AMPER

IVD

Store at 2-30°C

FOR PRESCRIPTION USE

FOR IN VITRO DIAGNOSTIC USE

FOR USE UNDER EMERGENCY USE AUTHORIZATION ONLY.

REF **MU003**

Instructions for Use

AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)

INTENDED USE

The AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold) is a colloidal gold-based lateral flow immunoassay, intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab (NPS) and oropharyngeal swab (OPS) and saliva specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity and high complexity.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasopharyngeal swab (NPS) and oropharyngeal swab (OPS) specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

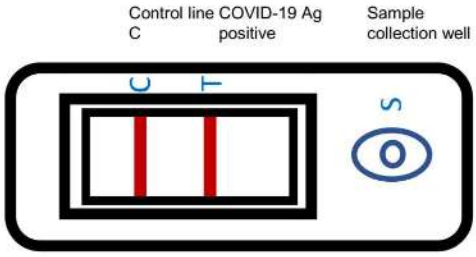
The AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold) is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel.

The AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold) is only for use under the Food and Drug Administration's Emergency Use Authorization.

BRIEF INTRODUCTION

Novel coronavirus belongs to the β-genus. COVID-19 is an acute respiratory infection disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection. Asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

At present, there are many methods to detect COVID-19 disease pathogen. An antibody test is helpful to determine whether the tested person has ever been infected, even if the person has never presented symptoms, but the premise of this detection method is that the infected host must have humoral immune response to SARS-CoV-2. Therefore, a serological detection cannot replace the direct detection method as the main tool for the diagnosis of active SARS-CoV-2 infection in monitoring and responding to COVID-19 epidemic Faces have some important applications. Direct virus detection methods, such as nucleic acid amplification or antigen detection, are the direct evidence of virus infection monitoring.



Compared with antibody serological detection, viral nucleic acid detection and virus antigen detection can detect the patients in the window period and detect the infected person as soon as possible. Nucleic acid detection requires high detection equipment or platform. High sensitivity RT-PCR is expensive and requires higher laboratory cleanliness and trained operators. In addition, nucleic acid detection takes longer time. Considering the specimen transportation and specimen backlog, the results can be reported as soon as 24 hours. The use of the same specimen for antigen detection is fast, simple, and convenient. The antigen can quickly identify the infected person and complement the nucleic acid detection. In addition, when the nucleic acid test is negative, adding antigen or antibody serological detection can make up for the defect that nucleic acid detection is easy to cause missed diagnosis.

This kit uses colloidal gold immunochromatography using double antibody sandwich technology to qualitatively detect SARS-CoV-2 antigen in NPS/OPS specimens. When the patient specimen is put into the sample collect hole of the device, the virus particles are destroyed in the specimen pad. The specimen is evenly dispersed in the sample hole of the device. The specimen migrates in various unique chemical environments through capillary siphon.

When the colloidal gold complex reacts with the antigen in specimen, it forms an antigen-antibody reaction. The complex continues to migrate and to bind to the second antibody in the detection area (T) of the nitrocellulose membrane, where is precoated with the monoclonal antibody against the nucleocapsid protein of SARS-CoV-2. In the quality control area (C), the chicken IgY-colloidal gold conjugate binds the goat anti-IgY precoated to develop a burgundy-colored band.

During the detection, if the specimen contains the SARS-CoV-2 antigen, the burgundy-colored band will develop in the detection area; if the specimen does not contain any antigen, the burgundy-colored band will not develop in the detection area. Due to the excessive presence of colloidal gold labeled antibodies, a burgundy-colored band will develop in the control area (C), regardless of the presence or absence of SARS-CoV-2 antigen in the specimen. The burgundy-colored band in the quality control area (C) is the standard for judging whether there are enough specimens and whether the chromatographic process is normal and serves as the internal control standard of the strip.

Reagents and Materials

This kit has four specifications: 1 test per box, 2 tests per box, 5 tests per box and 25 tests per box as listed in the following Table.

