MediPort Diagnostics™ COVID-19 Ag Card

CE

PRODUCT NAME

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

MODEL

1 test/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit; 50 tests/kit.

INTENDED USE

The product is intended for the full self test of qualitative detection of antigen against SARS-CoV-2 in clinical samples (nasal swab). The COVID-19 AG Card is suitable for testing in both asymptomatic and symptomatic individuals. The is intended for use by healthcare professionals or other trained operators who are proficient in performing rapid tests. Equally, healthcare professionals & trained operators can oversee non-trained personnel to undertake all steps of the test themselves as long as its carried out in a supervised capacity.

SUMMARY

Coronavirus, as a large virus family, is a single positive stranded RNA virus with envelope. The virus is known to cause major illnesses such as colds, Middle East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS). The core protein of SARS-CoV-2 is the N protein (Nucleocapsid), which is a protein component located inside the virus. It is relatively conserved among β-coronaviruses and is often used as a tool for the diagnosis of coronaviruses. ACE2, as a key receptor for SARS-CoV-2 to enter cells, is of great significance for the research of viral infection mechanism.

PRINCIPLE

The current test card is based on the specific antibody-antigen reaction and immunoanalysis technology. The test card contains colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad, matched SARS-CoV-2 N protein monoclonal antibody immobilized on the Test area (T) and corresponding antibody in the quality control area (C). During testing, the N protein in the sample combines with the colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad. The conjugates migrate upward under capillary effect, and subsequently captured by the N protein monoclonal antibody immobilized in the Test area (T). The higher the contents of N protein in the sample, the more the conjugates captures and the darker the color in the test area is. If there is no virus in the sample or the virus content is lower than the detection limit, then there is no color demonstrated in the test area (T). Regardless of the presence or absence of the virus in the sample, a purple stripe will appear in the quality control area (C). The purple stripe in the quality control area (C) is a criterion for the judgment of whether or not there is enough sample and whether or not the chromatography procedure is normal.

COMPONENT

The product consists of test cards, Instructions for use, sample treatment solution. And in each test card bag, it includes one SARS-CoV-2 antigen detection card and one package of desiccant.

Model	Test Card	Instructions for us	Sample Treatment Solution
1 test/kit	1 test	1	1ml×1
5 tests/kit	5 tests	1	1ml×1
10 tests/kit	10 tests	1	2ml×1
25 tests/kit	25 tests	1	3ml×2
50 tests/kit	50 tests	1	5ml×2
For each test card bag, it contains one test card and one package of dessicant			

The test card consists of gold standard mat (coated with colloidal gold labelled SARS-CoV-2 N protein monoclonal antibody), sample mat, nitrocellulose membrane (Test area (T) is coated with an SARS-CoV-2 N protein monoclonal antibody; the quality control area (C) is coated with goat anti-mouse antibody), absorbing paper, and hydrophobic stiff card.

STORAGE & STABILITY

It should be stored at 4°C~ 30°C, be kept dry and away from sunlight. The shelf life is 12 months. For per test card, it should be used within 1 hour after unsealing. Production Date and Expiration date are shown in the package label.

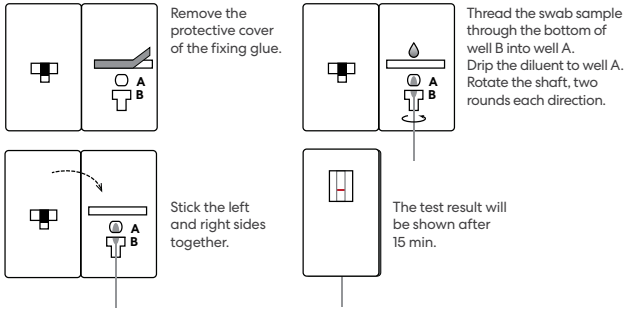
SAMPLE REQUIREMENTS

The product is used to test the human nasal swab sample. The test sample collection is by a self swab method and during the collection procedures for samples, take care to make proper protection, , and avoid direct contact with the sample. In case of accidental contact, disinfection treatment should be carried out in time and necessary measures should be taken. Nasal swab sample: During sampling, the swab head should be completely inserted into the nasal cavity and gently rotated 5 times. After removal, the swab head should be sampled in the other nasal cavity in the same way to ensure that enough samples are taken.
Sample preservation: after sample collection, please complete the test within 1 hour.
The sample should come to room temperature before testing.

TEST METHOD

Please read the instruction for use carefully before performing the test. Before testing, restore the reagents and sample to room temperature.

1. During sampling, the swab head should be completely inserted into the nasal cavity and gently rotated 5 times. After removal, the swab head should be sampled in the other nasal cavity in the same way to ensure that enough samples are taken.
2. Before the test, the double-sided adhesive protective layer should be removed in advance to prevent liquid splashing. If the double-sided adhesive protective layer is torn off after adding diluent, it is easy to cause liquid splashing.
3. Thread the swab sample through the bottom of well B into well A.Add 6 drops of the diluent into well A. Do not drop the diluent into the other wells. Rotate the shaft, two rounds each direction.
4. During the test, the test card should be placed on the horizontal desktop. The test card should be fixed and do not remove the test card.
5. After covering the left side, gently press the adhesive position to make the two sides completely fit and start timing. Wait until the purple band appears. The test result should be read within 15-20 minutes.

