COVID-19 Antigen Test Kit (Colloidal Gold) *(Cassette)*

PRODUCT NAME

COVID-19 Antigen Test Kit (Colloidal Gold)(Cassette)

PACKING SPECIFICATION

1test/kit, 5tests/kit, 20tests/kit

INTENDES USE

The SAR-COV-2 Ag Rapid Test Cassette is a lateral flow immunoassay intended for the qualitative detection of nucleoprotein from SARS-CoV-2 in anterior nasopharyngeal swab. It is intended to be used by layperson as a test and provides a preliminary test result to aid in the diagnosis of infection with SARS-CoV-2.

Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this test.

SUMMARY AND EXPLANATION OF THE TEST

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). A SARS-CoV-2 (COVID-19) is a new strain that has not been previously identified in humans and was discovered in 2019. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough and dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, and acute breathing. Distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. are even life-threatening.

Nasopharyngeal swab detection is a common method for the diagnosis of infection with SARS-CoV-2. This test is used for detection of SARS-CoV-2nucleoprotein antigen.

The SAR-COV-2Ag Rapid Test Cassette detects the nucleoprotein of SARS-CoV-2 in human nasopharyngeal swab sample. It can be performed within 15-20 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLCE

The SAR-COV-2 Ag Rapid Test Cassette is a lateral flow chromatographic immunoassay. The test strip in the cassette consists of: 1) a colormicroparticles conjugate pad containing mouse anti-SARS-CoV-2 nucleoprotein monoclonal antibody conjugated with color microparticles and a control antibody conjugated with color microparticles, 2) a nitrocellulose membrane strip containing one test lines (T lines) and a control line (C line). The T line is pre-coated with antibodies for the detection of SARS-CoV-2nucleoprotein, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action along the cassette.SARS-CoV-2nucleoprotein, if present in the specimen, will bind to the mouseanti-SARS-CoV-2nucleoproteinantigen conjugates. The immunocomplex is then captured by the pre-coated mouseanti-SARS-CoV-2nucleoproteinmonoclonalantibody, forming a red T line, indicating a SARS-CoV-2 positive test result and suggesting an infection with SARS-CoV-2.

Absence of T lines suggests a negative result. Each test contains an internal control (C line) which should exhibit a red line of the control antibodies regardless of color development on any of the test lines. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Sealed Extraction Buffer: 0.3ml/bottle
3. Sterile Swabs
4. Quick Reference Instructions

MATERIALS REQUIRED BUT NOT PROVIDED

5. Clock or timer
6. Tube workstation
7. 0.2-mL Calibrated Micropipette with pipette tips

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1. To obtain accurate results, the Package Insert instructions must be followed.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use the kit contents beyond the expiration date printed on the outside of the box.
4. Bring all reagents to room temperature (2-30°C) before use.
5. Do not use the components of any other type of test kit as a substitute for the components in this kit.
6. Discard and do not use any damaged or dropped Test Cassette or material.
7. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-bornepathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Sample collection and handling procedures require specific training and guidance.
11. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
12. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
13. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
14. Do not pour sample from the Reagent Tube into the Test Cassette sample well. Use the provided extraction tube that closed with extraction tube tip when adding the sample to the Test Cassette.
15. The testing results should be read 15 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 20-25 minute window should be considered invalid and must be repeated.
16. Do not reuse the used Test Cassette, Fixed Volume Pipettes, Reagent Tubes, solutions, or Control Swabs.

STABILITY AND STORAGE

The lifespan of the kit is 12 months. All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable until the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

1. Use the nasopharyngeal swab oranterior nasopharyngeal swab supplied in the kit.
2. To collect a nasopharyngeal swab sample, carefully insert the swab 1-2cm (provided in the kit) into the nostrilor.
3. Using gentle rotation, push the swab until resistance is met at the level of the turbinate.
4. Rotate the swab several times against the nostrilor pharynx wall then remove it from the nostrilor pharynx.

SAMPLE PREPARATIONPROCEDURE

1. Insert the extraction tube into the workstation. Make sure that the tube is standing firm and reaches the bottom of the workstation .
2. Broken the sealed extraction buffer with fingers, and squeeze all the extraction buffer into extraction tube.
3. Put the swab into the extraction tube, Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube. Leave the swab in the sample tube for 1 minute.
4. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. Closed the extraction tube tip. The extracted solution will be used as test sample.

SPECIMENTRANSPORTANDSTORAGE

Specimens should be tested as soon as possible after collection. If transport of samples with viral transport medium (VTM) is required, minimal dilution of thesample is recommended, as dilution may result in decreased test sensitivity. Whenever possible, 1 milliliter or less is best to avoid excessive dilution of the patient sample. While holding the swab, remove the cap from the tube. Insert the swab into the tube until the breakpoint is level with the tube opening. Bend the swab shaft at a 180 degrees angle to break it off at the breaking point. You may need to gently rotate the swab shaft to complete the breakage. Based on data generated with SARS-CoV-2, or nasopharyngeal swabs in VTM are stable for up to 24 hours at 2 to 8℃.

Note: When using viral transport medium (VTM), it is important to ensure that the VTM containing the sample is warmed to room temperature. Cold samples will not flow correctly and can lead to erroneous or invalid results. Several minutes will be required to bring a cold sample to room temperature.

ASSAY PROCEDURE

Bring the specimen and test components to room temperature, if refrigerated or frozen.Once the specimen is thawed, mix well prior to performing the assay.

