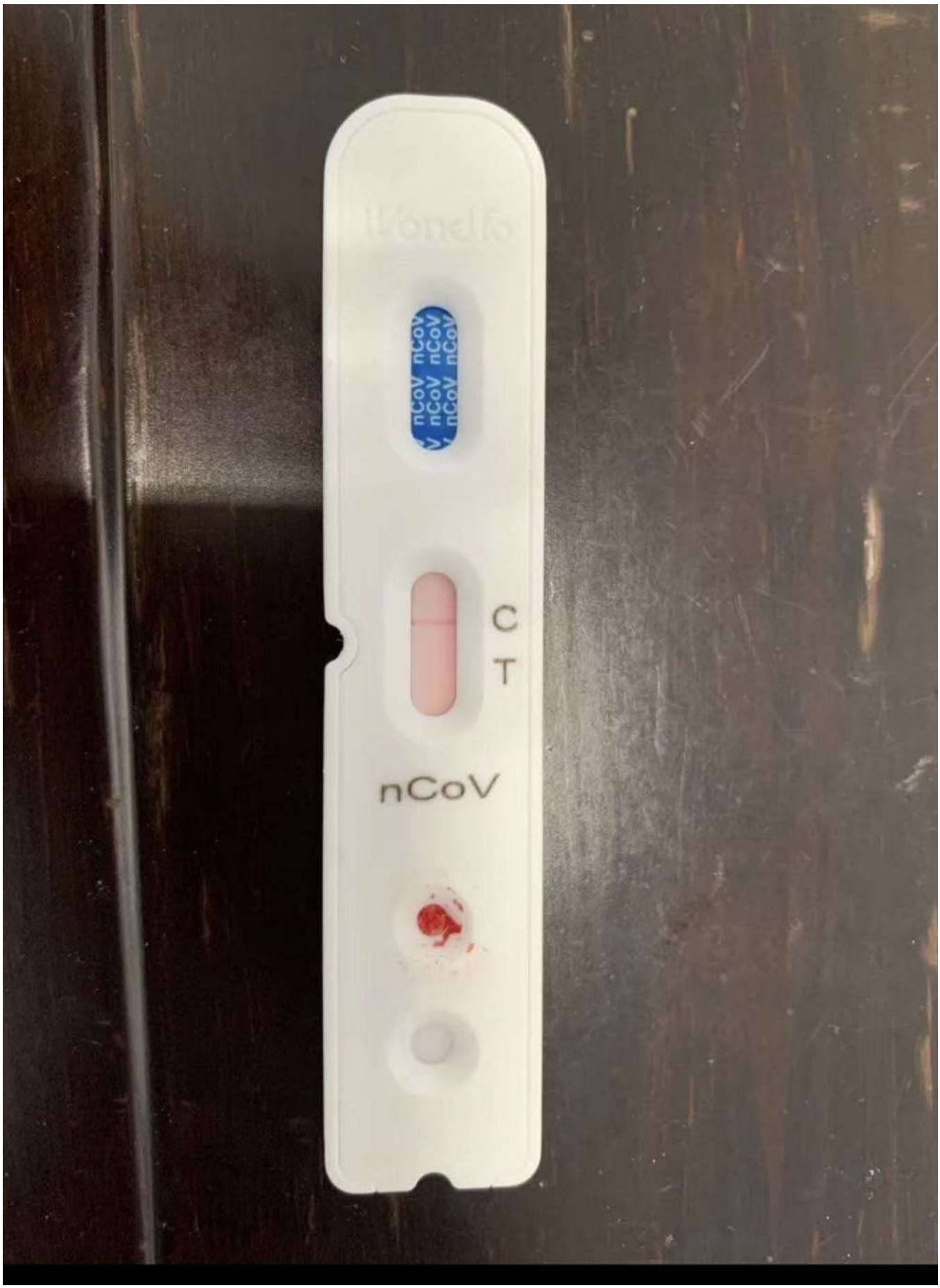
