COVID-19 Antigen Test Kit For Saliva
(Dry Color Latex Immunoassay)
For Self-testing Use

[NAME]

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

[PACKAGE SPECIFICATION]

1 pc/bag

REF	Specification	Content		
		Test strip	Bio-safety bag	IFU
0902-01	1pc/box	1	1	1
0902-03	5pcs/box	5	5	1
0902-05	25pcs/box	25	25	1
0902-06	1pc/kit	1	1	1
0902-07	5pcs/kit	5	5	1

[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 7 days, 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 self-testing use.

[STORAGE AND VALIDITY]

Stored at 4°C-30°C, the test kit is with a valid period of 18 months.

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.

[OPERATION STEPS]

1. Preparation

Before testing, please add a timing function device.

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

Put the cotton sheet at the front end of the test strip into the mouth and stay under the tongue until the blue control line appears in the reaction window.

Do not suck.

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

Result observed after 20 minutes is invalid

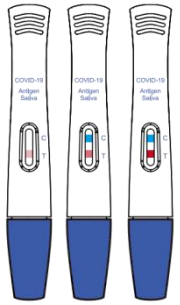
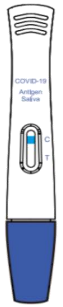
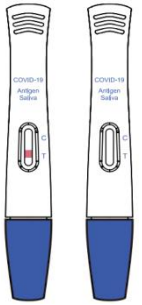
Preferably test in the morning.
If you've already had something, e.g. caffeinated or alcoholic drinks, please rinse mouth with water.
After 30minutes, you can test.

3. End

Put the used test strip into bio-safety bag and dispose the bag in medical waste container according to local laws and regulations.

Assuming that there is no special biological waste bin, it should be sealed with a bio-safety bag and discarded together with household waste.

[INTERPRETATION OF RESULT]

1. Positive 	The presence of two lines— the blue control line (C) and the red test line (T) — both within the result window indicates a positive result. Any Faint of color in the test line region (T) should be considered positive. ***Note: The color intensity of the T line is related to the concentration of SARS-CoV-2 antigens contained in the sample. The result should be determined by whether the T line is colored or not, regardless of the color intensity.***
	• There is a suspicion of COVID-19 • Contact your doctor / general practitioner or the local health department immediately • Carry out a PCR confirmation test • Continue to comply with all applicable rules regarding contact with others and protective measures
2. Negative 	The presence of only a blue control line(C)within the result window indicates a negative result. Negative results should be treated as presumptive only and may not mean you are not infectious.
	• Continue to comply with all applicable rules regarding contact with others and protective measures • Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with patients. • If it is suspected, repeat the test after 1-2 days, as the coronavirus cannot be precisely detected in all phases of an infection • If you are experiencing COVID-19 symptoms, you must seek immediate further laboratory PCR testing. ***Note: For the detection of novel coronavirus and possible subtypes (mutant strains), the changes of epitopes caused by mutation sites of Nucleocapsid Protein may reduce the analytical sensitivity of the reagent and lead to false negative results.***
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 to repeat test with a new test kit. • If the test results are still invalid, contact a doctor or a COVID-19 testing center for a laboratory PCR test • If symptoms persist, you should self-isolate at home and avoid contact with others prior to the re-test

[TEST PRINCIPLE]

COVID-19 Antigen Test Kit For Saliva (Dry Color Latex 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 dyed microspheres. (Red means T Line) This marked complex is attached to the detection area of immobilized antibody and the other dyed microspheres (Blue means C Line) are attached to the control area. After the detection time, judge negative or positive according to the line on the test strip.

[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. 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.
7. Used accessories may be potentially infectious which should be established with local regulatory requirements. Dispose of test strip and materials as biohazardous waste in accordance with federal, state, and local requirements.

Note: Assuming that there is no special biological waste bin, it should be sealed with a bio-safety bag and discarded together with household waste.

