FungiXpert®

CE IVD

COVID IgM Lateral Flow Assay

Model: CoVMLFA-01

Instructions for use

CONTENTS

1 INTENDED USE

This product is used for the qualitative detection of novel coronavirus IgM antibodies in human whole blood / serum / plasma samples in vitro. It is mainly used in the auxiliary clinical diagnosis of novel coronavirus pneumonia.

2 PRINCIPLE

This kit uses the principle of colloidal gold immunochromatography. When a positive sample is detected, the novel coronavirus IgM antibody in the sample is combined with the gold-conjugated mouse anti-human IgM antibody to form an immune complex. The complex flows forward along the nitrocellulose membrane through chromatography and passes the detection line (T line). When it reacts with the pre-coated novel coronavirus-specific antigen detection band, it forms a sandwich structure and displays a red band. When the remaining gold-labeled antibodies pass the quality control line (C line), they react with the pre-coated goat anti-mouse IgM. The antibody binds and shows a red line. Negative samples develop color only at the control line.

3 SUMMARY AND EXPLANATION

The novel coronavirus (COVID-19) is a positive single-stranded RNA virus. Unlike any known coronavirus, the population is generally susceptible, and it is more threatening to the elderly or people with fundamental diseases. IgM antibodies positive is an important indicator of novel coronavirus infections. Detection of novel coronavirus-specific antibodies will aid clinical diagnosis.

4 PACKAGE SPECIFICATION

	Components	**Specification**
1	COVID IgM Detection strip	50
2	Sample diluent	6.0mL/vial × 1 vial
3	Instructions for use	1

5 STORAGE AND VALID PERIOD

Store at 2-30℃ for 24 months, store in a dry and cool place.

The Sample diluent can be stored for 1 month after opening.

The date of manufacture and expiration are detailed in the label.

6 MATERIAL NEEDED BUT NOT SUPPLIED

Disposable gloves

Pipettes and tips

Timer

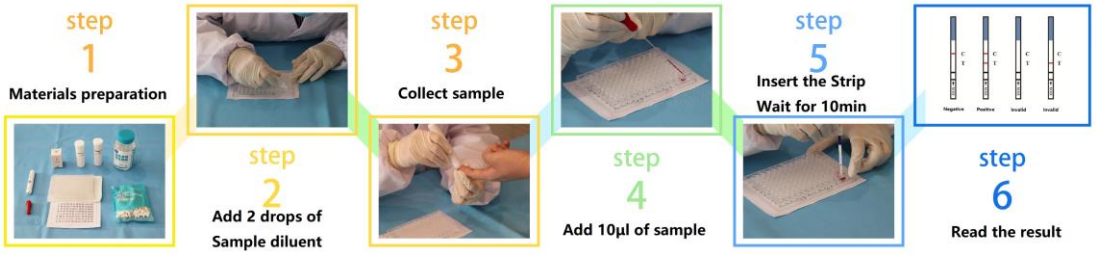
7 SAMPLE PREPARATION

1. Collect patient whole blood / serum / plasma samples according to the clinical collection guidelines for laboratory test samples.
2. Avoid contamination during the collection, transportation and storage.
3. The sample should be stored at 2-8 °C up to 48h, if cannot be tested in time within 48h, please store below -20°C.
4. Avoid repeated freeze-thaw of sample.

8 TEST PROCEDURE

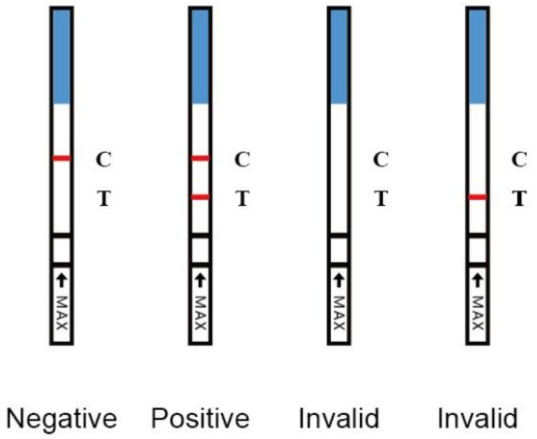
1. Make the kit temperature reach room temperature;
2. Dilute the sample with Sample diluent at a ratio of 1:10 (add 10 µl of sample into 2 drops of Sample diluent) and mix well;
3. Insert the Detection Strip into the microplate well;
4. Standing for 10 minutes and read the result.
   (Dilution and test steps can be performed in the provided microplate)

9 FLOW CHART OF TESTING PROCEDURE



10 INTERPRETATION OF RESULTS

The presence of two lines (line T and line C), regardless of the intensity of the test line, indicates a positive result If the control line (line C) does not appear, the result is invalid and the test should be repeated.



1. Negative results cannot exclude Novel Coronavirus infection;
2. The color depth of the test results cannot be used as the basis for determining the total content of Novel Coronavirus IgM antibody.

11 QUALITY CONTROL

The control line (line C) is internal quality control. The test result is invalid if there is no control line.

12 PERFORMANCE INDICATORS

1 Positive reference product coincidence rate: The positive reference product coincidence rate should be 100%.

2 Negative reference product coincidence rate: The negative reference product coincidence rate should be 100%.

3 Lowest detection limit: Use the lowest detection limit reference for testing, which should not be higher than 4 AU/mL.

4 Repeatability: Test the repeatable reference product 10 times, the reaction results should be consistent, the color development should be uniform, and all are positive.

5 Specificity: There was no cross-reactivity in positive sample with common respiratory pathogens (Legionella pneumophila, Mycoplasma pneumonia, Rickettsia q, Rickettsia pneumonia, Chlamydia pneumonia, adenovirus, respiratory syncytial virus, influenza A virus, influenza B virus, and parainfluenza virus Types 1, 2, and 3)

13 WARNINGS AND PRECAUTIONS

1 This product is only used for *in vitro* diagnosis, one-time use.

2 Please read the test results within the specific time to avoid wrong medical interpretation.

3 Please properly handle the used Strip and do not throw them away at will.

4 When the content of Novel Coronavirus IgM antibody in the sample is very high, the line C may be weakened, which is a normal phenomenon.

14 LIMITATIONS

1. The product is only used for the detection of Novel Coronavirus IgM antibody in the human whole blood / serum / plasma samples.
2. The detection results of the reagents just for reference, cannot be used as the only basis, the clinical management of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response.

15 REFERENCES

1 Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study.

2 Identification and neuroprotective evaluation of a potential c-Jun N-terminal kinase 3 inhibitors through structure-based virtual screening and in-vitro assay.

3 Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China.

4 Diagnosis and treatment recommendations for pediatric respiratory infection caused by the 2019 novel coronavirus.

5 Ji, W., Wang, W., Zhao, X., Zai, J. and Li, X., 2020. Homologous recombination within the spike glycoprotein of the newly identified coronavirus may boost cross‐species transmission from snake to human. Journal of medical virology.

6 Zhang, N., Wang, L., Deng, X., Liang, R., Su, M., He, C., Hu, L., Su, Y., Ren, J., Yu, F. and Du, L., Recent advances in the detection of respiratory virus infection in humans. Journal of Medical Virology.

16 MANUFACTURERS

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17 SYMBOLS

SYMBOLS LEGEND

	"Use By"
LOT	**"Batch Code"**
IVD	**"*In Vitro* Diagnostic Medical Device"**
REF	**"Catalogue No."**
	"Temperature Limitation"
	"Manufacturer"
	"Consult Instructions For Use"
EC REP	**"Authorised Representative"**
CE	**"CE Mark"**