EN

SARS-CoV-2 Antigen Saliva Rapid Test Kit

(Immunochromatography)

FOR PROFESSIONAL USE ONLY

PRODUCT NAME

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

INTENDED USE

This rapid test kit is intended for the qualitative detection of SARS-CoV-2 antigen in human saliva samples from novel coronavirus suspected person with symptoms within 9 days from onset. Positive result of the antigen test can be used for early triage and rapid management of suspected populations, but it cannot be used as diagnosis basis of SARS-CoV-2 infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Further nucleic acid detection should be carried out for suspected population whose antigen test result is positive or negative.

PRINCIPLE

This kit is an immunochromatography assay. According to the gold immunochromatographic test principle, double antibody sandwich method was used to detect SARS-CoV-2 nucleocapsid antigen in the samples. When there is virus antigen presence in the sample, the antigen binds with the corresponding colloidal gold monoclonal antibody and the coated monoclonal antibody at the detection line to form a compound and then condenses into a red band, indicating a positive result. If there is no antigen in the sample, complex cannot be formed at the detection line, and no red band is shown, indicating negative result.
Whether the sample contains antigen or not, the gold monoclonal antibody will bind to the enveloped antibody at the quality control line, form a compound and condense into a red band.

TEST KIT COMPONENTS

Package Size	Components
1Test/ Kit	1 Test Cassette 1 Saliva Collectors with collection tubes 1 Sample extraction buffer (single dose) 1 Tube stand, 1 Instruction Insert
10Tests/ Kit	10 Test Cassettes 10 Saliva Collectors with collection tubes 10 Sample extraction buffer (single dose) 1 Tube stand ,1 Instruction Insert
20Tests / Kit	20 Test Cassettes 20 Saliva Collectors with collection tubes 20 Sample extraction buffer (single dose) 1 Tube stand, 1 Instruction Insert

MATERIAL MAYBE NEEDED BUT NOT PROVIDED

1. Timer.
2. Personal protective equipment, such as protective gloves, medical mask, goggles.
3. Appropriate biohazard waste container and disinfectants.

STORAGE AND EXPIRY

Store as packaged in the sealed pouch at 2-30℃, avoid heat and sunshine, dry place, valid for 24 months. Do not freeze. Do not open the inner packaging until ready, it must be used within one hour if opened (Humidity≤60%, Temp: 20℃-30℃). Please use immediately when the humidity＞60%.

SAMPLE COLLECTION

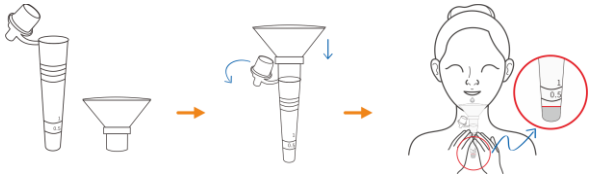
30 minutes before sampling, please do not eat, smoke, drinking alcohol or drinks.
Place the tip of tongue against the upper or lower tooth root to enrich saliva, and then swallow saliva to the throat without ingesting saliva to esophagus, followed by returning saliva to the mouth. Repeat the process for 5 times.
Note: The sample should not be inactivated.

SAMPLE PRESERVATION

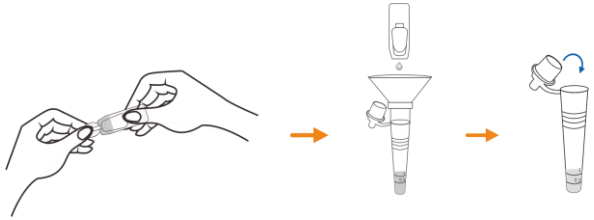
After the samples of human saliva are collected, the saliva should be processed as soon as possible and tested within 1 hour. If it cannot be tested immediately, it can be stored at 2-8℃ for 4 hours and long-term storage is not recommended.

STEP BY STEP TEST PROCEDURE

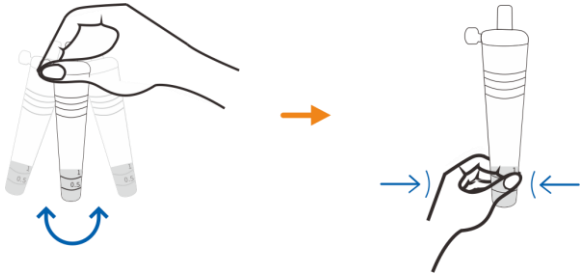
1. Open the cap of the collection tube and install saliva collector.
2. Put the collection tube with saliva collector close to lips and let the saliva flow into the collection tube. The volume of saliva needs to be half of 0.5 scale mark (0.25).



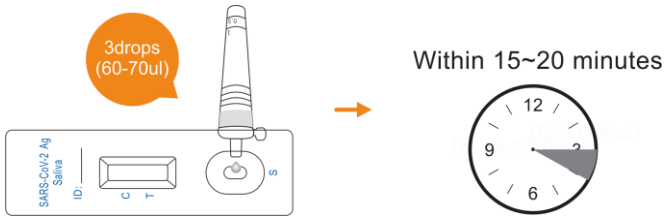
3. Screw the sample extraction buffer carefully.
4. Hold the sample extraction buffer upside down vertically and squeeze the tube, let the solution drop into the collection tube. Add all sample extraction buffer
to the collection tube.
5. Discard the saliva collector, tighten the cap onto the specimen collection tube.



6. Shake the specimen collection tube at least three times vigorously to mix the saliva and the extraction buffer.
7. Squeeze bottom of the collection tube to ensure the saliva is thoroughly mixed.



