COVID-19 Antigen Test Kit

【Product Name】

COVID-19 Antigen Test Kit

【Intended Use】

COVID-19 Antigen Test Kit uses Colloidal Gold Immunochromatographic Assay (GICA) technology which is intended for the in vitro qualitative detection of the SARS-CoV-2 virus antigen nucleocapsid (N) protein in human nasal swab, nasopharyngeal swab, oropharyngeal swab samples.

SARS-CoV-2 with envelope and round or oval particles is a new type of coronavirus within the genus of betacoronaviruses. Respiratory droplet transmission and contact transmission are the main transmission routes. The population is generally susceptible, the incubation period is generally 3 to 7 days, a few cases exceed 14 days, and there is infectiousness during the incubation period. Nucleocapsid protein (NP) is an important conserved structural protein of SARS-CoV-2. It plays a key role in the process of virus assembly, replication and protein translation. It can usually be detected in upper respiratory tract specimens in the acute phase of infection. This kit can be used for the clinical diagnosis of patients with the novel coronavirus infection. A negative result needs to be supplemented by PCR testing and is not the only criterion for clinical diagnosis.

【Test Principle】

This kit uses Colloidal Gold Immunochromatographic Assay (GICA) technology, which is composed of mouse anti-SARS-CoV-2 NP antibody nitrocellulose membrane and NP antibody labeled the gold labeling pad and other reagents. During detection, if SARS-CoV-2 is present in the sample, after the sample is processed, will specifically bind to the SARS-CoV-2 NP to form a complex. This complex moves forward along the test strip due to the chromatographic effect and is captured by the mouse anti-NP antibody in the testing line.

where forms a sandwich complex and agglomerates to develop color.

If it is a negative specimen, it cannot form a complex and cannot be captured by a specific antibody in the detection area, so it does not develop color. Regardless of whether there is SARS-CoV-2 in the sample, a colored bar will appear at the quality control line (C) as an internal control standard for whether the chromatography process is normal and whether the reagent is invalid.

【Main Components】

1.Test strips individually foil pouched with a desiccant

2.Sample Processing Solution (SPS), 1 bottle.

3.Disposable Extraction tubes .

4.Disposable Extraction tube cap.

5.Sample Collecting Swab

Note: Components in different batches of reagent kits are not interchangeable, otherwise there will be mistakes.

【Storage Conditions & Shelf Life】

1.The kit should be stored at 2~30°C and keep away from light. The validity period is 18 months.

2.If the test card is unused, it must be immediately put back into the packaging bag with desiccant and sealed for storage.

3.Production date and expiration date are shown on the label.

【Sample Requirements】

1.This kit is limited to the detection of human nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, etc.

2.Collection requirements:

Nasal swab: When collecting a nasal swab sample, carefully insert the swab into the nostril with the most secretions. Rotate gently and push the swab until the resistance is encountered. Rotate the swab against the nasal wall several times, and then remove the swab from the nostril.

Nasopharyngeal swab: The subject cleans the nasal cavity in advance. After gently insert the nasopharyngeal swab through the subject's nostrils, it goes deep perpendicular to the surface of the head or face, from the lower nasal passage to the posterior wall of the nasopharynx. The nasopharyngeal swab should be twisted on the nasopharyngeal mucosa, and kept for 10-15 seconds, and then take it out.

Oropharyngeal swab: The subject cleans the nasal cavity/oral cavity in advance. Use a tongue depressor (spatula) to depress the tongue. The swab crosses over the subject's tongue to the posterior wall of pharyngeal and the crypts and sidewalls of tonsil etc. Repeatedly wipe 3 to 5 times to collect mucosal cells.

3.Open the disposable extraction tube, place the swab in the extraction tube. The head of the swab should be completely immersed in the extraction tube. Stir 3~5 times for 1 minute. Take out the swab and tighten the extraction tube cover.

4.The sample can be stored at room temperature for 8 hours. If it's not available for testing immediately, it can be stored at 2~8 ℃ for 7 days. Samples over 7 days are not applicable.

[Assay Procedure]

Step 1: Equilibrate kit components and the collected specimen to room temperature for at least 30 minutes before testing.

Step 2: Fill the Sample Processing Solution 10 drops(400 μL) into the disposable extraction tube .

Step 3:Collect the samples from the patient using provided swab.

Step 4: Mix the swab with Sample Processing Solution in the disposable extraction tube .

Step 5: Place the cap .

Step 6: Drop 4 drops (100μL) from the disposable extraction tube into the specimen well of the test device.

Step 7: Set up a timer.

Step8: Observe the result at 15 minutes. Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 15 minutes only.

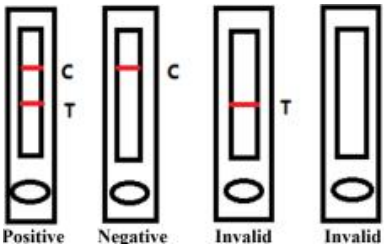
【Interpretation of Test Results】

1.NEGATIVE RESULT: If only the C line is present, the absence of burgundy color in test lines (T) indicates that no SARS-CoV-2 is detected. The result is negative or non-reactive.

2.POSITIVE RESULT: In addition to the presence of C line, if the T line develops, the test result indicates that SARS-CoV-2 is detected. The result is SARS-CoV-2 positive or reactive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

3.INVALID: If no C line develops, the assay is invalid regardless of burgundy color in the test lines as indicated below. Repeat the assay with a new device.



【Limitations of Test Method】

1.This kit is only for testing human nasal swab, nasopharyngeal swab and oropharyngeal swab samples.

2.This kit is only used for qualitative testing and cannot accurately determine the content of antigen in the sample.

3.The test results of this reagent are for clinical reference only, not as the only basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively

considered in conjunction with their symptoms/signs, medical history, other laboratory tests, and treatment responses.
4.Unreasonable sample collection, transportation and processing, and low virus titers in the sample may lead to false negative results.
5.Due to the limitations of immunochromatographic methodology, for negative test results, it is recommended to use nucleic acid amplification testing or virus culture identification methods for review and confirmation.

【Matters Needing Attention】

1.This kit is only used for *in vitro* diagnosis. The test results of the kit are for clinical reference only. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests, and treatment responses.
2.Please read this manual carefully before use.
3.The components in the kits of different batch numbers shall not be mixed.
4.Please use the product within the validity period.
5.This product is sensitive to humidity, so pay attention to the possibility that degradation of detection performance may occur due to the humidity changes.
6.When removing the test card, avoid touching the test line with your hands or other foreign matters which may cause the contamination.
7.Collectors should take appropriate personal protection as required.
8.When collecting samples, if the patient has a recent history of nasal trauma or surgery, or a significant deviation of the nasal septum, or a history of chronic nasal obstruction and severe coagulopathy, clinicians should be cautious.

【Index of symbol】

IVD *In Vitro* Diagnostic Use	See Instruction for Use	Expiry Date
Σ Tests per Kit	Manufacturing Date	Keep Dry
LOT Batch Number	Manufacturer	Keep away from Sunlight
Store between 2～30ºC	Do not reuse	REF Catalog #

【Manufacturer】

Company Name:Surge Medical Inc.
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