COVID-19 Antigen Saliva Rapid Test Kit (Colloidal Gold)

Instruction for use

GF102B8 Revision Date: 23/01/2021

1 Product Name

COVID-19 Antigen Saliva Rapid Test Kit (Colloidal Gold)

2 Package and Specification

1 Test/box (10 boxes/kit)

3 Intended Use

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

4 Test Principle

Green Spring® COVID-19 Antigen Saliva Rapid Test Kit (Colloidal Gold) uses COVID-19 antibodies labelled with gold particles that attach to the membrane of the test card near the specimen application position. Once applied, the specimen migrates from the application position to the reading field of the test card due to capillary forces. When the liquid reaches the COVID-19 antibodies, they detach from the membrane and are transported along the test card. There is a test line and a control line in the reading field of the test card.

If the specimen contains SARS-CoV-2 antigens ("analyte"), these bind to the gold-labelled antibodies and create so-called antigen-antibody-gold conjugate complexes. When these complexes reach the test line of the test card, they are retained there by another set of COVID-19 antibodies immobilized on the membrane.

These double complexes appear as a colored stripe on the test line. If the specimen does not contain SARS-CoV-2 antigens, no double complexes are formed and no colored stripe appears on the test line.

Whether or not the specimen contains SARS-CoV-2 antigens, a colored stripe appears on the control line of the test card. If no colored stripe appears on the control line, the Test Card has not functioned properly.

5 Components

Component	10 boxes/kit
Test cassette	1 Test/box
Desiccant	1 pack
Tube	1 single-use reaction tubes, each with 1× Filter cap
Saliva collector	1 pack
Buffer	1 bottle
Package Insert	1 Instruction for Use

Materials required which are not supplied

Timer or stopwatch

6 Storage and Stability

Do not freeze.

Keep away from sunlight, moisture, and heat.

The test cassette should be used within 1 hour after taking out from the aluminum foil bag.

Store at 2~30ºC in the sealed pouch up to the expiration date and the validity is tentatively 12 months.

7 Specimen Collection and Handling

7.1 Specimen Preparation

1)Do not eat, smoke or drink anything except water for 30 min before specimen collection. These may affect the test results.

2)Freshly collected specimens should be processed in one hour after specimen collection. Correct specimen collection and preparation methods must be followed.

3)Avoid bubbles and sputum while collecting saliva.

4)Remove the test card from the bag and use it immediately to avoid long-term exposure to air. Exposure of the test card to air for a long time will affect the test results.

8 Test Performance

1)Open the test card bag and put the test card on a flat surface.

2)Twist off the top of the buffer bottle, dispense entire buffer into the tube(0.5mL).

3)Screw saliva collection funnel on to the saliva collector tube.

4)Place the tip of tongue against the mucous membrane of the oral cavity to enrich saliva, then spit saliva into a saliva collector (add to 1000 μL, about 1:1).

5)Vertically hold the saliva collector tube and unscrew the saliva collector funnel to remove it from the tube. Discard the funnel.

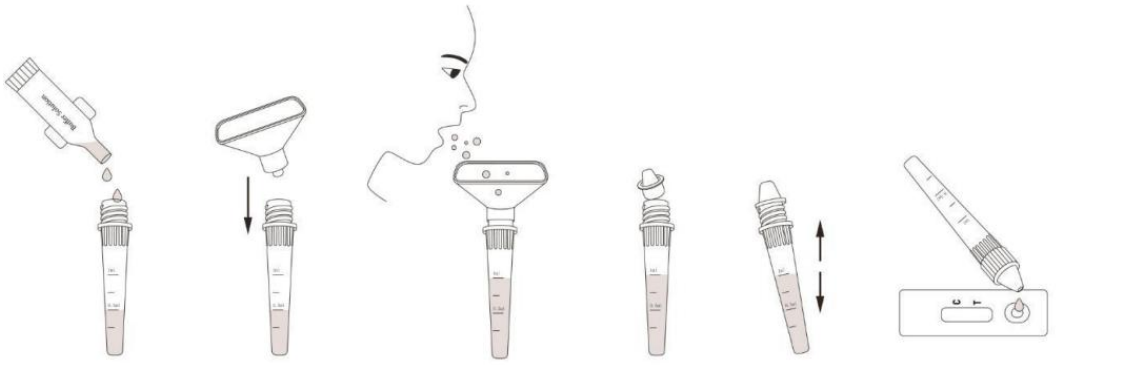
6)Close the tube tightly with the filter cap.Mix the contents by rotating the tube upside down ten times.

7)Add 3 drops of the mixed solution vertically into the sample well (S) of the test cassette.

Please note that there should be no liquid applied to the result windows marked with the letters (T) and (C). Do not touch or move the test cassette after adding the drops to the sample well (S).

8)Read the result in 15-20 minutes after adding the sample.

9)Result got after 20 minutes is invalid.



Step 1
dispense entire buffer into the tube(0.5mL)

Step 2
Screw saliva collection funnel on to the saliva collector tube

Step 3
spit saliva into a saliva collector(add to 1000μL, about 1:1)

Step 4
Close the tube tightly with the filter cap.

