COVID-19 Antigen Rapid Detection Kit (Colloidal Gold) (for professional use) (nasal swab)

【Product Name】

COVID-19 Antigen Rapid Detection Kit(Colloidal Gold)

【Model】

One test/package; 1 test/kit; 5 tests/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit.

【Intended Use】

The product is intended for the qualitative detection of antigen against COVID-19 in clinical samples (nasal swab).

【Summary】

The test kit only detects the N protein, and cannot detect the S protein and its mutation structure. 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 COVID-19 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.

【Principle】

The current test card is based on the specific antibody-antigen reaction and immunoanalysis technology. The test card contains colloidal gold labeled COVID-19 N protein monoclonal antibody which is pre-coated on the combination pad, matched COVID-19 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 COVID-19 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 card, instructions for use, sample treatment solution, sterile swab, sample tube and tube rack. And in each test card bag, it includes one COVID-19 antigen detection card and one package of desiccant.

Model	Test card	Instructions for use	Sample treatment solution	Sterile swab	Sample tube	Tube rack
1 test/kit	1 test	1	1	1	1	/
5 tests/kit	5 tests	1	5	5	5	1
10 tests/kit	10 tests	1	10	10	10	1
20 tests/kit	20 tests	1	20	20	20	1
25 tests/kit	25 tests	1	25	25	25	1
30 tests/kit	30 tests	1	30	30	30	1
40 tests/kit	40 tests	1	40	40	40	1
50 tests/kit	50 tests	1	50	50	50	1
For each test card bag, it contains one test card and one package of desiccant.						

The test card consists of gold standard mat (coated with colloidal gold labelled COVID-19 N protein monoclonal antibody), sample mat, nitrocellulose membrane (Test area (T) is coated with an COVID-19 N protein monoclonal antibody; the quality control area (C) is coated with goat anti-mouse antibody), absorbing paper, and hydrophobic stiff card.

【Storage and Stability】

It should be stored at 2℃~ 30℃, be kept dry and away from sunlight. The shelf life is 18 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.

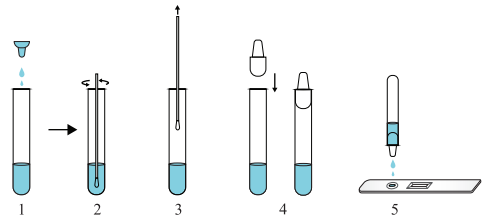
【Sample Requirements】

The product is used to test the human nasal swab sample.

1. Sample collection: 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.
2. Nasal swab sample: During sampling, the swab head should be completely inserted into the nasal cavity in the same way to ensure that enough samples are taken.
3. Sample preservation: after sample collection, please complete the test within 1 hour. The sample should come to room temperature before testing.

【Sample collection】

1. Insert the sample tube into the sample tube rack to ensure that the sample tube is vertical .Take one sample treatment solution and add all sample treatment solution into the sample tube.
2. Put swab sample into prepared sample tube and rotate at least 10 times. Standing all the materials 1 minute for well-extracting.
3. Throw the used swab as medical waste.
4. Cover dripper tightly on the top of sample tube.
5. Add 80μL or 3 drops processed sample into the sampling well of cassette.



【Testing method】

Step1: If the sample is stored in refrigeration or frozen, the medical staff will take out the sample and the reagents and balance at room temperature (15~30℃) then mix the sample thoroughly after thawing.

Step2: When preparing for the test, the tear the aluminum foil bag , take out the test card and place it flat on a table.

Step3: Pre-marked the sample number on the test card.

Step4: Used a pipette to suck 80μL or used the sample tube drop 3 drops (about 80μL) of the sample to ensure that no bubbles are generated during the operation.

Step5: Strictly control to observe the test card within 15 minutes after the start of the test to determine the result. It is invalid to observe after 20 minutes.

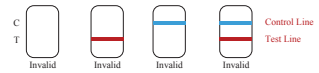
Note: After observing and recording the results, please discard the test card so as not to confuse the result judgment. If you need to store it for a long time, please take a photo of the result.

【The Explanation of the Testing Results】

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

• Negative (-): There is only one purple stripe in the quality control area (C), and without purple stripe in 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 deterio-rated. 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】

1. The test results of this product should be comprehensively judged by the physician in combination with other clinical information, and should not be used as the only criterion;
2. The product is used to test the COVID-19 antigen of the clinical sample.

【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 treatment solution 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 treatment solution for the samples

The volume of the treatment solution for the samples should be no less than 400μL.