8. Open the tear hole of the aluminum foil bag, take out the test cassette and lay it flat. Add 3 full drops of the solution to the sample well(S).
9. Read the result at 15 minutes. Do not interpret the result after 20 minutes.

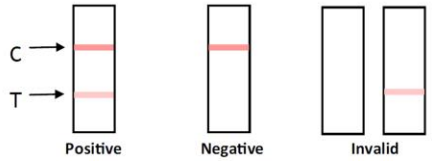


Note: Bubbles are likely to occur during sample processing and blowing. Do not add bubbles when dropping samples to the sample well of the test cassette.

INTERPRETATION OF RESULTS

POSITIVE: Two (2) distinct colored lines appear. One line should be in the control region (C) and the other line should be in the test region (T).
NEGATIVE: One (1) colored line appears in the control region(C). No apparent colored line appears in the test region (T). The negative result does not indicate the absence of analytes in the sample, it only indicates the level of tested analytes in the sample is less than the minimum detection limit.

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.



LIMITATIO

1. This kit is a qualitative detection, which cannot determine the exact content of antigen.
2. The test results of this kit are only for the reference of clinicians and should not be taken as the sole basis for clinical diagnosis and treatment. Clinical management of patients should be considered in the light of their symptoms/signs, medical history, other laboratory tests and treatment responses.
3. Restricted by antigen detection reagent method, the lowest detection limit (sensitivity analysis) is generally lower than that of nucleic acid detection, so the researchers deal with negative result to give more attention, should be combined with other test results comprehensive judgment, advice to doubt the negative result of nucleic acid detection or virus isolation culture identification method for review.
4. False negative results may be caused by unreasonable sample collection, transport and treatment, and low viral load in samples.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance

The performance of SARS-CoV-2 Antigen Saliva Rapid Test was established with a total sample size of 505 samples.

SARS-CoV-2 Antigen Saliva Rapid Test Kit against with PCR
(Statistics of the test reagent results and PCR results on nasopharyngeal swab samples)

SARS-CoV-2 Antigen Saliva Rapid Test Kit	Comparator Method		Total
	Positive	Negative	
Positive	99	4	103
Negative	6	396	402
Total	105	400	505

Diagnostic sensitivity: 94.29%（95%CI: 87.98%-97.87%）
Diagnostic specificity: 99.00%（95%CI: 97.46%-99.73%）
Total coincidence rate: 98.02%（95%CI: 96.39%-99.05%）
CI: Confidence Interval

2. Limit of Detection

The limit of Detection (LOD) of the SARS-CoV-2 Antigen Saliva Rapid Test is $1.6x10^2$TCID50/mL

3. Cross-reactivity

With human coronavirus 229E, human coronavirus OC43, human coronavirus NL63, adenovirus, human metapneumovirus, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, influenza A, type B Influenza, enterovirus, respiratory syncytial virus, rhinovirus, Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans, Bordetella pertussis, Mycoplasma pneumonia, pneumonia Chlamydia, Legionella pneumophila, etc. have no cross reaction.

4. Interference

Common interfering substances in the sample, such as blood, mucin, and pus, have no effect on the test results.

PRECAUTION

1. For IN VITRO diagnostic use only.
2. The kit is a disposable rapid test kit, which is only used for the detection of human saliva samples. The operation should be carried out strictly according to the instructions. Do not use expired or damaged products.
3. The strength of the quality control line does not mean the quality of the test kit. As long as its color is clear and visible, that means it is effective.
4. The kit should be sealed and kept away from moisture. Reagents or samples stored at low temperature should be balanced to room temperature before using.
5. The test cassette should be used as soon as possible after removal from aluminum foil bags. Avoid exposure to air for too long and affecting test results due to dampness.
6. Do not use samples that have been placed for longer than one hour or contaminated.
7. Waste should be treated in accordance with infectious substances and should be discarded properly.
8. Incorrect operation may affect the accuracy of the results, such as sample extraction reagent insufficient or excessive, insufficient sample mixing, insufficient amount, inaccurate detection time, etc.
9. Components in different batch should not be mixed; Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test.
10. If the saliva is not well mixed in the sample extraction tube, false negative results may occur.
11. Keep away from children. Any child under age 13 shouldn't perform the test without parental guidance, or professional aid.
12. There should be appropriate biosafety assurance procedures for those substances containing and suspected sources of infection. The following are relevant considerations:
Handle samples and reagents by wearing gloves;
Do not ingest samples or reagents;
Do not smoke, eat, drink, cosmetic or touch contact lenses while handling these items;
Disinfect the spilled sample or reagents with disinfectant;
Disinfect and treat all samples, reagents and potential pollutants in accordance with relevant local regulations;
Each component of the reagent remains stable until the expiry date under proper handling and storage conditions. Do not use the expired reagent kit.
13. The extraction reagent contains preservative agent which may be toxic if ingested. When disposed of through a sink, flush with a large volume of water.

MANUFACTURER

LABNOVATION TECHNOLOGIES, INC.
Add.: 101 and 5th Floor, Building 1, No. 68, 18th Road, Guangming Hi-Tech Park, Tangjia Community, Fenghuang Street, Guangming District, Shenzhen 518107, Guangdong, China
Tel: 0086-755-86368398 Fax: 0086-755-86368318
Web: www.labnovation.com E-mail: export@labnovation.com

CE

EC REP MedNet EC-REP GmbH
Borkstrasse 10,48163
Muenster,Germany

INSTRUCTIONS OF SYMBOL

	Consult instruction for use		Keep dry
	Temperature	LOT	Batch number
	For single use	IVD	In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Expire date	Σ	Contains sufficient for <n> tests
EC REP	European representative	CE	CE Marked

Ver. V2.0
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