COVID-19 Antigen Rapid Test Kit (Saliva/Swabs)
Instruction for Use

[Product name]

COVID-19 Antigen Rapid Test Kit (Saliva/Swabs)

[Type/Spec.]

Saliva collector (Saliva collection tube)				
Type	B-1	B-5	B-10	B-20
Spec.	1 test/kit	5 tests/kit	10 tests/kit	20 tests/kit
Saliva collector (Saliva collection bag)				
Type	B-1	B-5	B-10	B-20
Spec.	1 test/kit	5 tests/kit	10 tests/kit	20 tests/kit
Saliva collector+Swabs				
Type	B-1	B-5	B-10	B-20
Spec.	1 test/kit	5 tests/kit	10 tests/kit	20 tests/kit

[Intended use]

This product is intended for in vitro qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in oropharyngeal (throat) swabs/nasopharyngeal swabs/nasal swabs/saliva from individuals suspected of COVID-19 by their healthcare provider. The kit is intended for use by trained personnel.

Coronaviruses are a large family of viruses which could cause illness in animals or humans. The Novel Coronaviruses (SARS-CoV-2) belong to the RNA virus of the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible.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.

[Test principle]

This kit employs immunochromatography for detection. The specimen will move forward along the test card under capillary action. If the SARS-CoV-2 viral antigen is present, they will be bound to the colloidal gold-labeled SARS-CoV-2 specific antibodies. The immune complex will be captured by coronavirus monoclonal antibody fixed in the detection T line. A fuchsia line would form, and the test result would be positive. If the line does not show color, the negative result will be displayed. The test card also contains a quality control C line, which shall appear fuchsia regardless of whether there is a T line.

[Main components]

General components:

Components \ Type	B-1	B-5	B-10	B-20
Spec.	1 test/kit	5 tests/kit	10 tests/kit	20 tests/kit
Antigen test cassette	1 piece	5 pieces	10 pieces	20 pieces
Antigen extract R1: 0.28mL/tube	1 piece	5 pieces	10 pieces	20 pieces
Instruction for use	1 piece	1 piece	1 piece	1 piece
Antigen extraction tube	1 piece	5 pieces	10 pieces	20 pieces
Tube stand	1 piece	1 piece	1 piece	1 piece
Saliva collector tube/bag + Saliva Dropper	1 piece	5 pieces	10 pieces	20 pieces

Optional components

Components \ Spec.	1 test/kit	5 tests/kit	10 tests/kit	20 tests/kit
Oropharyngeal swabs	1 piece	5 pieces	10 pieces	20 pieces
Nasopharyngeal swabs	1 piece	5 pieces	10 pieces	20 pieces
Nasal swabs	1 piece	5 pieces	10 pieces	20 pieces

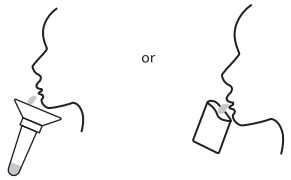
[Storage conditions & period of validity]

1.Store at 2°C~30°C, and it is stable for 24 months. DO NOT FREEZE.
2.After the aluminum foil bag is unsealed, the test card should be used as soon as possible .
3.Sample of oropharyngeal (throat) swabs/nasopharyngeal swabs/nasal swabs/saliva should be processed as soon as possible after sample collection. If the test cannot be performed immediately, the sample should be stored in a sealed state, stored at 2~8°C for 24 hours, and stored below -20°C for 7 days. Long-term storage is not recommended.

[Specimen request]

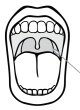
Saliva:

Do not drink or eat at least 1 hour before taking the test, relax the cheeks and gently massage for 15-30 seconds with the fingers before the specimen collection. To collect the saliva, install the saliva collecion tube or open the collection bag, and collect saliva specimen according to the following procedure:
Bring the saliva collector or the collection bag close to the lips, gently spit in it for 3 times, let the saliva flow into the bottom of the collection tube or collection bag.



Oropharyngeal (throat) swabs:

Remove the swab from the package. Do not touch the soft end with your hands or anything else. Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and insert into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx back and forth for at least 3 times and do it with moderate pressure applied; Avoid touching the tongue, teeth, and gums.

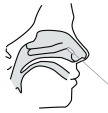


Nasopharyngeal swabs:

Remove the swab from the package. Do not touch the soft end with your hands or anything else. Let the patient's head relax naturally and insert the swab through the nares parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient indicating contact with the nasopharnyx. Gently, rub and roll the swab. Leave the swab in place for several seconds to absorb secretions before removing. Use the same swap and repeat the same steps for the other side of nares parallel.