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. Analytical Specificity

6.1 Cross-reactivity: This test device has no cross reactivity with the microorganism at the following concentrations.

Microorganism	Concentration
Human coronavirus 229E	$2.0\times10^6TCID_{50}$/mL
Human coronavirus OC43	$2.0\times10^6TCID_{50}$/mL
Human coronavirus NL63	$2.0\times10^6TCID_{50}$/mL
Human coronavirus HKU1	$1.0\times10^6TCID_{50}$/mL
Adenovirus 1	$2.0\times10^6TCID_{50}$/mL
Adenovirus 2	$2.0\times10^6TCID_{50}$/mL
Adenovirus 3	$2.0\times10^6TCID_{50}$/mL
Adenovirus 5	$2.0\times10^6TCID_{50}$/mL
Adenovirus 7	$2.0\times10^6TCID_{50}$/mL
Adenovirus 55	$2.0\times10^6TCID_{50}$/mL
Parainfluenza virus type 1	$2.0\times10^6TCID_{50}$/mL
Parainfluenza virus type 2	$2.0\times10^6TCID_{50}$/mL
Parainfluenza virus type 3	$2.0\times10^6TCID_{50}$/mL
Parainfluenza virus type 4	$1.0\times10^6TCID_{50}$/mL
EB virus	$2.0\times10^6TCID_{50}$/mL
Measles virus	$2.0\times10^6TCID_{50}$/mL
Human cytomegalovirus	$2.0\times10^6TCID_{50}$/mL
MERS coronavirus	$1.0\times10^6TCID_{50}$/mL
Human metapneumovirus	$1.0\times10^6TCID_{50}$/mL
Mumps virus	$2.0\times10^6TCID_{50}$/mL
Rotavirus	$2.0\times10^6TCID_{50}$/mL
Norovirus	$2.0\times10^6TCID_{50}$/mL
Varicella-zoster virus	$2.0\times10^6TCID_{50}$/mL
Enterovirus	$2.0\times10^6TCID_{50}$/mL
Rhinovirus	$2.0\times10^6TCID_{50}$/mL
Mycoplasma pneumoniae	$2.0\times10^6TCID_{50}$/mL
Mycobacterium tuberculosis	$2.0\times10^6TCID_{50}$/mL
Chlamydia pneumoniae	$2.0\times10^6TCID_{50}$/mL
Legionella pneumophila	$2.0\times10^6TCID_{50}$/mL
Haemophilus influenzae	$2.0\times10^6TCID_{50}$/mL
Streptococcus pyogenes A	$2.0\times10^6TCID_{50}$/mL
Streptococcus pneumoniae	$2.0\times10^6TCID_{50}$/mL
Staphylococcus aureus	$2.0\times10^6TCID_{50}$/mL
Candida albicans	$2.0\times10^6TCID_{50}$/mL
Bordetella pertussis	$2.0\times10^6TCID_{50}$/mL
Pseudomonas aeruginosa	$2.0\times10^6TCID_{50}$/mL
Escherichia coli	$2.0\times10^6TCID_{50}$/mL
Influenza A（H1N1）	$2.0\times10^6TCID_{50}$/mL
Influenza A（H1N1 drn09）	$1.0\times10^6TCID_{50}$/mL
Influenza A（H3N2）	$2.0\times10^6TCID_{50}$/mL
Influenza B（yamagate）	$2.0\times10^6TCID_{50}$/mL
Influenza B（victoria）	$2.0\times10^6TCID_{50}$/mL
Respiratory syncytial virus	$2.0\times10^6TCID_{50}$/mL

6.2 Interfering substances:

Interfering substances:The kit is not affected by blood and Mucin and drugs at the following concentrations.

Interfering samples	Concentration
Whole blood	1% v/v
Mucin	2% v/v
Ricola（Menthol）	0.15% w/v
Chloraseptic（Benzocaine）	0.15% w/v
Mupirocin	0.25% w/v
Tamiflu（Oseltamivir phosphate）	0.5% w/v
Homeopathic（Alkalol）	10% v/v
CVS Nasal drops（Phenylephine）	15% v/v
Afrin（Oxymetazoline）	15% v/v
CVS Nasal spray（Cromolyn）	15%v/v
Fluticasone propionate	5% v/v
Zicam	5% v/v
Oseltamivir phosphate	10mg/mL
Arbidol	5mg/mL
Triamcinolone	10mg/mL
Histamine dihydrochloride	10mg/mL
Zanamivir	5mg/mL
Ribavirin	5mg/mL
Dexamethasone	5mg/mL

7. Clinical performance

312 clinical samples based on the nucleic acid detection method（PCR）test results were obtained for testing. Including 133 positive and 179 negative samples. The test kit was compared with nucleic acid method（PCR）using the collected clinical samples. The result were summarized in the table below.

Rapid detection kit	Nucleic acid test (PCR)		
	Positive(+)	Negative(-)	Total
Positive(+)	125	1	126
Negative(-)	8	178	186
Total	133	179	312
Diagnostic sensitivity	93.98% (95%CI:88.58%-96.92%)		
Diagnostic specificity	99.44% (95%CI:96.90%-99.90%)		
Overall coincidence rate	97.12% (95%CI:94.61%-98.48%)		

【Precautions】

1. The test is only suitable for professionals to use in vitro auxiliary diagnosis. Do not use expired products.
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 ℃ and the humidity should be below 70%.
4. The test card bag contains desiccant, and it should not be taking orally.
5. When testing, please wear protective clothing, medical mask, gloves and goggles.
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.

【Approval Date and Revision Date of the Instruction for use】

Approval Date: 05/02/2021

Revision Date: 05/02/2021

Date of Issue: 05/02/2021

【Index of CE Symbols】

	Don't use the product when the package is damaged		Please read the instruction book carefully before using
	Please don't reuse it		Validity
	Temperature scope within which the product is reserved		Date of manufacture
	Manufacturer	LOT	Batch number
	Avoid overexposure to the sun		Keep dry
IVD	The product is used in vitro, please don't swallow it.		Warning, please refer to the instruction in the annex
EC REP	European union authorization representative	CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC

【Basic Information】

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