CE IVD

SARS-CoV-2 Antigen Rapid Test Kit (Saliva Test)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of SARS-COV-2 antigen in saliva specimens.For professional medical institutions use only,Not for self testing.

PRODUCT NAME
SARS-CoV-2 Antigen Rapid Test Kit (Saliva Test)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE
The SARS-CoV-2 Antigen Rapid Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of Novel coronavirus in human saliva. It is suitable for the auxiliary diagnosis of SARS-COV-2 virus infection.

INTRODUCTION
COVID-19 caused by SARS-CoV-2 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 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. The SARS-CoV-2 Antigen Rapid Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of SARS-CoV-2 Antigen in human saliva specimen.

PRINCIPLE
The SARS-CoV-2 Antigen Rapid Test Kit is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant antigen conjugated with colloid gold (monoclonal mouse anti SARS-CoV-2 antibody conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing test band (T bands) and a control band (C band). The T band is pre-coated with monoclonal mouse anti- SARS-CoV-2 NP antibody for the detection of SARS-CoV-2 NP antigen, and the C band is pre-coated with goat anti rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. SARS-CoV-2 virus if present in the specimen will bind to the monoclonal mouse anti- SARS-CoV-2 NP antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti- SARS-CoV-2 NP antibody, forming a burgundy colored T band, indicating a Covid-19 NP antigen positive test result. Absence of test band (T) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid, and the specimen must be retested with another device.

MAIN COMPONENTS
Materials Provided

Components	25 tests/kit	5 tests/kit	1 tests/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution With Dropper	25tubes (300ul/tube)	5tubes (300ul/tube)	300ul/tube
Saliva Collection Bag	25 pcs	5 pcs	1 pcs
Transfer Tube	25 pcs/bag	5 pcs/bag	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

Main ingredients of test cassettes:
Mouse anti-SARS-COV-2 NP antibody, Goat anti-rabbit IgG polyclonal antibody, SARS-COV-2 antibody, rabbit IgG, Colloidal gold conjugate, Other test device support; one desiccant.

Main ingredients of Sample Diluent Solution:
Neutral salt buffer

Reagents of different batch numbers cannot be used interchangeably.

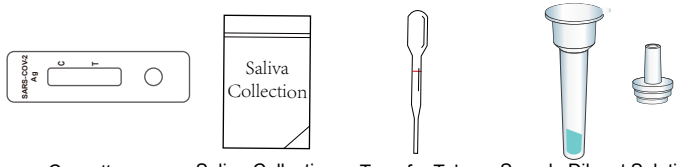
MATERIALS REQUIRED BUT NOT PROVIDED
Timer for timing use

PRECAUTIONS
- Read this IFU carefully before use.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Diluent Solution and Transfer Tubes from different lots.
- Do not open the Test Cassette foil pouch until ready to perform the test.
- Do not spill solution into the reaction zone.
- For professional use only.
- For in-vitro diagnostic use only
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C.

STORAGE AND STABILITY
- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

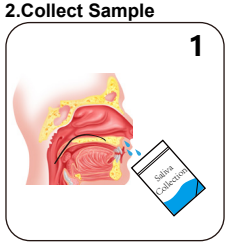
SPECIMEN COLLECTION AND HANDLING
1.Prepare Materials

Open the package,take out the pouch of the SARS-COV-2 Antigen test card, the Sample Diluent Solution and the Saliva Collection Bag. When you are ready to proceed with the test,open the foil pouch of the SARS-COV-2 Antigen test card.

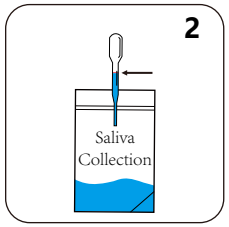


Cassette | Saliva Collection Bag | Transfer Tube | Sample Diluent Solution With Dropper

2.Collect Sample



1. open the Saliva Collection Bag, and spit saliva into it.

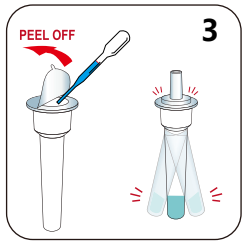


2.use Transfer tube suck the saliva.

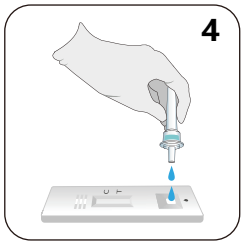
3.Process Sample

3.1 Instructions must be read entirely before test, Leave the reagent and sample at room temperature for 30min before use to rewarm to room temperature.
3.2 Use the cassette as soon as possible after opening the inner packing.
3.3 Open the aluminum foil bag at the tear hole, take out the test card and lay it flat.
3.4 Apply 3 full drops of the sample diluent solution(90-100ul) vertically into the sample well of the test cassette.

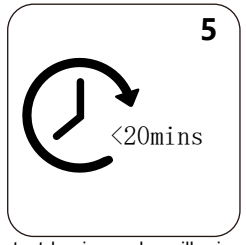
The results are observed after 20minutes and showed on clinical significance after 20 minutes.The results are observed after 20minutes and showed on clinical significance after 20 minutes.



3.add 18~20 drops(600μL) of saliva into the sample diluent solution tube , put on the dropper and gently mix it well.



4.add 3 drops(100μL) of extracted sample into the sample well.

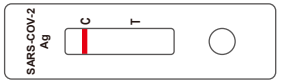


5.As the test begins, color will migrate across the membrane. The result should be read at 15 minutes.

