COVID-19 Antigen （Saliva）Test Kit User Manual (Dry Color Latex Immunoassay)

[NAME]

COVID-19 Antigen（Saliva）Test Kit (Dry Color Latex Immunoassay)

[PACKAGE SPECIFICATION]

1 Test/Kit , 2 Tests/Kit , 5 Tests/Kit , 10 Tests/Kit , 25 Tests/Kit

[INTENDED USE]

The product is intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in saliva from individuals suspected of COVID-19 by their healthcare provider or personage within the first seven days of the onset of symptoms. Antigens are generally detectable in nasopharyngeal specimens during the acute phase of infection. COVID-19 is an acute respiratory infectious disease that is highly susceptible to human infection. Currently, the patients infected by the novel coronavirus are the main source of infection, asymptomatic infected people can also bean infectious source. Based on the current epidemiological investigation, the incubation period for COVID-19 ranges from 1 to 14 days, with most cases ranging from 3 to 7days, the main manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose,sore throat, myalgia, and diarrhea are found in a few cases.

For professional or self-testing use.

[TEST PRINCIPLE]

COVID-19 Antigen（Saliva）Test Kit 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 dyed microspheres. (red) This marked complex is attached to the detection area of immobilized antibody and the other dyed microspheres (blue)are attached to the control area. After the detection time, judge negative or positive according to the line on the test strip.

[MAIN COMPONENTS]

1.COVID-19 test strip in a sealed pouch with desiccant

.....1 test /2 tests /5 tests /10 tests /25 tests

2.User manual.....1 piece

[MATERIALS REQUIRED BUT NOT PROVIDED]

1.Clock, timer or stopwatch

2.Disposable gloves

[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 1hour 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.

[SAMPLE COLLECTION]

Used only for human saliva. Other bodily fluids and specimens may not get the accurate result.

[TEST PROCEDURE]

1.Before the test, the test strip should be recovered to room temperature (15°C-30°C).

2.Remove the test strip from the sealed pouch and pull out the cover of the test strip.

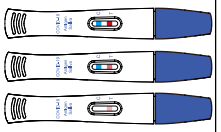
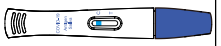
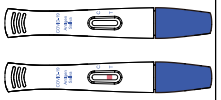
3.Put the cotton sheet at the front of the test strip into the mouth and please it under the tongue for about 3 minutes until the blue control line show up in the reaction window.

Note: Bending the cotton sheet will cause the reaction to fail, please try to keep the cotton sheet and the strip on the same level as possible.

4.Take out the reagent strip and put it on the desktop, cover it, wait for 12 minutes and read the results.

Note: The test is intended to be read at 15 minutes. If the test is read before this or is read more than 5 minutes after the indicated read time, results may be inaccurate (false negative, false positive, invalid) and the test should be repeated.

[INTERPRETATION OF RESULT]

1.Postive 	The presence of two lines as the blue control line(C) and the red test line(T) within the result window indicates a positive result. Any shade of color in the test line region(T) should be considered positive.
2.Negative 	The presence of only a blue control line(C) within the result window indicates anegative result.
3.Invalid 	If the blue control line(C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.

Note:

1.The intensity of color in the test line region (T) may vary depending on the concentration of analyses present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive. This is a qualitative test only and can not determine the concentration of analytes in the specimen.

2.Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

[WARNINGS AND PRECAUTIONS]

1. IVD For in vitro diagnostic use only.

2.The test device should remain in the sealed pouch until use.

3.Do not use kit past its expiration date.

4.All accessories are for single use only.

5.Do not interchange or mix components from different kit batches.

6.Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.

7.Specimens must be processed as indicated in the sample collection and test procedure of this user manual.Failure to follow the instructions for use can result in inaccurate result.

8.Used accessories may be potentially infectious which should be established with local regulatory requirements.

9.Dispose of test strip and materials as biohazardous waste in accordance with federal, state, and local requirements.

10.Patients with oral ulcers or other oral trauma, please use with caution.

[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.

[LIMITATION]

1.The etiology of respiratory infection caused by microorganisms other than SARS-CoV-2 will not be established with this test. The performance of the COVID-19 Antigen (Saliva) Test Kit (Dry Color Latex Immunoassay) depends on antigen load and may not correlate with viral

culture results performed on the same specimen.

2.Failure to follow the usermanual may adversely affect test performance and or invalidate the test result.

3.If the test result is negative and clinical symptoms persist,additional testing using other clinical methods is recommended. A negative result does not at any time rule outthe presence of COVID-19 antigens in sample, as they maybe present below the minimum detection level of the test or if the sample was collected or transported improperly.

4.As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluate.

5.Positive test results do not rule out co-infections with other pathogens.

6.The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after 10days of illness are more likely to be negative compared to a RT-PCR assay.

7.Negative results from patients with symptom onset beyond ten days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

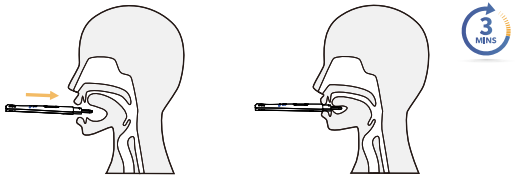
8.Negative results do not rule out SARS-CoV-2 infection and should not be used as thesole basis for treatment or patient management decisions, including infection control.

[OPERATION STEPS]

1.Prepration

Wash hands and remove accessories in the test kit. Read the user manual carefully. Remove the test strip from the sealed pouch and pull out the cover of the test strip.

2.Sample collection and test



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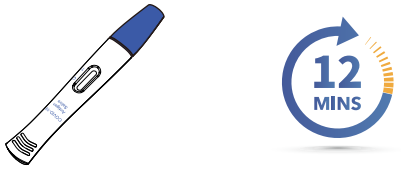

Take out the reagent strip and put it on the desktop, cover it, wait for 12 minutes and read the results.

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Revision Date: September 01, 2021
Version No.: 0.0
Production date and expiration see the label.

Operational guidelines

http://en.lansionbio.com/article/type/330_1.html

IVD	For in vitro diagnostic use only
REF	Catalog number
	Manufacturer
LOT	Lot number
EC REP	European Authorized Representative
	Date of Manufacture
	Use by date
	Consult instructions for use
	Store between 4-30℃
	Contents Sufficient for < n > Tests
	Do not reuse
	Keep away from sunlight
	Fragile handle with care
	Keep dry
	Forbidden to inversion