Table 1. Specification

Catalogue number	**MU00301**		**MU00302**		**MU00305**		**MU00325**	
Component	1 test/kit		2 tests per box		5 tests per box		25 tests/kit	
	Quantity	Specification	Quantity	Specification	Quantity	Specification	Quantity	Specification
Specimen Collection Swab	1	1 per bag	1	1 per bag, 2 bags	5	1 per bag, 5 bags	25	1 per bag, 25 bags
Cotton Swab	1	1 per bag	1	1 per bag, 2 bags	5	1 per bag, 2 bags	25	1 per bag, 25 bags
sample extraction buffer	1	0.3 mL per tube	2	0.3 mL per tube, 2 tubes	5	0.3 mL per tube, 5 tubes	25	0.3 mL per tube, 25 tubes
sample bottle with lid	1	1 per bag	2	2 per bag	5	5 per bag	25	25 per bag
test cartridge*	1	1 per bag	2	1 per bag, 2 bags	5	1 per bag, 5 bags	25	1 per bag, 25 bags
Desiccant*								
IFU leaflet	1	-----	1	-----	1	-----	1	-----

* Desiccant are packaged inside the test cassette pouch.

One test cartridge contains mouse anti-SARS-CoV-2 nucleocapsid monoclonal antibody/chicken IgY labeled colloidal gold, and paired mouse anti-SARS-CoV-2 nucleocapsid monoclonal antibody pre-coated in the test line T, mouse anti-chicken IgY monoclonal antibody precoated in the control line C, nitrocellulose membrane, glass fiber membrane, absorbent paper, and the support.

Sample extraction buffer (roughly 300 µL) contains phosphate buffer with casein sodium, Tween-20, Triton X-100, and ProClin™ 300 and SDS.

Other materials not provided but is essential to perform the test safely are alcohol, gloves, and Timer.

Reagent Storage:

- Store between 2ºC and 30ºC and a humidity should not be higher than 65%. Maintaining these parameters ensures higher accuracy of detection.
- Period of validity is tentatively 18 months.
- Production date and expiry date are shown on the label.
- Keep away from direct sunlight.

Reagents required but not provided

- oropharyngeal swab (OPS)
- Vortex mixer
- Various calibrated micropipette and tips
- Calibration reagents
  - An external positive control: a swab contains un-infectious inactivated SARS-CoV-2 (500 $TCID_{50}$/swab).
  - An external negative control: a swab contains un-infectious inactivated adenovirus (500 $TCID_{50}$/swab).

PRECAUTIONS

- For in vitro diagnosis only.
- Effective protective measures should be taken when collecting, handling, storing and handling patient specimens.
- The contents of used kits are considered as biological hazards.
- Wear nitrile, latex (or equivalent) protective gloves when handling patient specimens.
- Do not reuse the test kit, pipette, reagent tube, solution or various swabs.
- Use the device within 1 hour after tearing.
- Do not use any contaminated, damaged or dropped device.
- The reagent solution contains high salt solution (saline). If it contacts the skin or enters the eyes by mistake, please rinse it with plenty of pure water.
- Read the instructions carefully before using the kit.
- Improper specimen collection, storage and transportation may affect the test results.
- Specimen collection and processing require professional training and guidance.
- Please read the instructions carefully before using the virus preservation solution.
- Do not add excessive specimen into the specimen hole of the device.
- Use this product at room temperature.
- Dispose of waste in accordance with government regulations.
- Wear protective clothing, gloves and eye and face protection.
- Wash hands thoroughly after contacting specimens and testing.

STORAGE CONDITION AND VALIDITY PERIOD

- The test kit should be stored at 2-30ºC in a dry place, away from light, within a validity period of 18 months.
- The shelf life is 1 hour after tearing the pouch and should not be stored in frozen

condition.