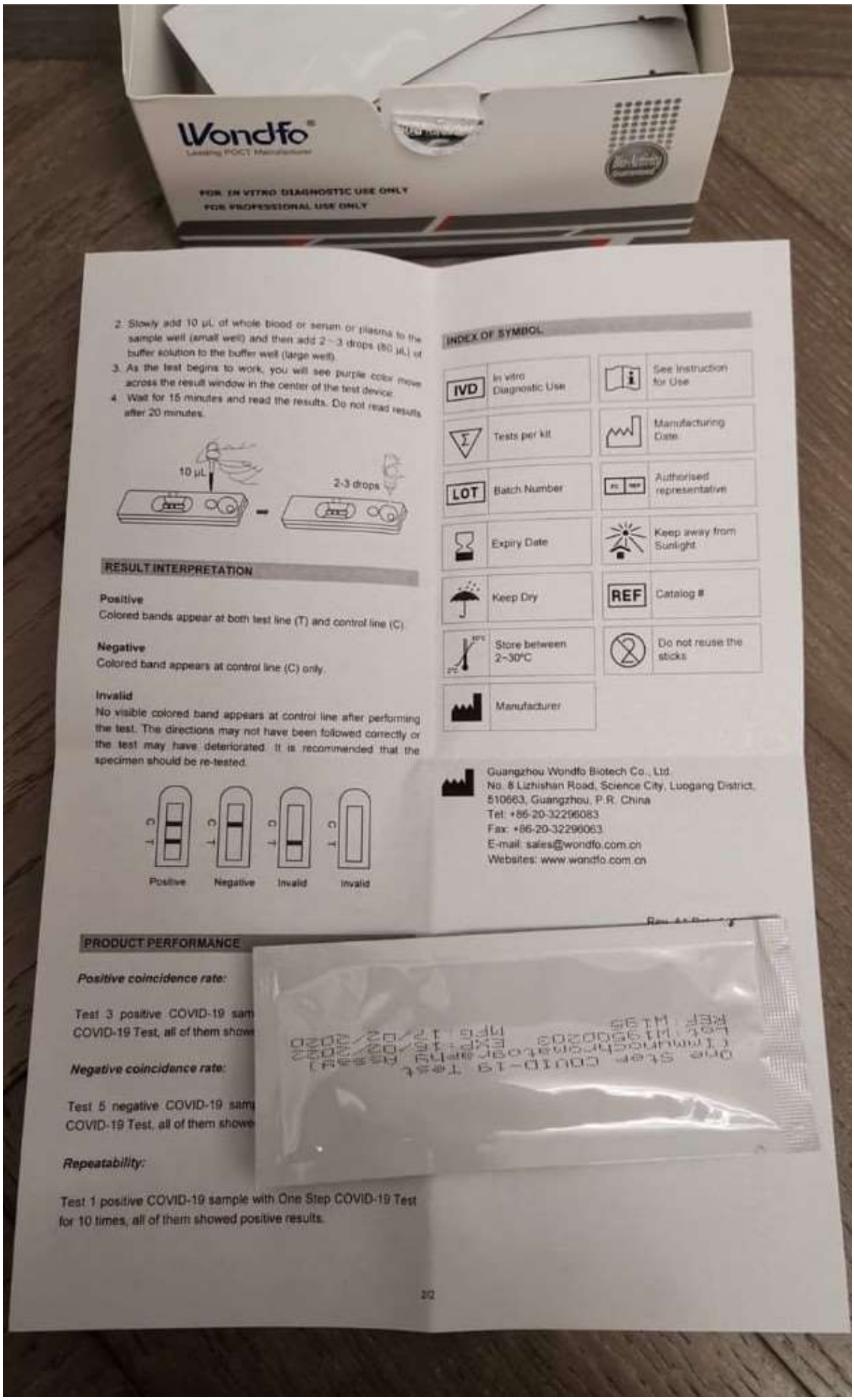

