SARS-CoV-2 Antigen Rapid Test (Immunochromatography)

FOR PROFESSIONAL USE ONLY

Product Name

SARS-CoV-2 Antigen Rapid Test (Immunochromatography)

Packing Specification

The combination form of the product is single cassette.

Intended Use

For in vitro diagnostic use. The SARS-CoV-2 Antigen Rapid Test is a immunochromatographic assay for the qualitative detection of SARS-CoV-2 antigen in human nasopharyngeal swab or oropharyngeal swab samples. This reagent is only used in clinical laboratory, medical institutions and real-time inspection by professional medical personnel, not suitable for family test. The test results are only for clinical reference, recommending to conduct comprehensive analysis of the disease condition in combination with clinical manifestations of patients and other laboratory tests; it is not suitable for screening of general population.

Test principle

The reagent detect SARS-CoV-2 antigen in the samples according to double antibody sandwich immunochromatographic assay.

When the sample contains antigen, the antigen react with the colloidal gold labeled monoclonal antibody 1,that complex then moves upward on the membrane by capillary action. The coated monoclonal antibody 2 present on the membrane (test line) capture the coloured conjugated and the red line will be visible, indicating positive result. When the sample does not contain antigen, complex cannot be captured at the test line, and the red line will not appear, indicating negative result.

Whether the sample contains the SARS-CoV-2 antigen or not, the gold labeled antibody will bind with the coated antibody at the C line and the red line will be visible**.**

Main Components

Cassette: The test line is coated with SARS-CoV-2 monoclonal antibody 2. The label absorbent pad is conjugated with SARS-CoV-2 monoclonal antibody 1. The control line is coated with goat anti-mouse IgG antibody.

Extraction Reagent: Tris (hydroxymethyl)methyl aminomethane buffer with surfactant.

This product provides two different packaging forms, the packaging form 1 or 2 can be selected according to the demands.

Package type 1:

Specification / Ingredients	20 tests/kit	25 tests/kit	40 tests/kit	Remark
Test cassettes and desiccants in a sealed foil pouch	20	25	40	
Extraction Reagent	6.5mL*2	7.5mL*2	6.5mL*4	
Extraction tube	20	25	40	Optional
Swab	20	25	40	Optional
IFU	1	1	1	

Package type 2:

Specification / Ingredients	20 tests/kit	25 tests/kit	40 tests/kit	Remark
Test cassettes and desiccants in a sealed foil pouch	20	25	40	
Extraction Reagent	0.5mL*20	0.5mL*25	0.5mL*40	
Swab	20	25	40	Optional
IFU	1	1	1	

MATERIAL NEEDED BUT NOT PROVIDED

1. Timer
2. Personal protective equipments, such as protective gloves, medical masks, goggles and lab coats.
3. Appropriate biohazard waste container and disinfectant.

Storage and Shelf-Life

The kit is stored at 4~30℃ in the sealed pouch, avoid hot and sunshine and is valid provisional for 12 months. DO NOT FREEZE and use expired products.

The reagent can be transported in short time at room temperature.

Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze- thaw. Do not open the inner packaging until ready, it must be used in an hour if opened (Humidity≤60%, Temp: 20℃ ~30℃). Please use immediately when the humidity＞60%.

Sample Requirement

Sample Collection

Collection method of Nasopharyngeal swab:

Hold the head of the patient by the left hand fixedly and insert the swab by the right hand carefully. Do not overexert to avoid traumatic hemorrhage. When the cusp of the swab touching the surface of the posterior nasopharynx, let the swab remain in this place for a few seconds (about 3 seconds) and rotate the swab gently for one cycle, and then withdraw the swab from the nasal cavity slowly. Repeat this process for the other nostril using the same swab to ensure that an adequate sample is collected from both nasal cavities.

Collection method of oropharyngeal swab:

The head of the patient is slightly tilted and his mouth is wide open, exposing both sides of the pharyngeal tonsils. Wipe the swab across the root of the tongue, and then wipe both sides of the pharyngeal tonsils and upper and lower of the posterior pharyngeal wall at least 3 times separately. Avoid touching tongue, cheeks or teeth when sampling. Samples after drinking water or beverages cannot be used for testing.

Note: The sample should not be inactivated.

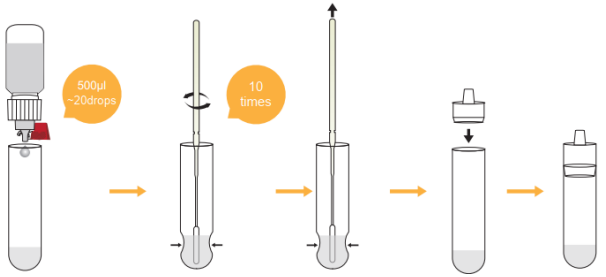
Sample Preservation

The samples of human nasopharyngeal swabs and oropharyngeal swabs should be placed in the sample extract immediately and tested as soon as possible within 1 hour. Long term storage is not recommended.