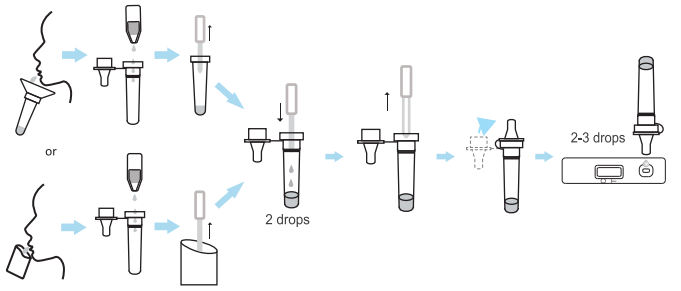
Nasal swabs:

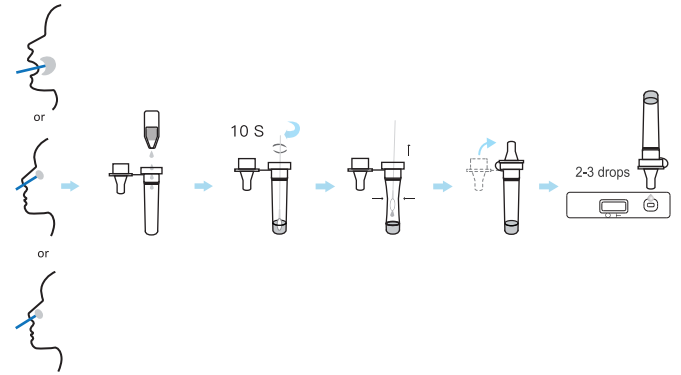
Remove the swab from the package. Do not touch the soft end with your hands or anything else. Insert the entire soft end of the swab into your nostril for 1.5-2.0cm. Slowly rotate the swab, gently pressing against the inside of your nostril at least 5 times for a total of 15 seconds. Get as much nasal discharge as possible on the soft end of the swab. Gently remove the swab. Use the same swap and repeat the same steps for the other side of nostril.



[Test methods]

1.Unseal the aluminum foil bag and take out the antigen test cassette.
2.Place the extraction tube on the tube stand. Twist the tip to open the Antigen extract R1 container, place the Antigen extract R1 container vertically downward to allow the solution to drip into the extraction tube without touching the edges of extraction tube, add all the R1 by squeezing it vertically.
3.Collect the sample, please refer to [Specimen request].
Saliva: Add 2 drops of saliva into the extraction tube by saliva dropper, shake the extraction tube vigorously to mix the saliva and the extraction buffer. Squeeze the tube at least 10 times to allow a thorough mixing.
Oropharyngeal/Nasopharyngeal/Nasal swabs: Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab. Squeeze the swab over the head while taking the swab out of the extraction tube to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.
4.Install the dropper head on the extraction tube, add 2~3 drops into the specimen well of the test cassette, and start the timer.
5.Read the results in 15 minutes. Strong positive results can be reported within 15 minutes, however, negative results must be reported after 15 minutes, and the results after 25 minutes are no longer valid.



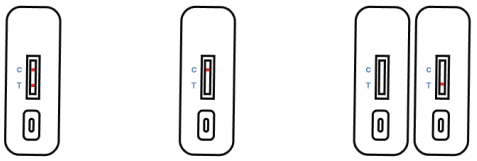


[Interpretation of test results]

Positive result: if both the quality control line C and the detection line appear, novel coronavirus antigen has been detected and the result is positive for antigen.

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that novel coronavirus antigen has not been detected and the result is negative.

Invalid result: if the C line is not observed, it will be invalid regardless of whether there is T line (as shown in the figure below), and the test shall be repeated.



Positive Negative Invalid

[Limitations of inspection methods]

1.This reagent is only used for in vitro diagnosis.
2.This reagent is only used to detect human sterile swab and saliva extracts. The results of other specimens may be inaccurate.
3.This reagent is only used for qualitative detection and cannot indicate the level of novel coronavirus antigen in the specimen.
4.This reagent is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor' s diagnosis shall prevail.

[Product Performance Indicators]

