SARS-CoV-2 Neutralizing Antibodies Test Kit User Manual

(Dry Fluorescence Immunoassay)

[NAME]

SARS-CoV-2 Neutralizing Antibodies Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

25 tests/kit

50 tests/kit

[INTENDED USE]

SARS-CoV-2 Neutralizing Antibodies Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro diagnostic of SARS-CoV-2 Neutralizing Antibodies in human serum, plasma.

This test kit cannot be used as the basis for the diagnosis and exclusion of pneumonia infected by novel coronavirus.

This test kit is only used in medical institutions, is not suitable for the screening of general population, and cannot be used for self-test.

For professional use only.

[TEST PRINCIPLE]

This test kit uses immumofluorescence method to detect SARS-CoV-2 Neutralizing Antibodies in human serum, plasma. The testing sample will migrate forward due to capillary action, then the SARS-CoV-2 Neutralizing Antibodies of the sample will combine with the SARS-CoV-2 S protein which is attached to fluorescence microspheres. The microspheres without binding to neutralizing antibodies is attached to the detection area of human ACE2 receptor protein and the other fluorescence microspheres are attached to the control area. When the test strip is inserted into the analyzer, the analyzer automatically scans the ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. Analyzing the fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. SARS-CoV-2 Neutralizing Antibodies test strip in a sealed pouch with desiccant.....25 tests/50tests
2. Sample diluent… .....1 piece/2 pieces
3. QR code card for calibration.....1 piece
4. User Manual .....1 piece

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months. Test strip is individually packaged. Test strip should be used within 1 hour once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-2000 Dry Fluorescence Immunoassay Analyzer
3. LS-1100 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
6. LS-7000 Dry Fluorescence Immunoassay Analyzer
7. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer
8. LS-7800 Automatic Microfluidic and Dry Fluorescence Immunoassay Analyzer
9. LS-3000 Automatic Fluorescence Immunoassay Analyzer
10. LS-3100 Automatic Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENTS]

1. Used for human serum, plasma and whole blood. Other bodily fluids and samples may not get the accurate result.
2. Serum can be vascularized in a vacuum without anticoagulant. Plasma and whole blood can be anticoagulant with EDTA. Blood collection: 5mL.
3. The sample should be tested immediately after being collected. The sample to be measured can be stored at 2°C-8°C for 3 days if they cannot be tested immediately. For long-term storage, it should be placed at -20°C. Samples should avoid repeated freezing-thawing.
4. In order to ensure the accuracy of the result, the sample with large amount of lipid, hemolysis or turbidity should not be used. The sample with microbial contamination should be avoided.
5. The frozen samples should be completely melted and mixed evenly before use. Repeated freezing-thawing should be avoided. It is recommended that the freezing-thawing of the sample should not be more than one time. If there is sediment in the thawed sample, the sample should be centrifuged before testing.

[TEST PROCEDURE]

1. Preparation

The test strip, sample and sample diluent should be recovered to room temperature (15°C-30°C) before testing.

2. Calibration

Turn on the device and insert the calibration curve by scanning the QR code of the test kit to complete the calibration.

3. Add the sample

Use pipette to draw 10μL sample into diluent, then blow gently and thoroughly. Use the special tip blow mixed fluid more than 10 times to ensure complete mixing of the material in the special tip and then standing for 5 minutes.

Note: It is required to use the special tip which is sealed in the sealed pouch.

Draw 100μL mixed fluid into the sample port in the test strip.

4. After 15 minutes, insert the test strip with sample mixture into the analyzer for testing (for details, see the device operating instructions).
5. The analyzer performs analytical testing and displays the results.
6. Remove the used test strip.
7. Quality control: the test kit doesn't include controls.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[INTERPRETATION OF RESULT]

1. SARS-CoV-2 Neutralizing Antibodies＜0.04, it indicates that the antigen test is negative.
2. SARS-CoV-2 Neutralizing Antibodies≥0.04, it indicates that the antigen test is positive.

If the reult is positive, other tests will be recommended to confirm diagnosis.

3. The test kit can't exclude the possibility of false positive completely due to the specificity of the antigen and antibody in the sample and the differences in the complex structure of biologically active substances. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

[LIMITATION]

1. The result of this kit is only one of the diagnostic aids for the

clinicians.

2. Samples containing interfering substances will affect the test results. The maximum allowable concentrations are: 3mg/mL hemoglobin, 2mg/mL bilirubin, and 10mg/mL triglyceride.

[PRODUCT PERFORMANCE]

1. Conformity rate of negative reference: meet the measured value of enterprise negative references.
2. Conformity rate of positive reference: meet the measured value of enterprise positive references.
3. Detection limit: meet the measured value of enterprise detection limit references.
4. Repeatability: meet the measured value of enterprise repeatability references.

[PRECAUTIONS]

1. IVD: In vitro diagnostic medical device.
2. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
3. The damaged test strip or package cannot be used.
4. Do not mix the components of different kits.
5. All samples from patients should be treated as potential sources of infection.
6. Used strips should be properly disposed according to local regulations to avoid contamination.

[REFERENCES]

1. Chinese Center for Disease Control and Prevention (2020) Public protection guidelines for Novel coronavirus pneumonia, People's Medical Publishing House (PMPH).
2. Testing of Reagent Water in the Clinical Laboratory. NCCLS Publication C3-A3.
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4. A SARS-CoV-2 surrogate virus neutralization test based on antibody-mediated blockage of ACE2-spike protein-protein interaction.Nature biotechnology,VOL38,September 2020,1073- 1078.
5. ZHOU Peng, YANG Xinglou. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature, 2020.

Lansion Biotechnology Co., Ltd.
Add: No.2, Qiande Road, Jiangning District, B Nanjing, China

EC REP

Website: en.lansionbio.com Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Venezuela
Tele: +58 414-8989868
Email: inmunofluorescencia@lansionbio.com.ve
Website: https://lansionbio.com.ve/

Importador exclusivo

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