Sample Treatment

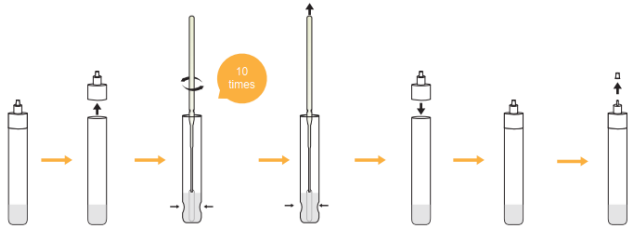
Package type 1 treatment method:

1. Add 500μL of sample extraction buffer into the extraction tube (add about 20 drops vertically if using a dropping bottle).
2. Insert the swab after sampling into the solution of the sample extraction tube, and rotate vigorously against the inner wall of the tube to squeeze the swab for 10 times to make the sample dissolve in the solution as much as possible.
3. Squeeze the swab head along the inner wall of the extraction tube to keep the extraction solution in the tube as much as possible. Take out and discard the swab and the extracted solution will be used as test sample.
4. Cover the emitter cap and wait for inspection.



Package type 2 treatment method:

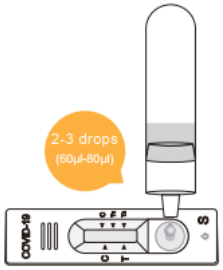
1. Open the sample extraction tube.
2. Insert the swab into the solution of the sample extraction tube. Rotate and squeeze the swab vigorously against the inner wall of the tube for 10 times to make the sample dissolve in the solution as much as possible.
3. Squeeze the swab head along the inner wall of the extraction tube to keep the extraction solution in the tube as much as possible. Take out and discard the swab, and the extracted solution will be used as test sample.
4. Cover the lid and open the emitter cap for inspection.



Test Procedure

Instructions must be read entirely before taking the test. Leave the reagent and sample at room temperature for 30 minutes before using to reach room temperature. Do not open the inner packing until it is ready. Use it as soon as possible after opening the inner packing.

1. Open the tear hole of the aluminum foil bag, take out the test card and lay it flat.
2. Add 2-3 drops of the treated sample extraction solution (60μL-80μL) vertically into the sample well of the test card.
3. The results are observed after 15 minutes and the results were invalid after 20 minutes.

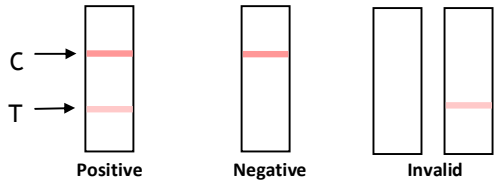


Interpretation of Results

POSITIVE: The presence of two lines as control line (C) and the test line (T) indicates a positive result.

NEGATIVE: The presence of only control line(C)indicates a negative result.

INVALID: The control line(C)fails to appear, indicating that the Operation error or reagent failure.



Limitation

1. The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemic condition and further clinical data.
2. If the virus antigen level in the sample is lower than the detection limit, the test result may be negative.
3. As the duration of the disease increases, the number of antigens in the sample may decrease. Compared with RT-PCR analysis, a sample collected five days after the onset of symptoms may be negative.
4. Due to the limitation of the detection method, the negative result cannot exclude the possibility of infection. The positive result should not be taken as a confirmed diagnosis. Judgement should be made along with clinical symptoms and further diagnosis methods.
5. This reagent can only qualitatively detect SARS-CoV-2 antigens in human nasopharyngeal swab, oropharyngeal swab. It cannot determine the certain antigen content in the samples.
6. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample transportation and storage or freezing and thawing of the sample will affect the test results.
7. It is optimum when eluting swabs with the matched samples extraction solution. Using other diluents may result in wrong results.
8. The solution and test card must be equilibrated to room temperature (20℃ ~30℃) before used, otherwise the results may be incorrect.
9. Sensitivity maybe decrease if the sample did not test directly. Please test the sample as soon as possible.
10. Cross reactions maybe exist due to the N protein in SARS has a high homology with the new coronavirus (SARS-CoV-2). However, the interpretation of the results is not affected during seasons without SARS infection.
11. Analysis the possibility of false negative results:
1) Inappropriate sample collection, using other non-matching solution, sample transfer time is too long (more than half an hour), the volume of solution added when eluted the swab are too much, non-standardized elution operation, low virus titer in the sample, these may all lead to false negative results.
2) Mutations in viral genes may lead to changes in antigen epitope, leading to false negative results.
12. Analysis the possibility of false positive results:
1) Inappropriate sample collection, using other non-matching solutions, non-standardized elution operation, these may all lead to false positive results.
2) Cross-contamination of samples may lead to false positive results.
13. Analysis the possibility of invalid result:
1) If the sample volume is not enough, the chromatography cannot be carried out successfully.
2) The test card would invalid if the package was broken. The packaging status must be carefully checked before use.
14. In different stages of infection, samples of different viral load may have different coincidence rates with nucleic acid test results.
15. When sampling a nasopharyngeal swab, both nostrils need to be sampled with the same swab. If you only one side is taken, it may cause wrong results.