Step 5
Mix the contents by rotating the tube upside down ten times.

Step 6
Add 3 drops of the mixed solution vertically into the sample well (S) of the test cassette.

9 Interpretation of Test Results

1)Positive

Two lines appear. A colored line should be in the control line region (C), a colored line appears in the test line (T) region. The test result means that SARS-CoV-2 antigen is detectable in your saliva sample. The detection of these antigens indicates with a high probability of infection with the SARS-CoV-2 virus. Please stay at home and contact your physician or the responsible health authority immediately to get information on how to

proceed further.

*Note: The thickness of the line is insignificant; any reddish color in the Test line (T) should be considered a positive result. The positive test result must be confirmed by PCR.

2)Negative

If only a colored line is visible in the Control line area (C) the test result is negative.

The test result indicates that there is no or too little SARS-CoV-2 Antigen in the saliva Sample and at the current time there is probably no infection with the SARS-CoV-2 virus.

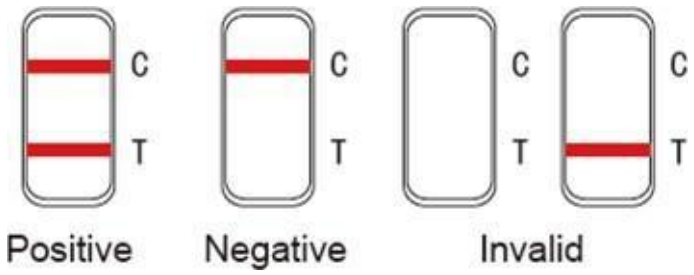
A negative result does not preclude SARS-CoV-2 infection, so please stay at home if you have clinical symptoms or if you have a well-founded suspicion and contact physician or responsible health authority to get information on how to proceed further.

False negative results can be from incorrect sampling, incorrect execution of the test, or insufficient virus in the sample.

3) Invalid

If there is no Control line (C) or only a Test line (T) in the result window, the test did not run correctly and the results are not valid.

It is important that you carefully follow the instructions for the test. You should test again with a new saliva sample and a new test.



(The picture is for reference only)

10 Limitations of Test Method

1)This product is only suitable for a qualitative test and auxiliary diagnosis.

2)Positive test results do not rule out co-infections with other pathogens.

3)A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.

4)The amount of antigen in a sample may decrease as the duration of illness increases.

Specimens collected after day 5 of illness are more likely to be negative compared to an RT-PCR assay.

5)Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.

6)The kit performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.

7)Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.

8)Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false-positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False-negative test results are more likely when the prevalence of disease caused by SARS-CoV-2 is high.

9)The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.

10) The sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay.

11 Performance Characteristics

11.1 Clinical performance

The clinical performance of Green Spring COVID-19 Antigen Saliva rapid test kit in fresh saliva was determined by comparison with Real Time PCR results. Saliva specimens for SARS-CoV-2 were collected from individuals diagnosed as positive and negative respectively by RT-PCR testing.

The kit showed 96.8% of sensitivity (95% Cl: 95.11-98.63%) and 100% of specificity (95% Cl: 100%-100%).

Table1. Clinical Study Results from symptom onset

Reagent test results	PCR Comparator		Subtotal
	Positive	Negative	
Positive	121	0	121
Negative	4	200	204
Subtotal	125	200	325

12 Limit of Detection (Analytical Sensitivity)

The LOD for Green Spring® SARS-CoV-2 antigen saliva rapid test kit is 4.0 x 10^2 $TCID_{50}$ /ml. The LOD for Green Spring® SARS-CoV-2 antigen saliva rapid test kit was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The material was supplied at a concentration of 1.3 x 10^6 $TCID_{50}$ /ml. In this study, designed to estimate the LOD of the assay when using a direct saliva sample, the starting material was spiked into a volume of virus dilution in saline. An initial range-finding study was performed testing devices in triplicate using a 10-fold dilution series. At each dilution, 50 μL samples were added to specimen and then tested using the procedure appropriate for patient saliva specimens. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using this concentration, the LOD was further refined with a 2-fold dilution series. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

13 Hook Effect

As part of the LOD study, the highest concentration of the sample ($TCID_{50}$ of 1.3 x10^6per ml) was tested. There was no Hook effect detected.

14 Warnings

1)A negative result can occur if the SARS-CoV-2 virus present in the specimen is below the sensitivity of the kit.

2)Not for the screening of donated blood.

3)Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.

4)Dispose of all specimens and materials used to perform the test as biohazardous waste.

5)Do not perform the test in a room with strong airflow, i.e. an electric fan or strong air-conditioning.

15 Explanation of Labels

IVD	In Vitro Diagnostic Use		Instruction for Use	CE	CE Mark
LOT	Batch Number		Expiry Date		Manufacturing Date
	Do not reuse	2° 30°	Store between 2 ~ 30ºC		Keep away from Sunlight
	Keep Dry		Manufacturer	EC REP	EU Authorized Representative

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