- During transportation, the complete packaging of the kit will not affect the test performance after 10 days of storage in the environment of high temperature and humidity (45°C and humidity of 80-90%) or low temperature and high humidity (-20°C and humidity of 60-70%) for 4 days. However, direct sunlight and heavy pressure should be avoided during transportation.
- The production date and expiration date are shown on the label.

SPECIMEN REQUIREMENTS

Consider any materials of human origin as infectious and handle using standard biosafety procedures. Specimen, NPS and OPS, are served in the sample extraction buffer in the kit for assay.

Specimen collection:

1) add all sample extraction buffer (roughly 300 μL) into a sample collect tube for use.
    a. Nasopharyngeal swab (NPS), oropharyngeal swab (OPS) collection. The disposable sterile small cotton swab is inserted into the nasopharyngeal/oropharyngeal cavity and rotated rapidly and gently 5 times in bilateral pharyngeal tonsils and posterior pharyngeal wall to collect mucosal epidermis to avoid contact with oral and lingual mucosa. The specimen collected is not affected by clinical symptoms and medication conditions. Insert the swab into the extraction tube which contains 300 μL of the extraction buffer. 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 extraction tube for 1 minute. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.
    b. Saliva collection:
    Keep mouth clean for 3 minutes and stir the upper wall of the mouth with tongue. Open the device pouch to collect the saliva in the device pouch. Insert a spare cotton swab and sink the cotton ball into the saliva until the cotton ball is completely wet. Put the swab into a tube with the extraction buffer, fully stir 10 times, squeeze the swab head along the inner wall of the tube. Take out and discard the swab.
    c. At this time, specimens in the sample extraction buffer are ready to test directly.

2) After collection, specimens in the sample extraction buffer provided by this kit should be assayed immediately. If it cannot be tested immediately, it should be sealed and kept at 2-8°C within 8h. For storage a longer time, it should be kept below -70°C. The repeated freeze-thaw should be avoided.
3) Self-provided: a nylon flocking swab, sterilized and packed independently, is suitable for throat sampling.

QUALITY CONTROL

- There are two types of quality control in the device: internal quality control and external quality control.

- An internal quality control is built in each device. The line C is a built-in quality control, with the characteristics of detection process control. Every test the line C should develop a burgundy color, indicating that the test is effective. Any no burgundy color develops in control area (C), indicating the test was invalid or the reagent has deteriorated and damaged. In this case, the determination should be reperformed.
- An external control can also be used to prove whether the reagent card is valid or not and the operation status of the device used. We recommend that each operator should test an external quality control before testing an actual specimen. External quality control shall be tested every time a new batch of the device is received.
- According to local governmental laws and regulations, external control reference materials need to be tested regularly. If any of the external quality control fails, do not perform a specimen assay and do not report the test results.

TEST METHOD

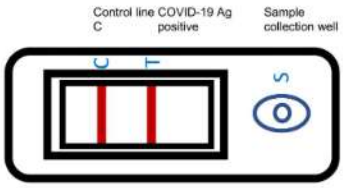
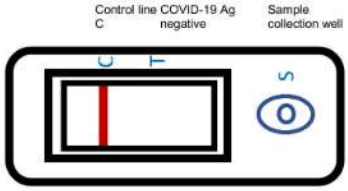
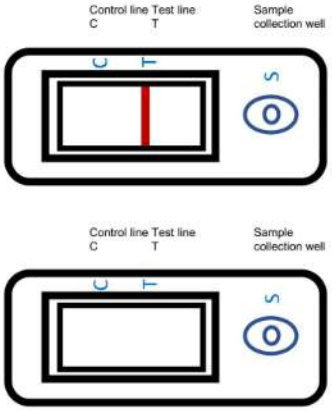
Please read the instruction for use before testing. Restore the reagent device, the sample extraction buffer, and swabs to room temperature before use. Insert the test extraction tube into the workstation. Make sure that the tube is standing firm and reaches the bottom of the workstation.