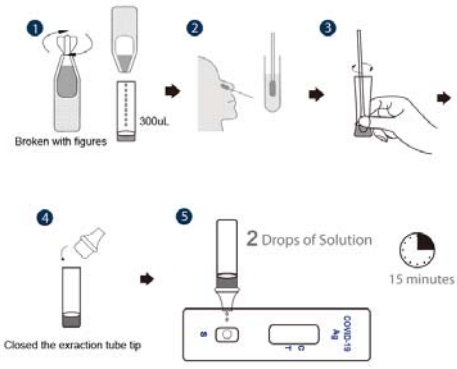
Step 1: Remove the cap of the extraction buffer with figures, add all the buffer into the extraction tube.

Step 2: Carefully insert the swab 1-2cm into the nostril of the patient and rotate the swab 5 times.

Step 3: Put the nasal swab into the extraction tube. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.

Step 4: Drop three extracted solution with extraction tube. The volume of the specimen needed is around60-90μL. ***For better precision, transfer the specimen by a pipette capable of delivering80μL of volume.***

Holding the capillary tube vertically, dispense three drop of the specimen (about 90μL) into the centerof the sample well (S well) making sure that there are no air bubbles.



Step 5: Set up a timer.

Step 6: Read 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. ***Any results interpreted outside of the 15 minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local laws governing the disposal of devices.***

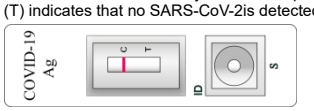
QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen and sample diluent. If there is no visible C line, review the whole procedure and repeat the test using a new device.
2. External Control: Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. A new operator uses the kit, prior to performing testing of specimens.
   b. A new lot of test kit is used.
   c. A new shipment of kits is used.
   d. The temperature during storage of the kit falls outside of 2-30℃.

e. The temperature of the test area falls outside of 15-30℃.
f. To verify a higher than expected frequency of positive or negative results.
g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

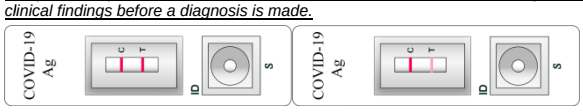
1. **NEGATIVE RESULT**: If only the C line is present, the absence of burgundy color in test lines (T) indicates that no SARS-CoV-2is detected. The result is negative or non-reactive.



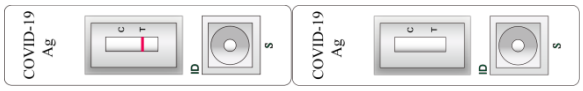
2. **POSITIVE RESULT:**

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 thetest lines as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. **Clinical Sensitivity, Specificity and Accuracy**

The Coronavirus Ag Rapid Test Cassette (Swab) has been evaluated with specimens obtained from patients. A commercialized molecular assay was used as the reference method. The results show that the COVID-19 Antigen Test Kit has a high overall relative accuracy.

	COVID-19 Antigen Test Kit (Colloidal Gold)(Cassette)		
PCR	Positive	Negative	Total
Positive	117	1	118
Negative	4	178	182
Total	121	179	300
Relative Sensitivity:	96.7%		
Relative Specificity	99.4%		
Overall Accuracy	98.3%		

2. **Cross Reactivity**

No false positive SAR-COV-2 test results were observed on 1-13 specimens from the following disease states or specific conditions, respectively:

Virus/Bacteria	Result
SARS Nucleocapsid (Expressed By 293 Cells)	Negative
MERSS N Protein (Expressed By 293 Cells)	Negative
Human Coronavirus-NL63 culture	Negative
HAV positive serum	Negative
HBV positive serum	Negative
HCV positive serum	Negative
HEV positive serum	Negative
HIV positive serum	Negative
TB positive serum	Negative
H. pylori positive serum	Negative
Dengue positive serum	Negative
Influenza A H1N1 culture	Negative
Influenza A H3N2 culture	Negative
Influenza A H5N1 culture	Negative
Influenza A H7N9 culture	Negative
Influenza B culture	Negative
Influenza C culture	Negative
RSV culture	Negative
Human Parainfluenza virus culture	Negative
Herpes simplex virus culture	Negative
Respiratory chlamydia culture	Negative
Mycoplasma Pneumonia culture	Negative
Mycobacteria tuberculosis culture	Negative
HCOV-HKU1	Negative
HCOV-NL63	Negative
HCOV-OC43	Negative
HCoV-229E	Negative
EB Virus	Negative
CMV	Negative
VZV	Negative
Parvovius B19	Negative

LIMITATIONS OF TEST

1. The contents of this kit are to be used for the qualitative detection of SARS antigens from anterior nasopharyngeal swab.
2. This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
3. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
4. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
5. Test results must be evaluated in conjunction with other clinical data available to the physician.
6. Positive test results do not rule out co-infections with other pathogens.
7. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
8. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
9. Negative results should be treated as presumptive and confirmed with an FDA authorized molecular assay, if necessary, for clinical management, including infection control.
10. Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.
11. Specimen stability recommendations are based upon stability data from influenza testing and performance may be different with SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection.
12. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

Index of CE Symbols

	Consult instruction for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog#	LOT	Lot Number	Σ N	Test per kit
2℃ 30℃	Store between 2-30℃	EC REP	Authorized Representative	2	Do not reuse
	Manufacturer		Date of manufacture		

Manufacturer: SINGUWAY BIOTECH INC.
Add: B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122 Guangdong, P.R. China
Tel: +86-755-23704711
Web: www.singuway.com

EC REP CMC Medical Devices& Drugs S.L.
Add:C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Date Released:2021-04-01
English Version

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