nCoV
C
T
nCoV



2. Slowly add 10 µL of whole blood or serum or plasma to the sample well (small well) and then add 2 – 3 drops (80 µL) of buffer solution to the buffer well (large well).
3. As the test begins to work, you will see purple color move across the result window in the center of the test device.
4. Wait for 15 minutes and read the results. Do not read results after 20 minutes.

RESULT INTERPRETATION

Positive
Colored bands appear at both test line (T) and control line (C).

Negative
Colored band appears at control line (C) only.

Invalid
No visible colored band appears at control line after performing the test. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen should be re-tested.

INDEX OF SYMBOL

IVD	In vitro Diagnostic Use		See Instruction for Use
Σ	Tests per kit		Manufacturing Date
LOT	Batch Number		Authorised representative
	Expiry Date		Keep away from Sunlight
	Keep Dry	REF	Catalog #
30°C 2°C	Store between 2~30°C		Do not reuse the sticks
	Manufacturer		

Guangzhou Wondfo Biotech Co., Ltd.
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510663, Guangzhou, P.R. China
Tel: +86-20-32296063
Fax: +86-20-32296063
E-mail: sales@wondfo.com.cn
Websites: www.wondfo.com.cn

PRODUCT PERFORMANCE

Positive coincidence rate:

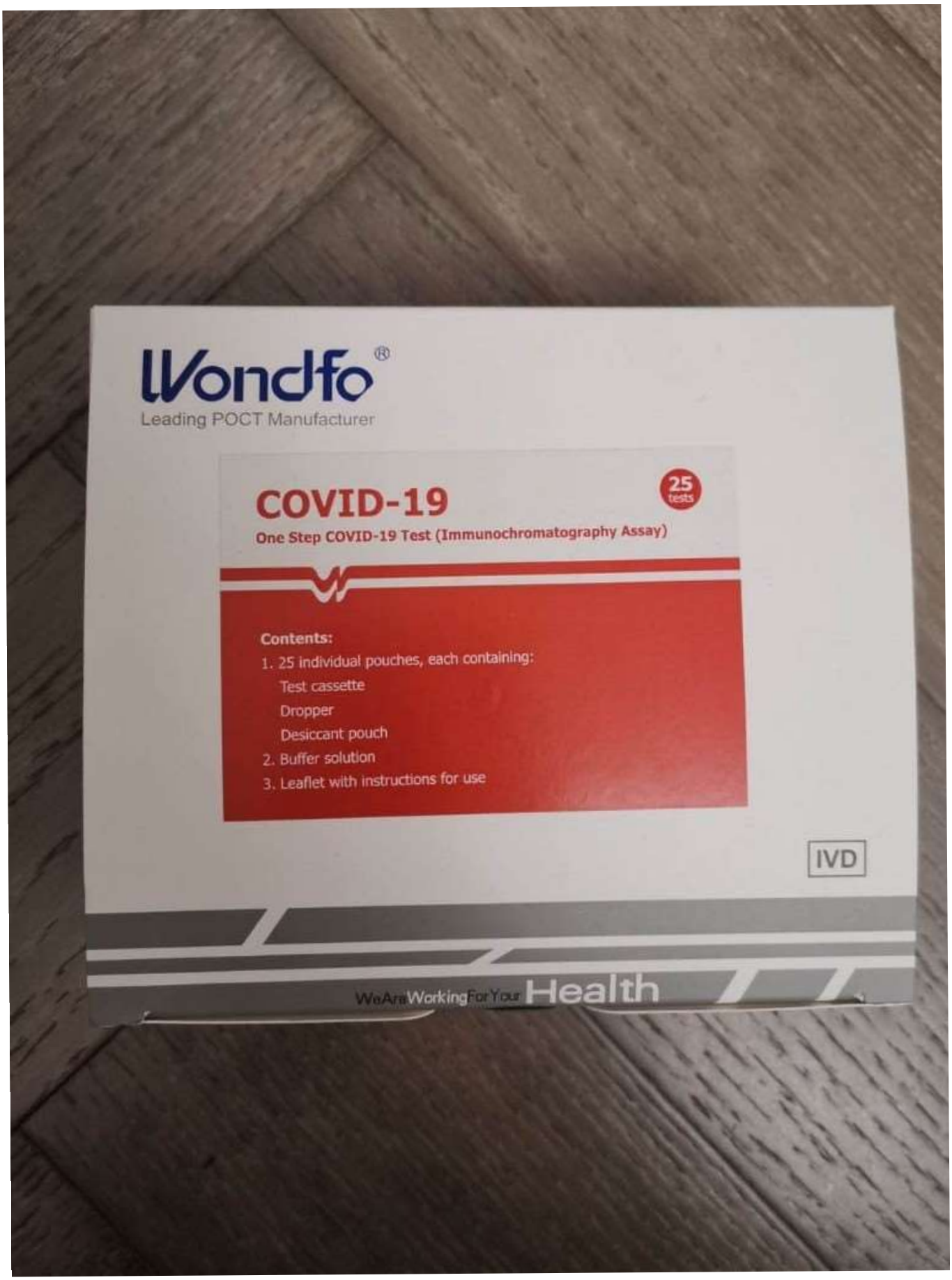
Test 3 positive COVID-19 sam
COVID-19 Test, all of them show