Specimen testing

1) Take a test device to room temperature and allow it sitting for a few minutes.
2) Equilibrate all components of the test kit to room temperature.
3) Tear off the pouch bag at the notch
4) Remove the lateral flow cartridge and microdropper
5) Lateral flow cartridges are single use only
6) Place the test device horizontally on a clean workbench
7) Label the device with specimen ID number
8) Transfer 80 µL or 3 drops of specimen in the sample extraction buffer into the sample (S) hole of the test device
9) Observe and record test results by 15 minutes. Do not record any result after 30 minutes.
10) Discard the test device after interpreting each result.
11) Report the result.

Note: Laboratories in the United States and its territories must report all positive results to the appropriate public health authorities. The product can rapidly detect COVID-19 antigen in NPS and OPS. For each separately processed specimen and control specimen, it tests single target result for each specimen, it tests the validity of quality control specimens, and also evaluates the overall tests.

INTERPRETATION OF TEST RESULT

Clinical Interpretation	Description	Legend
Positive Test	COVID-19 antigen positive (+): A burgundy-colored band in the line T and a burgundy-color band in the line C must develop in the observation window.	
Negative Test	COVID-19 antigen negative (-): a burgundy-colored band appear in the line C only and no burgundy-colored band develop in the line T, indicating that COVID-19 antigen is not detected in the specimen.	
Invalid Test	Invalid: in any case, no burgundy-colored band in the line C indicates an invalid assay, suggesting an incorrect test operation or the device is deteriorated and damaged. In this case, the test should be reperformed. If the problem still exists, contact the local supplier or manufacturer immediately for technological supports.	

LIMITATIONS

- COVID-19 antigen is tested in NPS, OPS, and the concentration of the antigen is not determined.
- Results are for reference only and cannot be used as the sole criterion for clinical diagnosis and treatment. The clinical management of patients should be combined with the symptoms/signs, medical history, other laboratory tests and treatment reactions.
- This product is used to detect active and inactive COVID-19 antigen. The test performance depends on the amount of virus (antigen) in the specimens, and the test results may or may not be related to the results of virus burden in the specimen.
- Negative results may occur if antigen concentration in the specimen is below the limit of detection or if the specimen is collected or transported improperly.
- Due to methodological limitations, low virus burden in a specimen may lead to false negative result; therefore, for patients with negative test results but with obvious clinical

symptoms, the possibility of infection cannot be ruled out, and other methods are recommended for detection.

- Failure to follow the test procedure may adversely affect the performance of the device and/or invalidate test results.
- Positive test results did not exclude co-infection with other pathogens.
- Negative results should be considered as presumptive results and confirmed by authorized molecular methods when necessary for clinical management, including infection control.
- The performance of devices evaluated with frozen specimens may be different from that of fresh specimens.
- if COVID-19 virus and specific strains are needed to differentiate, a public health department is required to conduct additional tests.

Sample type equivalency

- Equivalence between NPS, OPS sample types was evaluated using inactivated COVID-19 virus spiked into negative samples (one to one, not pooled) to prepare artificial low positive (approximately 624 $TCID_{50}$/mL inactivated virus) and moderate positive (approximately 1248 $TCID_{50}$/mL inactivated virus) samples for each sample type, see table below. A total of 10 low positive samples, 11 moderate positive paired samples, and 21 negative paired samples were tested with the *AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)*. As shown in Table 2 below, all low positive and moderate positive paired samples were positive in both sample matrices. All negative paired samples were negative in both sample types.

Table 2. Sample type equivalence

Sample Type	Inactivated virus added	N	Antigen tested positive	Antigen tested negative
NPS	625 $TCID_{50}$/mL	10	10/10 (100%)	0/10 (0%)
OPS		10	10/10 (100%)	0/10 (0%)
Saliva		10	10/10 (100%)	0/10 (0%)
VTM		10	10/10 (100%)	0/10 (0%)
NPS	3120 $TCID_{50}$/mL	11	11/11 (100%)	0/11 (0%)
OPS		11	11/11 (100%)	0/11 (0%)
Saliva		11	11/11 (100%)	0/11 (0%)
VTM		11	11/11 (100%)	0/11 (0%)
NPS	Saline	21	0/21 (0%)	21/21 (100%)
OPS		21	0/21 (0%)	21/21 (100%)
Saliva		21	0/21 (0%)	21/21 (100%)
VTM		21	0/21 (0%)	21/21 (100%)

