COVID-19/Influenza A+ B Antigen Test Kit

【Product Name】

COVID-19/Influenza A+ B Antigen Test Kit

【Intended Use】

COVID-19/Influenza A+ B 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/Influenza A/ Influenza B in saliva 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.

Influenza viruses are the pathogens that cause influenza, which can cause acute respiratory tract infection. Highly infectious, short incubation period and high incidence rate. It is an infectious disease that is easily transmitted by coughing and sneezing. Influenza outbreaks occur each year during the fall and winter months. Influenza viruses are immunologically diverse, single-strand RNA viruses. There three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and associated with most serious influenza epidemics. while type B infections are usually milder than that caused by type A. Type C viruses have never been associated with a large epidemic of human disease.Therefore, the detection of influenza A and B virus has great clinical significance.

【Test Principle】

This kit uses Colloidal Gold Immunochromatographic Assay (GICA) technology, which is composed of mouse anti-SARS-CoV-2 NP antibody、anti influenza A virus monoclonal antibody and anti influenza B virus monoclonal antibody nitrocellulose membrane and NP antibody、influenza A virus monoclonal antibody and influenza B virus monoclonal antibody labeled the gold labeling pad and other reagents.It was used to detect 2019- ncov antigen and influenza A / B virus extracted from saliva samples.

In the detection process, if sars-cov-2 exists in the sample, it will specifically combine with sars-cov-2 N protein to form a complex after sample treatment. Due to the matrix effect, the complex moved forward along the strip and was captured by the mouse anti-N protein antibody in the T detection line to form a sandwich complex, which was then colored by T.

If there is influenza B virus in the sample, it will specifically combine with the monoclonal antibody of influenza B virus to form a complex after sample treatment. Due to the matrix effect, the complex moves forward along the strip and is captured by the monoclonal antibody against influenza B virus in the B detection line to form a sandwich complex, which is then colored on B.

If there is influenza A virus in the sample, it will specifically combine with the monoclonal antibody of influenza A virus to form a complex after sample treatment. Due to the matrix effect, the complex moves forward along the strip and is captured by the monoclonal antibody against influenza A virus in the A detection line to form a sandwich complex, which is then colored by A.

If it is a negative sample, it can not form a complex and can not be captured by the specific antibody in the detection area, so it does not develop color. No matter whether there is sars-cov-2 / influenza A virus / influenza B virus in the sample or not, a color band will appear at the quality control line (c) as the internal control standard for whether the chromatographic process is normal and whether the reagent is invalid.

【Main Components】

1.Test strips individually foil pouched with a desiccant

2. Extraction Buffer, 20 bottle.

3.sampler, 20 bottle.

4.Dropper., 20 T.

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 saliva samples.

2.Collection requirements:

2.1 Rinse your mouth with water 30 minutes before sampling, and do not eat, smoke, drink alcohol or drinks after rinsing.

2.2 Saliva specimen collection:Put the tip of the tongue against the upper or lower root of the tooth to enrich the saliva. Spit the saliva directly into the sampler and let it stand for 5 minutes.

2.3The sample volume should be more than 3mL.

2.4 It is recommended that the specimen is tested at the time of specimen collection. If the specimens cannot be tested immediately, it could be stored at 2~8 ℃ or 4 hours and long-term storage is not recommended.

[Assay Procedure]

Step 1: Remove the cover of the extraction buffer (300 μ L / bottle)

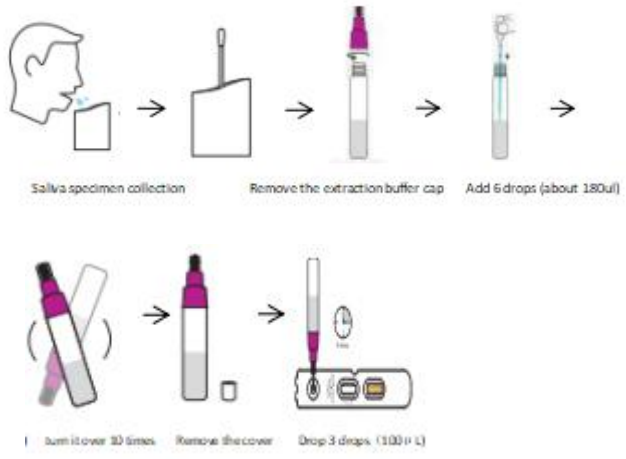
Step 2: Add 6 drops (about 180ul) of saliva sample into the extraction buffer with a dropper, then cover it, turn it over 10 times, and mix well.

Step 3:Remove a test kit from the sealed pouch by tearing at the notch and place it on a level surface.

Step 4: Drop 3 drops (100 μ L) from the extraction buffer tube into each specimen well of the test kit.

Step 5: Set up a timer.

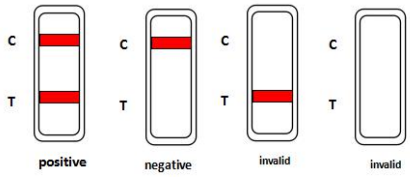
Step 6: Observe the result at 15 minutes. Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 15 minutes only.



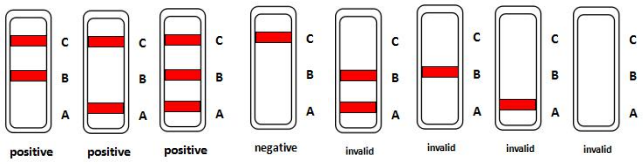
【Interpretation of Test Results】

COVID-19 Antigen Test

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.
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.



Influenza A+ B Antigen Test
1.NEGATIVE RESULT: If only the C line is present, the absence of burgundy color in test lines (B and A) indicates that no influenza A and B virus is detected. The result is negative or non-reactive.
2.POSITIVE RESULT: In addition to the presence of C line, if the B line develops, the test result indicates that influenza B virus is detected. If the A line develops, the test result indicates that influenza A virus is detected. If the A and B line develops, the test result indicates that influenza A/B virus is detected.
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 saliva 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.

【Index of symbol】

IVD *In Vitro* Diagnostic Use	See Instruction for Use	Expiry Date
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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Contact: +86-435-5187058 Post code: 134001
Name of after-sales service unit: Surge Medical Inc.
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