Performance Characteristics

1. Clinical performance

The performance of SARS-CoV-2 Antigen Rapid Test (Immunochromatography) was established with 135 patients who were suspected of SARS-CoV-2. Both nasopharyngeal swab and oropharyngeal swab were collected from one same patient and the results were consistent.

SARS-CoV-2 Antigen Rapid Test Performance against with Comparator Method(nasopharyngeal swab / oropharyngeal swab)

SARS-CoV-2 Antigen Rapid Test	Comparator Method		Total
	Positive	Negative	
Positive	30	1	31
Negative	3	101	104
Total	33	102	135

PPA: 90.91% (95%CI: 76.43%-96.86%)
NPA: 99.02% (95%CI: 94.66%-99.83%)
OPA: 97.04% (95%CI: 92.63%-98.84%)
EXPLANATION OF TERMS:
PPA: Positive Percent Agreement = True Positives / True Positives + False Negatives
NPA: Negative Percent Agreement = True Negatives / True Negatives + False Positives
OPA: Overall Percent Agreement = True Positives + True Negatives / Total
CI: Confidence Interval

2. Limit of Detection

The limit of Detection(LOD)of the SARS-CoV-2 Antigen Rapid Test is 2 x$10^3$$TCID_{50}$/mL.

3. Analytical performance

1) Cross-reactivity

The results showed no cross reactivity with influenza a virus, influenza B virus, respiratory adenovirus, respiratory syncytial virus and mycoplasma pneumoniae.

2) Interfering

The test results of SARS-CoV-2 Antigen Rapid Test do not be interfered with the following drugs： zanamivir, ribavirin, oseltamivir, levofloxacin, cefradine, meropenem, tobramycin, oxymetazoline hydrochloride nasal spray, budesonide.

4. Hook Effect:

No high dose hook effect was observed up to 1.6 x 10^5 $TCID_{50}$/mL of SARS-CoV-2 with SARS-CoV-2 Antigen Rapid Test.

Precautions

1. The reagent is a disposable diagnostic reagent in vitro, which is only used for the detection of human nasopharyngeal swab, or oropharyngeal swab. The operation should be carried out strictly according to the instructions. Do not use expired and damaged products.
2. The strength of the quality control line does not mean the quality of the reagent, as long as its color is clear and visible, that means the reagent is effective.
3. 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.
4. Reagents should be used as soon as possible after being taken out of the aluminum foil bag to avoid exposure to the air for too long, which may cause moisture and affect the test results.
5. Do not use samples that have been placed for too long or contaminated.
6. Please operate in accordance with the laboratory testing procedures for infectious diseases. Waste after use should be treated in accordance with infectious substances and should not be discarded at will.

Note: use clean pipettes or nozzles for each sample to avoid cross contamination.

7. Incorrect operations may affect the accuracy of the results, such as insufficient or excessive sample extraction solution, insufficient sample mixing, insufficient sample volume, and inaccurate detection time.
8. Components in different batch should not be mixed.
9. If the sample swab is not rotated and squeezed in the sample extraction tube for 10 times, false negative results may occur. If the swab is put into the packaging bag after sample collection, false negative results may occur.
10. 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 with gloves;
Do not suck samples with your mouth;
Do not smoke, eat, drink, cosmetic or handle contact lenses while handling these items;
Disinfect the spilled sample or reagent 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.

MANUFACTURER / POST-SALE SERVICE UNIT

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EUROPEAN REPRESENTATIVE

CMC Medical Devices & Drugs S.L.

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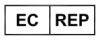
INSTRUCTIONS OF SYMBOL

	Consult instructions for use		Keep dry
	Temperature limit		Batch code
	For single use		In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Use-by date		Contains sufficient for <n> tests
	European representative		Keep away from sunlight