SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)

【Catalog Number】

REF CoV19-Ag

【Package Size】

☐ 1 Test/pack ☐ 20 Tests/box

【Intended Use】

The COVID-19 Antigen Rapid Test is intended for the qualitative detection of SARS-CoV-2 virus (cause of the COVID-19 disease). Kit is designed to detect the virus nucleocapsid protein in samples obtained from nasopharyngeal (NP) and nasal (NS) swabs. Test is recommended for individuals who are suspected of COVID-19 disease based on the clinical symptoms, especially within the first seven days of their onset. Test is recommended also for asymptomatic individuals with suspected COVID-19 disease, or to evaluate the COVID-19 epidemiological situation.

Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole method for diagnosis and patient management, including the rules for management of infectious diseases. Test results should be interpreted in accordance with patient history, clinical picture and epidemiological evaluation.

This kit is intended for use only by medical professionals or trained operators who are proficient in performing rapid, lateral flow assay tests.

This product is recommended only for use at the medical institutions (not for the home use).

【Test Principle】

This immunochromatographic membrane, sandwich assay uses two highly specific and sensitive antibodies to detect SARS-CoV-2 viral nucleocapsid protein from nasal swab specimens. First antibody (Antibody I) is a capture antibody stored in the detection area on the nitrocellulose (NC) membrane, second antibody (Antibody II) is a colloidal gold-labeled antibody positioned on the binding (conjugate) pad and in the control area (marked C on the cassette) of the NC membrane.

For the detection, the sample is moved through the NC membrane using the capillary forces. If the tested sample contains SARS-COV-2 antigen, the anti SARS-COV-2 N-protein monoclonal antibody (Antibody I) reacts with SARS-COV-2 antigen forming a complex which afterwards reacts with the second anti SARS-COV-2 N-protein monoclonal antibody (Antibody II) fixed at the detection line. Together they form the double antibody sandwich, and the color line appears in the detection area (marked T on the cassette). If the sample is negative, no color line appears in the detection (T) area.

The color line should appear in the control area (marked C on the cassette) regardless of the virus presence in the sample. This feature serves as an internal, quality control measure to assess the quality of the detection process.

【Content of the Kit】

Kit includes:

Component	1 Test/Pack	20 Tests/Pack
Cassette	1x	20x
Extraction Reagent	1x300µl	20x300µl
Package Insert (IFU)	1x	20x

Required but not provided are: collecting swabs, protective gloves and timer.

【Storage and Handling】

1. Store the kit at +2 to +30°C in a dry place, avoid exposure to the direct sunlight. **Do not freeze.**
2. After opening the cassette's pouch, the test should be used within 1 hour. Failure to do so can cause a test malfunctioning due to an environmental moisture absorption.

【Sampling】

1. Nasopharyngeal (NP) and nasal (NS) swabs are recommended as the best specimens for the test.
2. To collect the sample, carefully insert the swab into the nostril. Preferably, start with the nostril with the present discharge. Using gentle rotation, advance the swab until resistance is met at the level of the nasal turbinate (less than one inch into the nostril). Rotate the swab 5 times or more against the nasal wall then slowly remove from the nostril. For better chance to detect the virus, collect the sample from

the second nostril as well.

3. Freshly collected samples are recommended for immediate testing. If not possible, samples can be stored at +2 to +8°C for up to 24 hours; at -20°C for up to 3 months and at -70°C for a longer time period. Repeated freeze-thaw cycles should be avoided.

【Testing】

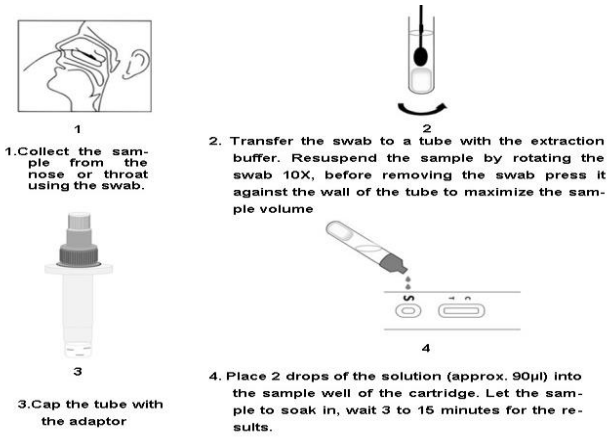
Prior to testing, components of the kit should be warmed up to the room temperature (25°C±5°C), especially when removed from the fridge.

Specimen extraction (see the diagram below)

1. Open the extraction reagent tube and place the swab with collected sample inside the tube.
2. Tilt the tube to allow extraction reagent to fully soak the swab. Rotate the swab in the extraction reagent about 10 times.
3. Straighten up the tube and rotate the swab about 10 times again to make sure the sample is dissolved properly.
4. For the better yield, squeeze the swab against the wall of the tube.
5. Remove the swab and cap the reagent bottle with adapter.

