BRILLIANT COVID-19 Antigen Rapid Test Kit

For in vitro Diagnosis Use

Intended Use

COVID-19 Antigen Rapid Test Kit is an in vitro immunochromatographic assay product for the qualitative detection of SARS-CoV-2 antigen with the nasopharyngeal swab.It is intended to aid in the rapid diagnosis of SARS-CoV-2 infection.

Summary

COVID-19 Antigen Rapid Test Kit is an infectious disease caused by a novel coronavirus which was discovered due to the case of viral pneumonia in Wuhan, China in December 2019. It was named as "severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)" by the International Committee on Taxonomy of Viruses (ICTV) on February 5th, 2020. SARS-CoV-2 is a positive-sense, single-stranded RNA virus. It belongs to beta coronavirus family, which is enveloped and has round or oval particles, usually pleomorphic. Its genetic characteristics are different from those of SARS-rCoV and MERS-rCoV, and its homology with bat-SARS-like coronavirus (bat-SL-CoVZC45) is higher than 85%. This virus can be excreted from the body through respiratory secretions, transmitted by saliva, sneezing and also by airborne droplets.

Detection Principles

COVID-19 Antigen Rapid Test Kit is applied the principle of highly specific antigen-antibody reaction and immunochromatography.

During testing, specimen is dropped into the sample well of cassette, and then the specimen migrates upward on the membrane chromatographically by capillary action. If the specimen contains

SARS-CoV-2 antigens, it will react with Anti-SARS-CoV-2 antibody-Colloidal gold particles in the test cassette. The mixture then migrates upward and reacts with the Anti-SARS-CoV-2 antibody on test line (T). A colored line will appear on test line (T), indicating a positive result. If the specimen does not contain SARS-CoV-2 antigen, no colored line will appear on the test line region, indicating a negative result. The control line (C) should always be visible after the testing step. It serves as a procedural control to confirm the kit is working properly.

Reagents and Materials Supplied

Test cassette x 15
Lysis buffer (5 mL) x 2
Sterile nasopharyngeal swab x 15
Sample extraction tube (tube + nozzle) x 15
Paper rack x1
Specimen ID label x15
Instruction for use x 1

Materials Required but Not Supplied

Timer

Storage

Store test kits at 8-35℃ (46-95℉) in the foil packet. Kit contents are stable within the expiration date. **DO NOT FREEZE.**

Before Test

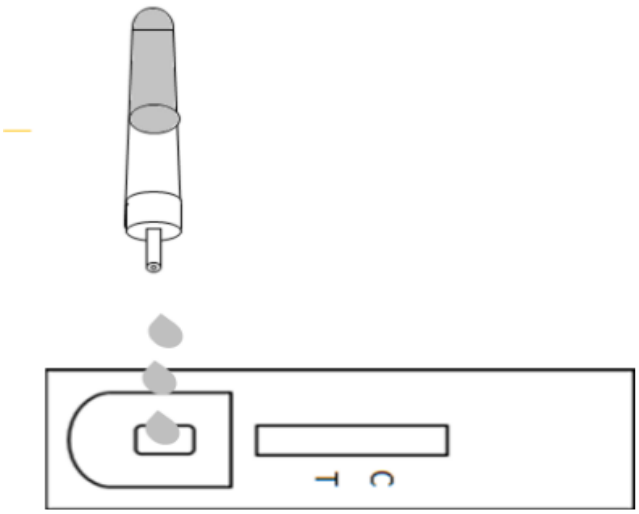
1. Assemble the paper rack.
2. Mark the information needed on the specimen ID label.
3. Label the sample extraction tube.

Sample Collection

1. Add 12 drops (about 300-350 μL) of lysis buffer into the sample extraction tube.
2. Nasopharyngeal swabbing: Completely insert the swab supplied in this kit into the nasopharyngeal, and swab several times to collect the nasopharyngeal secretion.
3. Insert the swab into the sample extraction tube which contains 12 drops of the lysis buffer. After mixing, squeeze the tube several times with fingers from the outside of the tube to immerse the swab.
4. Keep the tube of mixture still for 1 minute. After 1 minute, squeeze out the swab by squeezing the sample extraction tube with fingers. The extracted solution will be used as the test sample.
5. Insert a nozzle into the sample extraction tube tightly.

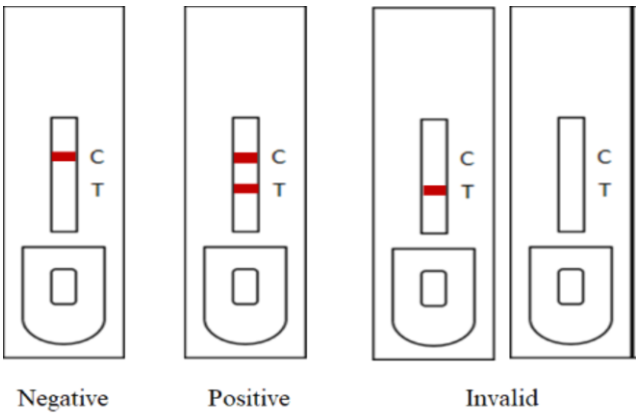
Test Procedure

1. Remove test device from the foil packet just prior to the testing and lay it flat on the work bench.
2. Add 3 drops (about 100-120 μL) of test sample by squeezing the extracted solution tube into the sample well.
3. Start the timer. Do not move the test device while testing.
4. Interpret the result at 15 minutes. Results interpreted after 20 minutes are invalid.



