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

The SARS-CoV-2 Antigen Rapid Test is intended for in vitro qualitative detection to SARS-CoV-2 antigen in human nasopharyngeal swab or oropharyngeal swab samples.

Test Principle

According to the gold immunochromatographic test principle, double antibody sandwich method is used to detect SARS-CoV-2 antigen in the samples. When the antigen is contained in the sample, the antigen binds with the corresponding gold labeled monoclonal antibody 1 and the coated monoclonal antibody 2 at the test line to form a compound and then condenses into a red band, indicating a positive result. When the sample does not contain antigen, complex cannot be formed at the test line, and no red band appears, indicating negative result.

Regardless of whether the SARS-CoV-2 antigen is contained in the sample, the gold labeled antibody will bind with the coated antibody at the C line to form a complex and develop color (C line).

Components

The test line is coated with SARS-CoV-2 monoclonal antibody 2. Gold conjugate pad solid phase SARS-CoV-2 monoclonal antibody 1.The quality control line is coated with goat anti-mouse IgG antibody.

Sample extract: Tris(hydroxymethyl)methyl aminomethane buffer with surfactant.

Swab and sample extraction tube are optional.

MATERIAL NEEDED BUT NOT PROVIDED

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

Storage and Shelf-Life

Store as packaged in the sealed pouch at 4-30℃, avoid hot and sunshine, dry place, valid for 12 months. DO NOT FREEZE. 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 one hour if opened (Humidity≤60%, Temp: 20℃-30℃). Please use immediately when the humidity＞60%.

Sample Requirement

Sample Collection

Nasopharyngeal swab collection method:

The operator holds the swab by the right hand and holds the head of the subject fixedly by left hand. Do not overexert to avoid traumatic hemorrhage. When the cusp of the swab touching the paries posterior of the pharyngonasal cavity, letting the swab remain in the place for a few seconds (about 3 seconds) and rotating the swab gently for one cycle,and then remove the swab slowly.Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.

Collection method of oropharyngeal swab:

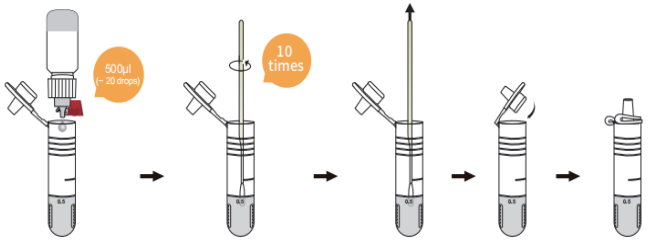
The head of the person to be collected is slightly tilted and his mouth is wide open, exposing the pharyngeal tonsils on both sides. Wipe the swab across the root of the tongue. Wipe the pharyngeal tonsils on both sides of the person to be collected back and forth with a little force for at least 3 times, and then wipe up and down the posterior pharyngeal wall for at least 3 times.

Sample preservation

Samples of human nasopharyngeal swabs and oropharyngeal swabs 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℃ for 8 hours, and stored below -20℃ for 1 month. Long-term storage is not recommended.

Sample Treatment

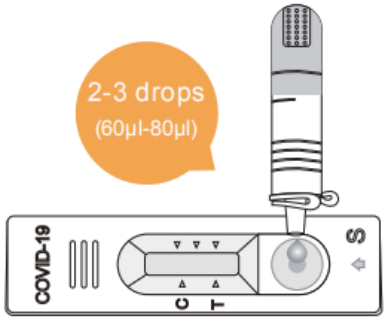
Add 500μl (~20 drops) of sample extract to the 0.5 mark of the sampling tube, dip the swab after collecting the sample into the sample extract, make the sample extract fully permeate the swab, rotate and squeeze the swab 10 times, then pull out the swab, and take the stranded liquid as the sample to be tested.



Test Procedure

Instructions must be read entirely before taking the test. Leave the reagent and sample at room temperature for 30 minutes before use. Return to 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. Apply 2-3 drops of the treated sample extract (60μl-80μl) vertically into the sample well of the test cassette.
3. The results are observed after 15 minutes and showed no clinical significance after 20 minutes.

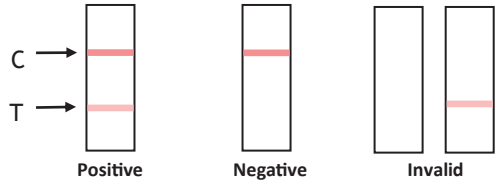


Interpretation of Result

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 analytes in the sample, it only indicates the level of tested analytes 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.



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. In the early stage of infection, the test result may be negative because the low SARS-CoV-2 antigen level or antigen has not yet appeared in the sample.
3. 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.
4. 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.
5. 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.
6. It is optimum when eluting swabs with the matched samples extraction solution. Using other diluents may result in wrong results.
7. The solution and test card must be equilibrated to room temperature (20℃ ~30℃) before used, otherwise the results may be incorrect.
8. Sensitivity maybe decrease if the sample did not test directly. Please test the sample as soon as possible.
9. 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.
10. 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.

11. 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.

3) False negative result from nucleic acid.

12. 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.

13. In different stages of infection，samples of different viral load may have different coincidence rates with nucleic acid test results.

14. When sampling a nasopharyngeal swab, both nostrils need to be sampled with the same swab. If you only take it once, it may cause wrong results.

Performance Characteristics

1. Positive coincidence rate

Test with positive references, the results should be positive.

2. Negative coincidence rate

Test with negative references, the results should be negative.

3.Limit of detection

Test with the limit of detection reference, the result should be positive.

4. Repeatability

The repeatable reference is tested in parallel for 10 times, and the test results should be all positive with uniform color.

5. Cross-reactivity

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

6. Interfering

The test result 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.

Precaution

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 they can be used.

4. Reagents should be used as soon as possible after removal from aluminum foil bags, so as to avoid exposure to air for too long and affecting test results due to dampness.

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.

7. Incorrect operation may affect the accuracy of the results, such as insufficient sample mixing, insufficient amount, inaccurate detection time, etc.

8. Components in different batch should not be mixed.

9. There should be appropriate biosafety assurance procedures for those substances containing and suspected sources of infection. The following are relevant considerations:

1) Handle samples and reagents with gloves;

2) Do not suck samples with your mouth;

3) Do not smoke, eat, drink, cosmetic or handle contact lenses while handling these items;

4) Disinfect the spilled sample or reagent with disinfectant;

5) Disinfect and treat all samples, reagents and potential pollutants in accordance with relevant local regulations;

6) 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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INSTRUCTIONS OF SYMBOL

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

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