Negative coincidence rate:

Test 5 negative COVID-19 sam
COVID-19 Test, all of them showe

Repeatability:

Test 1 positive COVID-19 sample with One Step COVID-19 Test for 10 times, all of them showed positive results.


Wondfo®
Leading POCT Manufacturer
COVID-19
25 tests
One Step COVID-19 Test (Immunochromatography Assay)
Contents:
1. 25 individual pouches, each containing:
Test cassette
Dropper
Desiccant pouch
2. Buffer solution
3. Leaflet with instructions for use
IVD
WeAreWorkingForYour Health

Wondfo®
One Step COVID-19 Test
(Chromatography Assay)

INTENDED USE

One Step COVID-19 Test is used for detecting COVID-19 antibodies in human whole blood, serum or plasma sample, and is suitable for the preliminary screening test for the patients with suspected COVID-19 infection.

For *in vitro* diagnostic use only.

PRINCIPLE

One Step COVID-19 Test uses with immunochromatography assay for the detection of COVID-19 antibodies in human whole blood, serum and plasma. When the COVID-19 antigen level in the specimen is at or above the target cutoff (the detection limit of the test), the antigen bound to the antibody-dye conjugate are captured by anti-COVID-19 antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the COVID-19 antigen level in the specimen is zero or below the target cut off, there is not a visible colored band in the Test Region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

PRECAUTION

1. This kit is for *in vitro* diagnostic use only. Do not swallow.
2. All specimens should be treated as capable of transmitting diseases.
3. Icteric, lipemic, hemolysed, heat treated and contaminated blood may cause erroneous results.
4. Discard after first use. The test cannot be used more than once.
5. Do not use test kit beyond the expiration date.
6. Do not use the kit if the pouch is punctured or not well sealed.
7. Keep out of the reach of children.
8. DISPOSAL OF THE DIAGNOSTIC: The used-device has the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation

MAIN COMPONENT

- Each individual foil envelope contains:

1 x Test cassette
1 x Dropper
1 x Desiccant pouch

- Buffer solution
- Instructions for use

STORAGE AND STABILITY

1. Store at 4-30℃ in the sealed pouch up to the expiration date printed on the package. The shelf life is 24 months.
2. The test cassette should be used within 1 hour after taking out from the foil envelope. Buffer solution should be re-capped in time after use.
3. Keep away from sunlight, moisture and heat.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with whole blood, serum and plasma.

For whole blood:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA, Heparin, Citrated sodium).
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2°C～8°C.
3. It's not suitable to test the whole blood samples which have been stored at 2°C～8°C for more than 7 days.

For Serum and Plasma:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA, Heparin, Citrated sodium).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
3. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2°C～8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

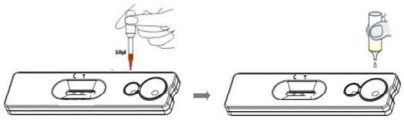
Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed

well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolyzed specimens can be used.

TEST PROCEDURE

Allow the device, buffer and specimen to equilibrate to room temperature (10°C ～30°C) prior to testing.

1. Remove a test cassette from the foil pouch by tearing at the notch and place it on a level surface.
2. Slowly add 10 µL of whole blood or serum or plasma to the sample well (A) and then add 2～3 drops (80 µL) of buffer solution to the buffer well (B).
3. As the test begins to work, you will see purple color move across the result window in the center of the test device.
4. Wait for 15 minutes and read the results. Do not read results after 20 minutes.

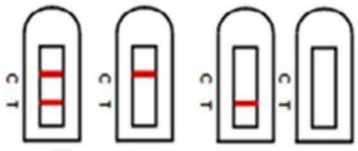


RESULT INTERPRETATION

Positive: colored bands appear at both test line (T) and control line (C).

