For In Vitro Diagnostic and Professional Use only.
* Please carefully read the instructions before use

Format: Cassette

Specimen: nasal swab specimens

COVID-19 Antigen Rapid Test Kit (Colloidal Gold)

1 INTENDED USE

COVID-19 Antigen Rapid Test Kit (Colloidal Gold) is the chromatographic immunoassay test
used for qualitative detection of the COVID-19 antigen in human nasal swab specimens.

INTRODUCTION

CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. Evidence suggests transmission via fecal-oral route. 7 kinds of HCoVs caused human s respiratory diseases are found by now: HCoV-229E, CoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and 2019-nCoV which are the serious pathogens for human' s respiratory diseas- es.Its clinical manifestation are fever, enervate and systemic symp- tom, with dry cough, difficult breathing etc. and it may aggravate to severe pneumonia, respiratory failure, acute respiratory distress syndrome ,septic shock, multiple organ failure, severe acid-base metabolic disorders etc and even life threatening rapidly.
The target antigen detected by the COVID-19 Antigen Rapid Test Kit (Colloidal Gold) is N protein with high maintenance. The Spike protein is the main mutation site of the UK mutant strain (B.1.1.7) , South African mutant (501.V2) and Brazil mutant (P.1). It has been verified that the virus antigens of these three mutants can be detected by the COVID-19 Antigen Rapid Test Kit (Colloidal Gold).

PRINCIPLE

This test kit uses COVID-19 monoclonal antibody and goat anti-mouse IgG polyclonal antibodies that are respectively immo- bilized on a nitrocellulose membrane. It uses colloidal gold to label sufficient COVID-19 monoclonal antibody. Using nano-col- loidal gold technology and applying highly specific antibody-anti- gen reaction and immunochromatographic analysis technology principle.
When testing, the novel coronavirus antigen in the sample combined with the colloidal gold-labeled COVID-19 monoclonal antibody to form a complex, which was then combined with the COVID-19 monoclonal antibody coated in the T line during chromatography, at this time there is one red line in the T area .When the samples do not contain novel coronavirus antigen, colloidal gold-labeled COVID-19 monoclonal antibody cannot combined with COVID-19 monoclonal antibody in the T line region, so there is no red colored line in the T area .Regard- less of the presence of novel coronavirus antigen in the sample, a red line will form in the quality control area (C). The red line appears in the quality control area (C) serves as: 1.verification that sufficient volume is added. 2.that proper flow is obtained 3. and as a control for the reagents.

MATERIALS PROVIDED

COVID-19 Antigen Rapid Test Kit (Colloidal Gold) contains the following items to perform the assay:
1. COVID-19 Antigen Rapid Test Kit (Colloidal Gold) cassette
2. Instruction for use
3. Sample collection tube
4. Nasal swab
5. Sample processing solution

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer 2. Glove

WARNING AND PRECAUTIONS

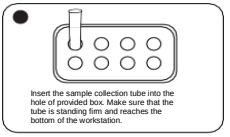
1. Read instruction for use carefully before performing this test.
2. For in vitro diagnostic use and professional use only.
3. Do not use the test cassette beyond the expiration date.
4. The test cassette should remain in the sealed pouch untiluse. Do not use the test cassette if the pouch is damaged or the seal is broken.
5. Do not reuse the cassette.
6. Treat and properly handle the specimens and used cassette as if they were potentially infectious. Dispose all specimens and used cassettes in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
7. There should be no eating, drinking or smoking where speci- mens are being handled.
8. Do not mix or interchange different specimens.
9. Wear disposable gloves, lab coat and eye protection while handling potentially infectious material and performing the assay. Wash hands thoroughly afterwards.
10. Clean spills thoroughly using an appropriate disinfectant.

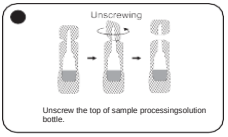
SPECIMEN PREPARATION

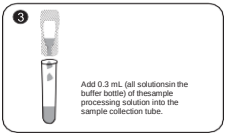
1. The collection method of nasal swab is shown in Figure 4 to 7.
2. The sample processing is shown in Figure 1 to 3 and 8 to 12.