ASSAY PERFORMANCE

1. The limit of detection:

A nasal swab matrix was collected in the sample extraction buffer. An initial LoD study was first determined by testing serial dilutions of virus (0 – 5000 TCID50/mL) spiked into nasal swab matrix in triplicate. Spiked samples were tested triplicate with the device of AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold). The lowest 100% positive concentration of inactivated SARS-CoV-2 was 156 $TCID_{50}$/mL (see table below). We set a higher-level concentration to determine the limit of detection (LoD) for the kit, which is 312 $TCID_{50}$/mL to determine the LoD of the kit.

Table 3. LoD Estimation

Effective Concentration (TCID50/mL)	% Positive	Tests		
		T1	T2	T3
5000	100% (3/3)	+	+	+
2500	100% (3/3)	+	+	+
1250	100% (3/3)	+	+	+
625	100% (3/3)	+	+	+
312	100% (3/3)	+	+	+
156	100% (3/3)	+	+	+
78	0% (0/3)	-	-	-
0	0% (0/3)	-	-	-

The LoD was then verified by testing 20 additional extraction replicates consisting of a nasal swab matrix spiked with 312 $TCID_{50}$ inactivated COVID-19 virus per ml. Samples were spiked with inactivated virus prior to testing. Tests were duplicate. As shown in the Table below, 20/20 (100%) tests of replicates containing 312 $TCID_{50}$/mL were positive successfully confirming the estimated LoD.

Table 4. LoD Confirmation using the effective concentration (312 TCID50/mL)

Spiked Inactivated Virus	Replicate	Interpretation	% positive
312 $TCID_{50}$/mL	1	Positive	20/20 = 100%.
	2	Positive	
	3	Positive	
	4	Positive	
	5	Positive	
	6	Positive	
	7	Positive	
	8	Positive	
	9	Positive	
	10	Positive	
	11	Positive	
	12	Positive	
	13	Positive	
	14	Positive	
	15	Positive	
	16	Positive	
	17	Positive	

	18	Positive	
	19	Positive	
	20	Positive	

The LoD of the AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold) device was evaluated. We found that the limit of detection (LoD) of the AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold) device is 312 $TCID_{50}$/mL

2. Assay Cross Reactivity

We wet-tested the organisms in the table below in 255 negative clinical NPS matrix collected from healthy individuals. The concentrations of 10^6 CFU/ml for bacteria and 10^5 pfu/ml for viruses was used for the wet-tests.

The pathogens collected for cross reactivity are divided into two groups: respiratory pathogen (150 NPS) and blood pathogen (105 NPS).

Table 5. Samples Used for Cross Reactivity Assay

Organisms for Respiratory Specimens	Quantity	Organisms for Blood Specimens	Quantity
Adenovirus	5	Cytomegalovirus (CMV)	5
Human Metapneumovirus (hMPV)	5	Epstein-Barr Virus (EBV)	5
Parainfluenza virus 1	5	Varicella Zoster Virus (VZV)	5
Parainfluenza virus 2	5	Parvovirus B19	5
Parainfluenza virus 3	5	Human Immunodeficiency Virus – 1 (HIV-1)	5
Parainfluenza virus 4	5		
Influenza A virus	5	Human Immunodeficiency Virus – 2 (HIV-2)	5
Influenza B virus	5		
Enterovirus 71	5	Hepatitis C Virus (HCV)	5
Respiratory syncytial virus B	5	Hepatitis B Virus (HBV)	5
Rhinovirus	5	Herpes Simplex Virus-1 (HSV-	5
Haemophilus influenzae	5	Herpes Simplex Virus-2 (HSV-	5
Streptococcus pneumoniae	5	Escherichia coli	5
Streptococcus pyogenes	5	Streptococcus pneumoniae	5
Candida albicans	5	Streptococcus pneumoniae	5
Pooled human nasal wash-representative of normal respiratory	5	Streptococcus pyogenes	5
Bordetella pertussis	5	Staphylococcus aureus	5
Mycoplasma pneumoniae	5	Staphylococcus epidermidis	5
Chlamydia pneumoniae	5	Human coronavirus HKU1	5
Legionella pneumophila	5	Human coronavirus NL63	5
Staphylococcus aureus	5	Human coronavirus OC43	5
Staphylococcus epidermidis	5	Human coronavirus 229E	5
Mycobacterium tuberculosis	5	MERS-coronavirus	5
Pneumocystis jirovecii (PJP)	5	SARS-coronavirus	5