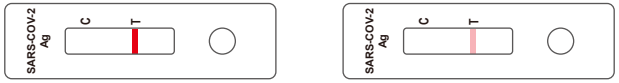
6.seal the saliva collection bag, and drop into the medical waste recycling bucket.

RESULT INTERPRETATION
POSITIVE: Two distinct red lines appear. One line should be in the control region(C) and the other line should be in the test region(T).

NEGATIVE: One red line appears in the control region(C). No red line appears in the test region(T).The negative result does not indicate the absence of analyses in the sample, it only indicates the level of tested analyses in the sample is less than cut-off level.



INVALID: No colored lines appear, or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



NOTE:
The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level cannot be determined by this qualitative test.Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

PERFORMANCE CHARACTERISTICS

1.Sensitivity, Specificity and Accuracy

A total of 650 patient samples from susceptible subjects were test by the PCR test. Comparison for all subjects is showed in the following table:

Note:There are different samples in different experiments from different hospital, each experiment have 200 positive samples and 450 negative samples.

SARS-CoV-2 Antigen Rapid Test Kit	RT-PCR(30≤Ct-Wert≤35)		
BESTest	Positive	Negative	Total
Positive	30	5	35
Negative	0	100	100
Total	30	105	135
CT value≤35:Relative Sensitivity: 85.7%; Relative Sp ecificity:100%; Overall agreement: 96.30%			

SARS-CoV-2 Antigen Rapid Test Kit	RT-PCR(25≤Ct-Wert≤30)		
BESTest	Positive	Negative	Total
Positive	50	2	52
Negative	0	100	100
Total	50	102	152
CT value≤30:Relative Sensitivity: 96.15%; Relative Sp ecificity:100%; Overall agreement: 98.68%			

SARS-CoV-2 Antigen Rapid Test Kit	RT-PCR(Ct-Wert≤25)		
BESTest	Positive	Negative	Total
Positive	113	0	113
Negative	5	245	250
Total	118	245	363
CT value≤25:Relative Sensitivity:100%(95%CI:97.18%-100%); Relative Specific ity:98%; Overall agreement: 98.62%			

In Conclusion

SARS-CoV-2 Antigen Rapid Test Kit	RT-PCR		
BESTest	Positive	Negative	Total
Positive	193	7	200
Negative	5	445	450
Total	198	452	650
Relative Sensitivity: 96.5%; Relative Specificity:98.89%; Overall agreement: 98.15%			

2. Limit of Detection（LOD）

The limit of detection of the SARS-COV-2 Antigen Rapid test has been studied.The LOD of the test to the SARS-COV-2 N protein is around 10pg/ml. The LOD of the test to the SARS-COV-2 virus(inactivated)is about $5*10^2$ $TCID_{50}$/ml.

Concentration	Positive Results	Agreement Rate
10pg/ml N protein	**100/100**	**100%**
$5*10^2$ $TCID_{50}$/ml	**100/100**	**100%**

3. Cross-reactivity

The SARS-COV-2 antigen rapid test kit is associated with a panel of proteins of other human coronavirus recombinant antigen and other respiratory symptoms relative virus. The cross-reactivity results showed in below sheet.

Substance	Concentration	Result
SARS-CoV-2 N-Protein	0.001μg/mL	positive
MERS-CoV N-Protein	10^5 pfu/ml	Negative
HCoV-NL63 N-Protein	10^5 pfu/ml	Negative
HCoV-229E N-Protein	10^5 pfu/ml	Negative
HCoV-HKU1 N-Protein	1μg/mL	Negative
Influenza-A-Virus	$1X10^5TCID_{50}$ /mL	Negative
Influenza B-Virus	$1X10^5TCID_{50}$ /mL	Negative
Respiratory Syncytial Virus	$1X10^5TCID_{50}$ /mL	Negative
Parainfluenza-Virus	$1X10^5TCID_{50}$ /mL	Negative
Chlamydia pneumoniae	$1X10^5TCID_{50}$ /mL	Negative

4. Interfering Substances

This kit has no interference with HAMA, Human serum Albumin, Antinuclear antibody, Antimitochondrial antibody, Cholesterol, Bilirubin conjugated, Lipids, Hemoglobin, Bilirubin unconjugated, Rheumatoid factor, et al.

QUALITY CONTROL

1.Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
2.External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST LIMITATIONS

1.The SARS-CoV-2 Antigen Rapid Test Kit (Saliva Test) is for in vitro diagnostic use only. This test should be used for the detection of SARS-CoV-2 antigens in human Saliva specimens.
2.The SARS-CoV-2 Antigen Rapid Test Kit (Saliva Test)will only indicate the presence to SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
3.If the symptom persists, while the result from SARS-COV-2 Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few hours later.
4.As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5.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 preclude the possibility of SARS-CoV-2 infection.
6.The potential impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated in the test.
7.Due to inherent differences between methodologies, it is highly recommended that, prior to switching from one technology to the next, method correlation studies are undertaken to qualify technology differences. One hundred percent agreement between the results should not be expected due to differences between technologies.
8.Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

CAUTION

1.This product is used for in vitro diagnosis only.
2.Must strictly follow the instructions for operation and interpretation of the results.
3.The product is qualitatively tested, and the result cannot be used as a quantitative basis.should be tested using reagents within the validity period.
3.The cassetes, collectors,droppers,and tubes are for single person one-time use, cannot be reused.
4.Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antibody titer in the sample.
5.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.
6.Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

Ningbo BESTest Bio-technology Co.,Ltd.
Address: No.80 building, No.777, Qing Feng Road, Cicheng Town,Jiangbei District, Ning Bo, Zhejiang, China 315033
Tel: 0086 571 2799 8736

EC REP

SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.