8. Patients with oral ulcers or other oral trauma, please use with caution.
9. This test kit is used in the later phase of infection and in asymptomatic individuals, and these tests are less reliable

[INTERNAL QUALITY CONTROL]

The test cassette contains a quality control C line. Regardless of what nucleocapsid antigens are present the C line should appear to indicate that the sample has been transported properly through the membrane. If the C line does not appear, it indicates that the test result is invalid and the sample is required to be retested.

[MUTATION VIRUS DETECTION COMPATIBILITY TIPS]

COVID-19 Antigen Test Kit For Saliva (Dry Color Latex Immunoassay) detects Nucleocapsid protein, NOT spike protein of SARS-CoV-2. The mutations of SARS-CoV-2 variants B.1.1.7 /B.1.351 /P.1 /B.1.617.1 /B.1.617.2 /B.1.526 /B.1.427 /B.1.429 should be confirmed. And all those variants Nucleocapsid proteins can be effectively detected by COVID-19 Antigen Test Kit For Saliva (Dry Color Latex Immunoassay).

[TEST METHOD LIMITATIONS]

- The accuracy of the test is dependent on the quality of the sample. Improper sampling or storage, using expired samples or repeated frozen-thawed samples can affect the test result. Test results can also be affected by temperature and humidity.
- Negative results may be caused by low concentration of SARS-CoV-2 antigens in the sample and therefore cannot completely rule out the possibility of infection.

Recommend repeat testing (e.g. within 1-3 days) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.

- Some medications, foods and drinks in the collected samples may interfere with the test result. Please perform the test again if the result is in doubt.
- This product is only for qualitative testing and the specific concentration of each indicator must be measured using other quantitative methodologies.
- For the detection of novel coronavirus and possible subtypes (mutant strains), the changes of epitopes caused by mutation sites of Nucleocapsid Protein may reduce the analytical sensitivity of the reagent and lead to false negative results

[PRODUCT PERFORMANCE]

● Limit of Detection -LoD

The limit of detection of COVID-19 Antigen Test Kit For Saliva (Dry Color Latex Immunoassay) for Recombinant SARS-CoV-2 N antigen is 0.25ng/mL.

SARS-CoV-2 N antigen	Test result
1ng/mL	25/25 positive
0.5ng/mL	25/25 positive
0.25ng/mL	25/25 positive
125pg/mL	15/25 positive

● High Dose Hook Effect

No hook effect was observed with the SARS-CoV-2 virus up to a concentration of 1.0 x 10^5 $TCID_{50}$/mL.

● Cross Reactivity

Cross reactivity and potential interference of COVID-19 Antigen Test Kit For Saliva (Dry Color Latex Immunoassay) were evaluated by testing commensal and pathogenic microorganisms diluted with saliva as sample matrix in the absence or presence of heat inactivated SARS-CoV-2 virus. The listed items in the following table may be present in the clinical samples.

Potential Cross-Reactant	Concentration	Cross-Reactivity (Yes/No)
Human coronavirus HKU1	1.0 x 10^5 TCID50/mL	No
Human coronavirus 229E	1.0 x 10^5 TCID50/mL	No
Human coronavirus OC43	1.0 x 10^5 TCID50/mL	No
Human coronavirus NL63	1.0 x 10^5 TCID50/mL	No
Influenza A	2.7 x 10^5 TCID50/mL	No
Influenza B	3.0 x 10^5 TCID50/mL	No
Respiratory syncytial virus	4.2 x 10^5 TCID50/mL	No
MERS-coronavirus	1.5 x 10^5 TCID50/mL	No
Adenovirus	1.0 x 10^5 TCID50/mL	No
Human Metapneumovirus	1.0 x 10^5 TCID50/mL	No
Parainfluenza virus 1	1.0 x 10^5 TCID50/mL	No
Parainfluenza virus 2	1.0 x 10^5 TCID50/mL	No
Enterovirus D68	3.6 x 10^5 TCID50/mL	No
Rhinovirus	1.0 x 10^5 PFU/mL	No
Haemophilus influenza	1.0 x 10^5 CFU/mL	No
Mycoplasma pneumoniae	1.0 x 10^5 CFU/mL	No
Staphylococcus aureus	1.0 x 10^6 CFU/mL	No
Staphylococcus epidermidis	1.0 x 10^6 CFU/mL	No
Bordetella pertussis	1.0 x 10^6 CFU/mL	No
Legionella pneumophila	1.0 x 10^6 CFU/mL	No
Streptococcus pneumonia	1.0 x 10^6 CFU/mL	No
Mycobacterium tuberculosi	1.0 x 10^6 CFU/mL	No
Candida albicans	1.0 x 10^6 CFU/mL	No