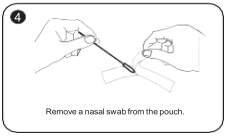
Note:

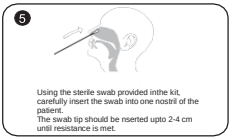
1. Please use swab for specimen colletion.
2. It is highly recommended to collect specimen with wearing a pair of safety gloves to avoid contamination.
3. Do not touch the tip(specimen collection area) of the swab.
4. Collect sample as soon as after onset of symptoms.
5. It is recommended to treat the sample immediately after collection.The sample can be stored at 2℃~8℃ for 72 hours,and it needs to be frozen at -20℃ for long-term storage, avoiding repeated freezing and thawing.

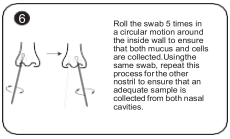


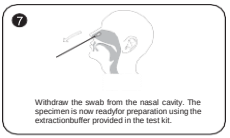


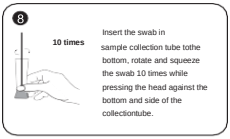


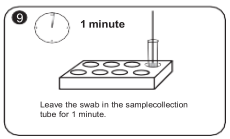


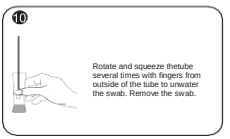


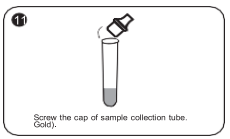


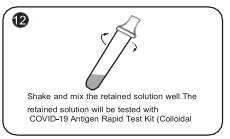




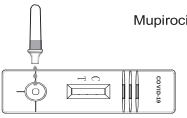








TEST PROCEDURE

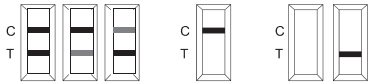


Read the instruction first prior to testing. Bring the pouched test to room temperature prior to testing. Do not open the pouch until readyto begin testing.

1. Remove the test from the sealed pouch. Lay it on a flat,clean and dry surface.
2. Reverse the sample collection tube, and add 2-3 drops (about 75~100 μL) of test sample by squeezing the collection solution tube into the sample well.
3. Read results within 10-15 minutes.

Mupirocin
Antibacterial,
Systemic
Tobramycin

INTERPRETATION OF RESULTS



POSITIVE NEGATIVE INVALID

Positive: Control line and T line appear in the show window.
Negative: Only one line appears in Control area, no line appears in T area.
Invalid: If no line appears in the control area,the test results are invalid regardless of the presence or absence of line in the test area.The direction may not been followed correctly or the test may be deteriorated.It is recommended that repeat the test using a new device.If the problem persist,please stop to use the product and contact local distributor.

STORAGE AND STABILITY

Storage: store at 2~30℃. Shelf life: 24 months.

LIMITATION OF THE TEST

This kit is a clinical auxiliary test product. Any sample with a positive test result should be further confirmed by other methods.

PERFORMANCE CHARACTERISTICS

1. Limit of Detection (Analytical Sensitivity)
The COVID-19 Antigen Rapid Test Kit (Colloidal Gold) LOD in natural nasal swab matrix was confirmed as 22.5 $TCID_{50}$/ml.

2. Analytic Specificity
Results demonstrated that COVID-19 Antigen Rapid Test Kit (Colloidal Gold) has nosignificant cross-reactivity with the seromarkers listed following :