Detection (see the diagram below)

1. Transfer 2 drops (approximately 90μL) from the reagent tube into the sample well on the cassette, let it soak in and start the timing;
2. The reagent should start to migrate through the NC membrane immediately. Test results should be visible within 3-15 minutes. The cut off time for the test evaluation is 30 minutes; anything visible after that is of no significance.



【Interpretation of the Results】

Two distinct lines could appear, when the test was run properly. Possible combinations are outlined below.

1. Negative Result

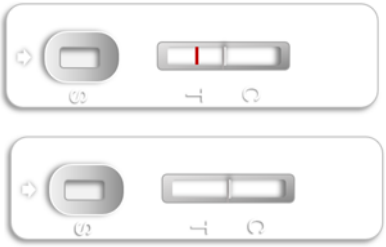
Only the control line (C) appears clearly in the C marked area of the cassette. Line in the T marked area is not visible. No SARS-COV-2 antigen has been detected and the test result is negative.

2. Positive Result

If two lines are visible, one in the C marked area and one in the T marked area of the cassette, then the SARS-COV-2 antigen has been detected and the test result is positive.

3. Invalid Result

In the case no line is visible in the C marked area, the test is invalid and a re-testing is required.



【Quality Control】

1. Each testing cassette includes a built-in control feature; a distinct, red colored line in the control (C marked) area of the cassette.
2. The control line will appear if the test procedure has been performed correctly. If the control line in the C marked area does not appear, the test is invalid and a new test must be performed.

【Performance Characteristics】

Specificity and Sensitivity Characteristics

A study using 110 nasopharyngeal (NP) swab samples (consisting of 60 negative samples and 50 positive samples) was performed. Test results of SARS-CoV-2 Antigen Rapid Test were compared with SARS-CoV-2 RT-PCR detection kit results.

Table1 Specificity and Sensitivity Tests Comparison

SARS-CoV-2 Antigen Rapid Test	SARS-CoV-2 RT-PCR Test Results		Total
	Positive	Negative	
Positive	48	0	48
Negative	2	60	62
Total	50	60	110

Positive Percent Agreement (PPA): 96%(48/50)

Negative Percent Agreement (NPA): 100%(60/60)

The results demonstrate a sensitivity of 96% and specificity of 100%

Cross-reactivity Study

No cross reaction with other coronaviruses or other viruses has been observed. This includes: human coronaviruses (hku1, OC43, nl63 and 229E viruses), SARS and MERS coronaviruses, influenza viruses (new H1N1 influenza virus (2009) and seasonal H1N1 influenza virus), H3N2, H5N1, H7N9 viruses, influenza B virus, Yamagata, or Victoria viruses, respiratory syncytial viruses A and B, parainfluenza viruses 1, 2 and 3, rhinoviruses A, B and C, adenovirus 1, 2, 3, 4, 5, 7 and 55, enteroviruses A, B, C and D, human pulmonary virus, Epstein-Barr virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus and varicella zoster virus. Also, no cross reaction with bacterial cells, Mycoplasma pneumoniae and Chlamydia pneumonia microorganisms was observed.

【Kit's Limitations】

1. This product is designated only for qualitative testing.
2. The "gold standard" for clinical diagnostic detection of SARS-CoV-2 remains the RT-PCR test. It is recommended to confirm the results obtained with this rapid antigen test result by the RT-PCR test, especially if the results of the antigen test are inconsistent with the clinical symptoms.
3. Negative results may be caused by a low concentration of SARS-COV-2 antigen in the sample and therefore cannot completely rule out the possibility of the viral infection.

【Warnings and Precautions】

1. This product is a single use, in vitro diagnostic test that should be used strictly in accordance with this manual. The kit should not be reused, or used when damaged or after its expiration date.
2. Use of this product should follow all clinical laboratory safety precautions.
3. It is recommended to use the testing cassette as soon as possible after its removal from the sealed package as the moisture in environment may cause the test failure.
4. To use the freshly obtained samples is highly recommended.
5. Wearing protective clothing, gloves, masks and goggles for the sample collection and for the testing is mandatory.
6. Moisture eliminating desiccants present in the package should not be taken orally.

【Disposal of the Device】

The samples used for testing shall be considered as infectious material. All samples, used reagents and testing cassettes shall be handled and managed in accordance with the local specifications for infectious medical waste.

【Contact Information】

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EC REP

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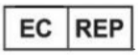	Authorized EU Representative
	Date of Manufacture
	Use-by date
	Batch Code
	Catalogue Number
	Consult Instructions for use
	In Vitro Diagnostic Medical Device
	Do not re-use
	Temperature limit