COVID-19 Antigen Test Kit User Manual

(Dry Fluorescence Immunoassay)

[NAME]
COVID-19 Antigen Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

25Test/Kit

[INTENDED USE]

The product is intended for the detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.

A recommendation that the kit and analyzer are intended for use by healthcare and laboratory professionals.

For professional use only.

[TEST PRINCIPLE]

COVID-19 Antigen Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing specimen will migrate forward due to capillary action, then the analyte of the specimen will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody and the other fluorescence microspheres are attached to the control area.
When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. COVID-19 Antigen test strip in a sealed pouch with desiccant..... 25 tests
2. QR code card for calibration..... 1 piece
3. User Manual..... 1 piece
4. Sample Extraction Reagent tube ..... 1 piece
5. Sample Extraction Vial (Optional)..... ..... 25 piece
6. Nasal Swabs (Optional)..... .... 25 piece

Note: Do not mix or interchange different batches of the 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. The reagent can be transported at room temperature for a short time. In hot summer and winter, some protective measures should be taken to avoid high temperature or freezing and thawing.

[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 Dry Fluorescence Immunoassay Analyzer (Handheld)
6. LS-7000 Fluorescence Immunoassay Analyze

[SAMPLE REQUIREMENTS]

Freshly collected specimens should be processed as soon as possible.

1. Used for human nasal swab. Other bodily fluids and specimens may not get the accurate result.
2. Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection.

It is essential that correct specimen collection and treatment.

The preparation methods are followed.

3. Sample Collection:

Nasal swabs by standard clinical methods: Gently holds the head of the patient to be collected specimen with one hand, holds the swab with the other hand, Insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times or more along the mucosa inside the nostril to ensure that both mucus and cells are collected. Using the same swab, repeat this process for the other nostril to ensure that the adequate specimen is collected from both nasal cavities. Withdraw the swab from the nasal cavity. The specimen is now ready for processing using the test kit.

4. Sample Treatment:

Add 8 drops(≈200μL) Sample Extraction Reagent into the Sample Extraction Vial . Insert swab into the sample Extraction Vial as soon as possible, Slowly squeeze near the bottom of the Sample Extraction Vial for 5 times and make the liquid infiltration the Swab head with fiber for 2 seconds each time to dissolve in the solution as much as possible. Remove the Patient Swab while squeezing the middle of the Extraction Vial to remove the liquid from the swab. Discard the swab in biohazard waste. Press the cap firmly onto the extraction vial containing the processed sample.

The extraction sample must be added to test strip immediately.

[TEST PROCEDURE]

1. Preparation
The test strip, Sample Extraction Reagent should be recovered to room temperature (15°C-30°C) before testing.
2. Calibration
Turn on the analyzer and insert the calibration curve by scanning the QR code of the test kit to complete the calibration.
3. Add the sample
Add 4drops (≈100μL) of sample into the sample port of the test strip immediately after specimen extracting.
4. Reaction Time: 15 minutes
5. For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click “Test”.
6. For panel outside: After reaction time 15 minutes is elapsed, insert the test strip into the analyzer and then click “Test”.
7. The result will be shown on the screen and printed automatically.
8. Remove the used test strip.
9. 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. COVID-19 Antigen＜0.04, it indicates that the antigen test is negative.

2. COVID-19 Antigen≥0.04, it indicates that the antigen test is positive.
If the test is positive, other tests will be recommended to confirm diagnosis.

3. The test kit cannot 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. Use in conjunction with the testing strategy outlined by public health authorities in your area.
3. Negative results cannot preclude COVID-19 infection and should not be used as the sole basis for patient management decisions.
4. False positive results for COVID-19 Antigen may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
5. The presence of specific antibodies are a sign of previous or current infection, and can also be used to determine the efficacy of treatment.
6. Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and confirmed with the molecular assay test. If necessary, there should be patient management. Negative results can not totally rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

[PRODUCT PERFORMANCE]

1. Positive specificity

The results of the tests were positive for the COVID-19 antigen positive reference samples.

2. Negative specificity

The results of the tests were negative for the COVID-19 antigen negative reference samples.

3. Repeatability:

The coefficient of variation (CV) of the precision reference products shall not less than 15%.

4. Between-run precision:

The coefficient of variation (CV) of the precision reference products shall not less than 20%.

[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.
7. The test kit is a rapid lateral flow immunoassay for the detection and diagnosis of SARS-CoV-2 directly from nasal swabs, without viral transport media.（VTM）.

[REFERENCES]

1. Henrickson KJ. Advances in the laboratory diagnosis of viral respiratory disease. Pediatr Infect Dis J. 2004; 23(1 Suppl):S6–S1.

2. Yu X, Lu R, Wang Z, Zhu N, Wang W,Julian D, Chris B, Lu J, Tan W.Etiology and clinical characterization of respiratory virus infections in adult patients attending an emergency department in Beijing. PLoS One. 2012; 7:e32174.

EC REP

.ansion Biotechnology Co., Ltd.

Add: No.2, Qiande Road, Jiangning District, B Nanjing, China

Website: en.lansionbio.com Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Venezuela

Email: inmunofluorescencia@lansionbio.com.ve

Website: https://lansionbio.com.ve/

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