● Interfering Substances Effect

A study was performed to evaluate and demonstrate that the endogenous substances naturally present or drugs that may be artificially introduced into clinical samples do not inference with the detection of SARS-CoV-2 in the COVID-19 Antigen Test Kit For Saliva (Dry Color Latex Immunoassay) at the concentrations listed below.

Potential Interfering Substances	Concentration	Interference(Yes/No)
Mucin	0.5% w/v	No
Whole Blood	5% w/v	No
Bilirubin	20μg/mL	No
Rheumatoid factor	200 IU/mL	No

Potential Interfering Substances	Concentration	Interference(Yes/No)
Triglycerides	1.5 mg/L	No
Hemoglobin	20μg/mL	No
Levofloxacin	20μg/mL	No
Zanamivir	18μg/mL	No
Oseltamivir	20μg/mL	No
Lopinavir	20μg/mL	No
Abido	20 μ g/mL	No
Histamine	20 μ g/mL	No
Hydrochloride	20 μ g/mL	No
Oxymetazoline	20 μ g/mL	No
Flunisolide	20 μ g/mL	No
Acetonide	20 μ g/mL	No
Mometasone	2ng/mL	No
Beclomethasone	2 μ g/mL	No
Anti-nuclear antibody	＞1:40	No
Progesterone	10-fold dilution	No
Total IgG	90 g/L	No
Total IgM	4 g/L	No
Total IgA	80g/L	No
Azithromycin	20 μ g/mL	No
Ceftriaxone	20 μ g/mL	No
Meropenem	20 μ g/mL	No
α -Interferon	20 μ g/mL	No
Ribavirin	25 μ g/mL	No
Paramivir	20 μ g/mL	No
Ritonavir	18 μ g/mL	No
Tobramycin	3mg/mL	No
Phenylephrine	15%	No
Dexamethasone	1.2mg/dL	No

Potential Interfering Substances	Concentration	Interference(Yes/No)
Triamcinolone	20 μ g/mL	No
Budesonide	4ng/mL	No
Fluticasone	126ng/dL	No

[CLINICAL SENSITIVIYT, SPECIFICITY AND ACCURARY]

The COVID-19 Antigen Test Kit has been evaluated with specimens obtained from patients. A commercialized molecular assay was used as the reference method. The results show that the COVID-19 Antigen Test Kit has a high overall relative accuracy.

Method	PCR		Total
COVID-19 Ag	Positive	Negative	Result
Positive	220	7	227
Negative	8	447	455
Total Result	228	454	682
*95%Confidence Interval			

Sensitivity: 220/(220+8) ×100%=96.49%

Specificity: 447/(447+7)×100%=98.45%

PPV:220/(220+7)×100%=96.91%

NPV: 447/(447+8)×100%=98.45%

Accuracy is: (447+220)/682×100%=97.80%

CE 2934	CE mark
IVD	In vitro diagnostic medical device
REF	Catalogue number
	Manufacturer
LOT	Batch code
EC REP	Authorized representative in the European Community

	Date of manufacture
	Use-by date
	Consult instructions for use
	Temperature limit 4-30℃
	Contents sufficient for < n > tests
	Do not re-use
	Keep away from sunlight
	Fragile, handle with care
	Keep dry
	This side up

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Revision Date: May 7, 2022
Version No.: 0.2
Production date and expiration see the label.

CE 2934