CE

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. Putting the swab downing backwards the bottom of the nasal cavity and penetrate slowly and gently. 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.

Collection method of oropharyngeal swab:

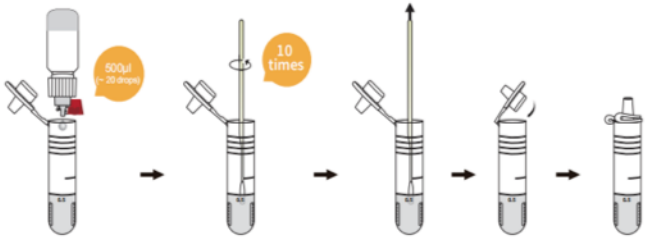
The head of the person to be collected is slightly tilted and his mouth is wide open, exposing the pharyngeal tonsils on both sides. Wipe the swab across the root of the tongue. Wipe the pharyngeal tonsils on both sides of the person to be collected back and forth with a little force for at least 3 times,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

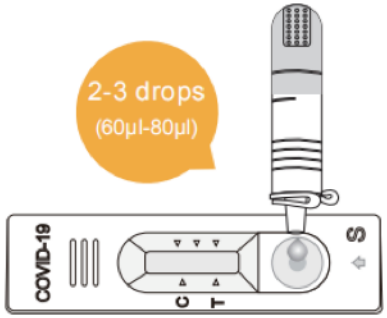
Add 500μl (~20 drops) of sample extract to the 0.5 mark of the sampling tube, dip the swab after collecting the sample into the sample extract, make the sample extract fully permeate the swab, rotate and squeeze the swab 10 times, then pull out the swab, and take the stranded liquid as the sample to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

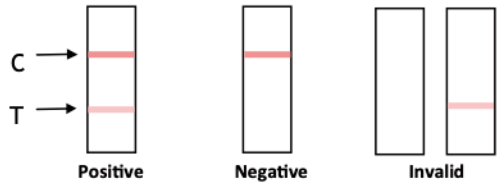


Interpretation of Result

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. This reagent is a qualitative detection reagent, which cannot determine the exact concentration of antigen.
2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. Restricted by the methodology of antigen detection kits, limit of detection (analysis sensitivity) is lower than the nucleic acid detection reagent, so the experimenters should pay more attentions to the negative results, the detection results should be judged comprehensively combining with the other detection methods. The suspected negative results are suggested to be re-checked by the way of nucleic acid detection reagent or virus isolation and culture identification.
4. False negative results may be caused by unreasonable sample collection, transport and treatment, and low virus titer in samples.

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. This reagent is disposable and only used for in vitro diagnosis. Please use it within the validity period. Before use, please check whether the package is complete and the contents are complete. If there is damage, please do not use.
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 waste in the process of use and after use has potential biological safety risk, and the waste should be used and disposed according to the requirements of the laboratory management regulations to prevent the harm and pollution to personnel and the environment.
4. The components in the kit shall not be mixed with different batch Numbers.

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		

IFU SARS-CoV-2 Antigen A/0

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