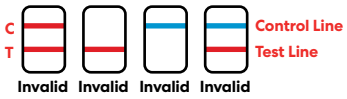


THE EXPLANATION OF THE TESTING RESULTS

Positive (+): There appear purple stripes in both quality control area (C) and either test area (T).

Negative (-): There is only one purple stripe in the quality control area (C), and without purple stripe in either test area (T).

Invalid:
There is no purple stripe in the quality control area (C), or there is blue stripe in the quality control area (C), indicating incorrect operating procedures or the test card has already deteriorated. Under this condition, it must read the instruction for use again carefully, and then use the new test card to test again. If the problem still exists, stop using the products with same lot number and contact the local suppliers immediately.



LIMITATION OF PROCEDURE

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 or SARS-CoV-2 infection.

PRODUCT PERFORMANCE INDEX

1 Physical Property

1.1 Appearance
The test card should be clean and integral, no burrs, no damage, no pollution; the material should be firmly attached; the label should be clear and not damaged. The sample dilution should be clear without impurities and flocs.

1.2 Liquid migration speed
The liquid migration speed should be no less than 10mm/min.

1.3 Membrane Strip Width
The membrane strip width of the testing card should be≥2.5mm.

1.4 The preparation quantity of the diluent for the samples
The volume of the diluents for the sample is no less than the indicated value.

2 Detection Limit
For the detection of sensitivity reference material, the positive detection rate should be no less than 90%.

3 Negative reference products compliance rate
For the detection of negative reference material, the negative detection rate should be 100%.

4 Positive reference products compliance rate
For the detection of positive reference material, the positive detection rate should be 100%.

5 Repeatability
For the detection of enterprise reference material P2 and P4, the results should be positive and the color rendering should be uniform.

6 Cross-reactivity
Cross-reactivity: This test device has no cross reactivity with endemicity human coronavirus OC43, influenza a virus, influenza B virus, respiratory syncytial virus, adenovirus, EB virus, measles virus, cytomegalovirus, rotavirus, Norovirus, mumps virus, varicella zoster virus, mycoplasma pneumoniae, Human metapneumovirus.

7 Clinical Performance
A total of 415 nasal swab samples were selected as the study objects, including 150 positive samples and 265 negative samples confirmed by the COVID-19 diagnosis and treatment protocol. All selected samples were tested. Consistency statistics for the 2019-nCoV Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) (Test Kit) produced by the Company and 2019-nCoV nucleic acid detection results was carried out to analyze the diagnostic sensitivity, diagnostic specificity, total coincidence rate, as well as Sensitivity Ct ≤32 and Sensitivity Ct≤25 of the Test Kit and nucleic acid detection results, and summarize the indicators in the form of four-fold table. The results are as follows:

SARS-CoV-2 Antigen R Test Kit	Nucleic acid detection method (PCR)	
	Positive	Negative
Positive	138	1
Negative	12	264
Diagnostic Sensitivity	Ct<25 97.32% (95% CI: 92.42% - 99.09%) Ct<32 94.37% (95%CI: 89.28% - 97.12%)	
Diagnostic specificity		99.62% (95% CI: 97.89% - 99.93%)

PRECAUTIONS

1. Please read all the information in this leaflet before performing the test.
2. Do not freeze or use after the expiration date (see the packaging for the expiration date).
3. Avoid excessive temperature and humidity in the experimental environment. The reaction temperature should be 15-30 ° C and the humidity should be below 70%.
4. The test card bag contains desiccant, and it should not be taking orally.
5. When collecting a sample, use the swab supplied in the kit. Use of alternative swabs may result in false results..
6. Do not use the test card with broken single packaging, unclear marks, and past the expiration date.
7. Dispose of used specimens, test cards and other waste in accordance with relevant local laws and regulations.
8. The test card should be used within 1 hour after being taken out of the aluminum foil bag.
9. The users should take samples according to the requirements of IFU.
10. Before the test, the double-sided adhesive protective layer should be removed in advance to prevent liquid splashing. If the double-sided adhesive protective layer is torn off after adding diluent, it is easy to cause liquid splashing.
11. Do not drop the diluent into the wrong well.
12. During the test, the test card should be placed on the horizontal desktop. The test card should be fixed and do not remove the test card.

EXPLANATION OF SYMBOLS

	Do not use if package is damaged		Consult instructions for use
	Do not reuse		Use-by date
	Temperature limit		Date of manufacture
	Manufacturer	LOT	Batch Code
	Keep away from sunlight		Keep dry
IVD	In Vitro Diagnostic Medical Device	CE	CE Mark
EC REP	European union authorised representative		

CONTACT DETAILS

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