Interpretation of Test Results

1. Negative Result:
   - Only the control line (C) appears and the test line (T) is not visible, indicating the result is negative.
2. Positive Result:
   - Both the control line (C) and the test line (T) appear, indicating the result is positive for SARS-CoV-2 antigen.
3. Invalid:
   - Control line fails to appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat \ the test with a new kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Test Method Limitations

1. The test results of kit are for reference only and should not be the sole basis for diagnosis and treatment. The infection result should be diagnosed and confirmed according to clinical symptoms and other conventional detection methods.
2. Incorrect specimen collection and operation can easily lead to erroneous results. Please read the instruction for use before using the kit.
3. The kit is for qualitative testing only; quantitative testing must be measured by other quantitative methodologies.
4. If the amount of viral antigen is too low, it is easy to cause the false-negative result. Using other clinical methods for further confirmation is suggested.

Precautions

1. For in vitro diagnostic use.
2. Do not use it after the expiration date.
3. Handle all specimens as if they contain infectious ingredients. Be sure to obey all precautions against microbiological hazards, and follow all the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and safety goggles during specimenscollecting and assaying.
5. Please ensure that an appropriate amount of sample is used for the test. Too much or too little sample volume may cause incorrect results.
6. The result of this kit is interpreted by visual inspection. In order to assure the accuracy of the test result, please do not interpret the result in a dark place.
7. The result should be interpreted at 15 minutes. Results interpreted after 20 minutes are invalid.
8. This test cassette is designed for a single, one-time use. After use, the

cassette and samples should be regarded as medical waste with risk of biological infection and properly disposed according to national regulations.

Performance Characteristics

1. Limit of Detection (LOD)

The study used SARS-CoV-2 strain CGMH-CGU-01 for the test of detection limit. The LOD of COVID-19 Antigen Rapid Test Kit reaches $1.67\times10^{2.4}$ $TCID_{50}$/mL virus particles.

Viral concentration ($TCID_{50}$/mL)														
$5\times10^{2.4}$			$2.5\times10^{2.4}$			$1.67\times10^{2.4}$			$1.25\times10^{2.4}$			Negative control		
+	+	+	+	+	+	+	+	+	-	-	-	-	-	-

2. Cross-reactivity

The 4 different viruses which could infect the respiratory tract were used for the cross-reactivity test of the COVID-19 Antigen Rapid Test Kit. There was no cross- reaction among these potential cross-reactive viruses listed below.

Viruses	Conc.	Results*
Hcov-229E	1×10^5 pfu/mL	-
Hcov-OC43	1×10^5 pfu/mL	-
Influenza A Virus	1×10^5 pfu/mL	-
Influenza B Virus	1×10^5 pfu/mL	-

* "-" means the result is negative.

3. Interference study

The 9 different kinds of interfering substances were used to carry out interference test of COVID-19 Antigen Rapid Test Kit. The results showed that there was no interference reaction between the COVID-19 Antigen Rapid Test Kit and the potential interfering substance listed below.

Interference substances	Conc.	Results*
Respiratory Specimens		
Mucin (Bovine submaxillary glands)	100 µg/mL	-
Biotin	100 µg/mL	-
Homeopathic allergy relief medicine		
Olopatadine Hydrochloride	10 mg/mL	-
Cromolyn sodium salt	20 mg/mL	-
Anti-viral Drug		
Oseltamivir phosphate	10 mg/mL	-
Zanamivir	5 mg/mL	-
Anti-Malaria Drug		
Artemether	50 µM	-
Lumefantrine	50 µM	-
Nasal sprays or drops		
Berton Nasal Spray (Oxymelazoline Hydrochloride)	10% (v/v)	-

* "-" means the result is negative.

4. Method comparison

The total of 55 clinical samples included 5 SARS-CoV-2 positive samples and 50 SARS-CoV-2 negative samples were tested, and then the results were compared with that of another available method - RT-PCR (referred to Taiwan CDC). COVID-19 Antigen Rapid Test Kit showed 100%, 98% and 98.2% on sensitivity, specificity, and accuracy respectively.

TRICAN COVID-19 Antigen Rapid Test Kit	RT-PCR method (referred to Taiwan CDC Method)		
	+	-	Total
+	5	1	6
-	0	49	49
Total	5	50	55

5. Accelerated test and stability

By accelerated stability test, it shows the kit will be stable under 8-35℃ (47-95℉) condition, and can be stored for 24 months.

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