Negative: colored band appear at control line (C) only.

Invalid: no visible colored band appear at control line after performing the test. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



Positive Negative Invalid

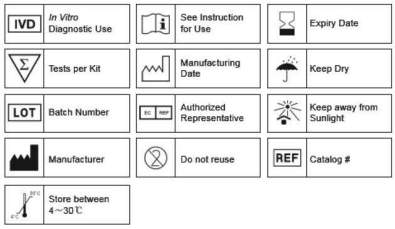
PRODUCT PERFORMANCE

Positive coincidence rate: Test 3 positive COVID-19 samples (P1～P3) with One Step COVID-19 Test, all of them showed positive results.

Negative coincidence rate: Test 5 negative COVID-19 samples (N1～N5) with One Step COVID-19 Test, all of them showed negative results.

Repeatability: Test 1 positive COVID-19 sample with One Step COVID-19 Test for 10 times, all of them showed positive results.

INDEX OF SYMBOL



Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R.China

Rev. A01

Rel: 2020.02.07

Guangzhou Wondfo Biotech Co., Ltd.

QMR—009—09 **Valid From: November 13, 2019**

Report of Finished Product Inspection

Report Code：C-202002112

Name of Product	SARS-CoV-2 Antibody Test (Lateral Flow Method)			
Lot Number	W19500205	**Batch**	/	
Specification	20 tests/kit	**Number**	100000T	
Manufacture Date	2020-02-23	**Expiration Date**	2020-08-23	
Sampling Date	2020-02-24	**Report Date**	2020-02-24	
Inspection Reference	TS-PM-738		**Sampling Amount**	208T
Inspection Items	**Quality Standards**		**Inspection Result**	**Determination of Result**
Physical Examination	Appearance: The appearance should be flat, the logo should be clear. The components should be firmly attached, and the content should be complete.		Coincidence rate: (208/208)	☑Compatible ☐Incompatible
	Migration Speed: Liquid migration speed should be not lower than 10mm/min.		Liquid migration speed is (26) mm/min	☑Compatible ☐Incompatible
	Width of Membrane: The width of membrane should be wider than 2.5mm.		Width of membrane is (4.0) mm.	☑Compatible ☐Incompatible
Positive Reference Coincidence Rate	Positive Reference Coincidence Rate should be 5/5.		Coincidence Rate is (5/5).	☑Compatible ☐Incompatible
Negative Reference Coincidence Rate	Negative Reference Coincidence Rate should be 10/10.		Coincidence Rate is (10/10).	☑Compatible ☐Incompatible
Lowest Limit of Detection	Enterprise Reference of Lowest Limit of Detection S1 should be negative, S2 and S3 should be positive.		Coincidence Rate is (3/3).	☑Compatible ☐Incompatible
Repeatability	Test 2 Enterprise Repeatability References (J1~J2), and each repeat for 10 times respectively, the results should be positive.		Coincidence Rate is (10/10, 10/10).	☑Compatible ☐Incompatible
Conclusion	☑Pass ☐Failure		**Use Determination**	☑Agree to release ☐Disagree to release
Remark				
Quality Inspector/Date	Yufeng Lin, 2020-02-24	**Reviewer/Date:**	Xiongjie Zhong, 2020-02-24	
Quality Authorizer/Date of Issue	Huadong Xu, 2020-02-24			

GUANGZHOU WONDFO BIOTECH CO.,LTD 广州万孚生物技术股份有限公司 业务专用章 FOR BUSINESS ONLY

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 058008 0025 Rev. 00

Holder of Certificate: **GUANGZHOU WONDFO BIOTECH CO., LTD.**
No. 8 Lizhishan Road, Science City
Luogang District
510663 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): GUANGZHOU WONDFO BIOTECH CO., LTD.
No. 8 Lizhishan Road, Science City, Luogang District, 510663
Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design, Production and Distribution of In Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers and Related Instruments, Sperm Concentration Test, Fluorescence Immunoassay System, Blood Glucose Monitoring System, Control Materials for Tumor Markers, ECG Event Recorder**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1814116

Valid from: 2019-03-11
Valid until: 2021-01-31

Date, 2019-03-11

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17