1.LoD: The LoD for direct swab was established using heat-inactivated SARS-CoV-2. The estimated LoD found from the initial serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for direct swab was 5 x 10^2 $TCID_{50}$/ml.
2.Negative agreement: Test the negative reference, and the negative accordance rate shall be 100%.
3.Positive agreement: Test the positive reference, and the positive accordance rate shall be 100%.
4.Precision: Test the precision references, the test results shall be positive with uniform color.
5.Analytical specificity
1) Cross-reactivity:
No false positive test results for either COVID-19 (SARS-CoV-2) Antigen Test Kit were observed on specimens from the following disease states or specific conditions:
Staphylococcus aureus, streptococcus pneumonia, measles, mumps virus, Adenovirus (type 3,C1,71), Mycoplasma pneumonia, parainfluenza virus (1-4), Mycobacterium tuberculosis, Coronavirus OC43, 229E, NL63, HKU1, bordetella pertussis, Influenza B Virus (Victoria), Influenza B Virus (Yamagata), H1N1, H3N2, EBV, Coxsackievirus A16 (CVA16), Rhinovirus, Respiratory syncytial virus, Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pyrogenes, Pneumocystis jirovecii (PJP), Pooled human nasal wash .
2) Interference:
No interference was observed with the potentially interfering substances listed below at the indicated concentration:
Commonly used drugs, i.e., Phenylephrine, Oxymetazoline, sodium chloride, beclomethasone, dexamethasone, flunisolide, triamcinolone acetonide, budesonide, mometasone, fluticasone, Histamine hydrochloride, alpha-interferon, zanamivir, ribavirin, oseltamivir, peramivir, Lopinavir, Ritonavir, Arbidol, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin, mucin, blood (human), Human Anti-mouse Antibody (HAMA), biotin have no effect on the test results of this kit.
6.Clinical performance
1) Saliva specimens:
Contrast Results Statistics of Clinically Confirmed/Excluded Results (555 saliva specimens).

Evaluation Reagent	Clinical Confirmed/Excluded Results (RT-PCR)		Total
	Confirmed	Excluded	
Positive	123	4	127
Negative	5	423	428
Total	128	427	555

Result calculation:
(1) Clinical sensitivity: 96.09%, 95% confidence interval: [91.49%, 98.01%].
(2) Clinical specificity: 99.06%, 95% confidence interval: [97.72%, 99.53%].
(3) Clinical accuracy: 98.38%, 95% confidence interval: [97.00%, 99.09%].
*In the stratified statistics of different stages of the disease, 52 specimens from 0-3 days, and the positive detection rate is 98.04%.

2) Oropharyngeal swabs and nasopharyngeal swabs specimens:
Contrast results statistics of clinically confirmed/excluded results (267 oropharyngeal swabs + 267 nasopharyngeal swabs).

Evaluation Reagent	Clinical Confirmed/Excluded Results (RT-PCR)		Total
	Confirmed	Excluded	
Positive	125	3	128
Negative	5	401	406
Total	130	404	534

Result calculation:
(1) Clinical sensitivity: 96.15%, 95% confidence interval: [91.62%, 98.04%].
(2) Clinical specificity: 99.26%, 95% confidence interval: [97.96%, 99.62%].
(3) Clinical accuracy: 98.50%, 95% confidence interval: [97.13%, 99.18%].
*In the stratified statistics of different stages of the disease, 52 specimens from 0-3 days, and the positive detection rate is 98.08%.

3) Nasal swabs:
Contrast Results Statistics of Clinically Confirmed/Excluded Results (582 nasal swabs)

Evaluation Reagent	Clinical Confirmed/Excluded Results (RT-PCR)		Total
	Confirmed	Excluded	
Positive	149	4	153
Negative	6	423	429
Total	155	427	582

Result calculation:
(1) Clinical sensitivity: 96.13%, 95% confidence interval: [92.05%, 97.98%].
(2) Clinical specificity: 99.06%, 95% confidence interval: [97.72%, 99.53%].
(3) Clinical accuracy: 98.28%, 95% confidence interval: [96.92%, 99.01%].
*In the stratified statistics of different stages of the disease, 62 specimens from 0-3 days, and the positive detection rate is 98.41%.

[Precautions]

1.This reagent must be used by trained or professional clinical testing personnel by following all laboratory management regulations.
2.Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.
3.The specimen shall be tested in a laboratory with certain conditions. All specimens and materials during testing should be handled in accordance with the laboratory practice for infectious diseases.
4.Keep away from moisture, do not open the aluminum platinum bag before it is ready for testing. Do not use when the aluminum foil bag is damaged or the test card is damp.
5.Please use it within the validity period.
6.Wait all reagents and specimens come to room temperature (15 ~ 30 °C) before use.
7.Do not replace the components in this kit with components in other kits.
8.Do not dilute the specimen for testing, otherwise you may get inaccurate results.
9.The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
10.The test methods and results must be interpreted in strict accordance with this specification.

[Index of Symbols]

2°C 30°C	Temperature Limit		Use-by date
LOT	Batch/Lot code	IVD	In vitro diagnostic medical device
	Manufacturer	REF	Catalogue number
Σ n	Contains sufficient for <N> tests		Consult instructions for use
	Do not re-use	CE	
	Date of manufacture	EC REP	Authorized representative in the European Community
	Do not use if package is damaged	STERILE R	Sterilized using irradiation
CE 0197	CE Certification		

[INFORMATIONENINQUIRIES AND GENERAL INFORMATION]

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[SWAB INFORMATION]

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