Potential Cross-Reactant		Test Concentration
Virus	Adenovirus	1.0 x 10^5 $TCID_{50}$/ml
	Human metapneumovirus (hMPV)	1.0 x 10^5 $TCID_{50}$/ml
	Rhinovirus	1.0 x 10^5 PFU/ml
	Enterovirus/Coxsackievirus B4	1.0 x 10^5 $TCID_{50}$/ml
	Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/ml
	Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/ml
	Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/ml
	Human parainfluenza virus 1	1.0 x 10^5 $TCID_{50}$/ml
	Human parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/ml
	Human parainfluenza virus 3	1.0 x 10^5 $TCID_{50}$/ml
	Human parainfluenza virus 4	1.0 x 10^5 $TCID_{50}$/ml
	Influenza A	1.0 x 10^5 $TCID_{50}$/ml
	Influenza B	1.0 x 10^5 $TCID_{50}$/ml
	Respiratory Syncytial Virus A	1.0 x 10^5 PFU/ml
Bacteria	Bordetella pertussis	1.0 x 10^6 cells/ml
	Chlamydia pneumoniae	1.0 x 10^6 IFU/ml
	Haemophilus influenzae	1.0 x 10^6 cells/ml
	Legionella pnuemophila	1.0 x 10^6 cells/ml
	Mycoplasma pneumoniae	1.0 x 10^6 U/ml
	Streptococcus pneumoniae	1.0 x 10^6 cells/ml
	Streptococcus pyogenes (group A)	1.0 x 10^6 cells/ml
	Mycobacterium tuberculosis	1.0 x 10^6 cells/ml
	Staphylococcus aureus	1.0 x 10^6 org/ml
	Staphylococcus epidermidis	1.0 x 10^6 org/ml
	Pooled human nasal wash	N/A
Yeast	Candida albicans	1.0 x 10^6 cells/ml

3. Interference
The following substances and conditions were found not to interfere with the test. List of potentially interfering compounds and concentrations tested are as follows:

Substance	Active Ingredient	Concentration
Endogenous	Mucin	2% w/v
	Whole Blood	1% v/v
OTC Nasal Drops	Phenylephrine	15% v/v
OTC Nasal Gel	Sodium Chloride (i.e. NeilMed)	5% v/v
OTC Nasal Spray 1	Cromolyn	15% v/v
OTC Nasal Spray 2	Oxymetazoline	15% v/v
OTC Nasal Spray 3	Fluconazole	5% w/v
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
OTC Homeopathic Nasal Spray 1	Galphimia glauca, Sabadilla,	20% v/v
OTC Homeopathic Nasal Spray 2	Zincum gluconium (i.e., Zicam)	5% w/v
OTC Homeopathic Nasal Spray 3	Alkalol	10% v/v
OTC Homeopathic Nasal Spray 4	Fluticasone Propionate	5% v/v
Sore Throat Phenol Spray	Phenol	15% v/v
Anti-viral Drug	Tamiflu (Oseltamivir Phosphate)	0.5% w/v
Antibiotic, Nasal Ointment	Mupirocin	0.25% w/v
Antibacterial, Systemic	Tobramycin	0.0004% w/v

DIAGNOSTIC SENSITIVITY AND SPECIFICITY

A study using a total 415 nasal swab samples was conducted. Test results of COVID-19 Antigen Rapid Test Kit (Colloidal Gold) were compared with nucleic acid detection test. The diagnostic sensitivity and specificity of the test results are shown in Table :

COVID-19 Antigen Rapid Test Kit (Colloidal Gold)

Reference		Results of Nucleic acid detection test		Total Results
		Positive	Negative	
Results of COVID-19 Ag test	Positive	152	2	154
	Negative	3	258	261
Total Results		155	260	415

Results gave sensitivity is 98.1% (152/155), specificity is 99.2% (258/260), and a total agreement of 98.8%(410/415).

PRECAUTIONS

1. This kit is used for one-time in vitro testing. The same kit cannot be reused.
2. This kit is suitable for qualitative detection of human nasal swab samples.
3. The experimental environment should be protected from wind, and experiments should not be performed in an exces- sively high temperature, high humidity, or excessively dry environment.
4. The test samples should be regarded as infectious agents and the operation should be in accordance with the infectiousdisease laboratory operating rules. After using this kit, the waste should be disposed according to the expected waste management system.
5. Do not use after the expiration date.
6. Before using this kit, you must read this manual carefully and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.
7. The results of samples are closely related to the methods of sample collection. Incorrect sample collection may result in negative results.
8. Do not use turbid contaminated samples for testing.
9. This kit will show negative results under the following condi- tions,when the new coronavirus antigen titer in the sample is below the minimum detection limit of the kit.
10. Incorrect sampling method may lead to inaccurate test results.

INDEX OF SYMBOLS

	Do not re-use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use-by date
	Store at 2-30℃		Consult instructions for use
EC REP	Authorized representative in the European Community		Manufacturer

MANUFACTURER CONTACT INFORMATION

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