a patient swab (refer to WELLlife™ COVID-19 / Influenza A&B Test Instructions for Use).

INTERPRETATION OF EXTERNAL QUALITY CONTROL RESULTS

When the Flu A/Flu B/SARS-CoV-2 Positive Control Swab is tested, the appearance of ANY shade of a very light or faint pink to red line at the “F-A” Test Line, “F-B” Test Line, and “CoV” Test Line, along with a “C” Control Line indicates that the influenza and SARS-CoV-2 antigen binding properties of the Test Stick are functional.

When the Flu A/Flu B/SARS-CoV-2 Negative Control Swab is tested, there should only be the appearance of the “C” Control Line without lines at the “F-A” Test Line, “F-B” Test Line, nor the “CoV Test Line to indicate that there is no non-specific antigen binding and the Test Stick is functional.

Refer to the WELLlife™ COVID-19 / Influenza A&B Test Control Kit Test Instructions for Use for a complete description of the assay procedure and interpretation of results.

DISPOSING OF EXTERNAL QUALITY CONTROL MATERIALS

Dispose of hazardous or biologically contaminated materials according to your institution’s practices. Discard all

materials in a safe and acceptable manner that is in compliance with all country, state, and local requirements.

REORDER

WELLlife™ COVID-19 / Influenza A&B Test Kit (Catalog Number WV01P0002)

WELLlife™ COVID-19 / Influenza A&B Test Control Kit (Catalog Number WV01P0003)

ASSISTANCE

If the test does not perform as expected, please email at wondfo@wondfousa.com or call 1-888-444-3657.

INDEX OF SYMBOLS

	Consult instructions for use		Manufacturer		Keep dry
	Do not reuse		Store between 2-30°C (35.6°F-86°F)	LOT	Batch code
	Prescription Use Only		Keep away from sunlight	IVD	For in vitro diagnostic use
REF	Catalog number		Use-by date		Contains sufficient for <n> Tests
CONTROL +	Positive Control	CONTROL -	Negative Control		

Wondfo USA Co., Ltd.
6720 Cobra Way,
San Diego, CA 92121

Manufacturing site
Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City
Huangpu District, 510663
Guangzhou, P.R. China
Made in China

Distributed by Wondfo USA Co., Ltd.
545 Willowbrook Centre Parkway, Unit B
Willowbrook, IL 60527
+1 (630) 468-2199
www.wondfousa.com