Human coronavirus HKU1	5		
Human coronavirus NL63	5		
Human coronavirus OC43	5		
Human coronavirus 229E	5		
MERS-coronavirus	5		
SARS-coronavirus	5		

3. Microbial Interference Study:

As cross-reactivity is not observed between the assay and any of the microorganisms, we conducted a microbial interference study. An inactivated SARS-CoV-2 at the concentration of 3xLoD is present in pooled NPS specimen with the microorganisms listed in the Table above. We prepared contrived specimens in NPS matrix with SARS-CoV-2 with 5 replicates. As the result, we did not find a cross reactant from the microorganisms listed in the table. We did not test the microorganisms individually.

4. Interference study:

Following substances were added to the low titer COVID-19 antigen positive solution (containing 624 $TCID_{50}$ /mL inactivated virus) and COVID-19 antigen negative solution to the marked concentration. The test was 3 replicates. No interference was found in any of the following tests at the listed concentration with this device, see table 6 below.

Table 6. Substances Tested for Interference

Spiked Interference Substances	Final Concentration	AMPER Ag Test Positive Samples		AMPER Ag Test Negative Samples	
		T: antigen	C: Control	T: antigen	C: Control
Abidol	200 mg/L	+	+	-	+
Azithromycin	500 mg/L	+	+	-	+
Amlodipine besylate	500 µg/L	+	+	-	+
Beclomethasone	1.0 mg/L	+	+	-	+
Benzolin	10 mg/L	+	+	-	+
Bilirubin	574 µmol/L	+	+	-	+
Biotin	246 nmol/L	+	+	-	+
BSA	5%	+	+	-	+
Budesonide	1.6 mg/L	+	+	-	+
Cefatriaxone	4 g/L	+	+	-	+
Chlorphenamine	8 mg/mL	+	+	-	+
Abidol	200 mg/L	+	+	-	+
Azithromycin	500 mg/L	+	+	-	+
Amlodipine besylate	500 µg/L	+	+	-	+
Nasal Spray (Cromolyn)	15% v/v	+	+	-	+
Dexamethasone	500 mg/L	+	+	-	+
Dextromethorphan HBr	5 mg/ml	+	+	-	+
Ethylenediamine tetraacetate	30 mg/mL	+	+	-	+
Fluticasone	2 mg/L	+	+	-	+
Fluconazole	250 µg/L	+	+	-	+

Gentamicin	1×10^7 U/L	+	+	-	+
Hemoglobin	694 µmol/L	+	+	-	+
Histamine hydrochloride	1.0 mg/mL	+	+	-	+
Hydrochlorothiazide	2.5 mg/L	+	+	-	+
Hydroxymethazoline	500 mg/L	+	+	-	+
α-Interferon	1×10^7 U/L	+	+	-	+
Lopinavir	400 mg/L	+	+	-	+
Losartan potassium	10 mg/L	+	+	-	+
Menthol/Benzocaine	1.5 mg/mL	+	+	-	+
Meropenem	50 mg/mL	+	+	-	+
Mometasone	880µg/L	+	+	-	+
Mucin	0.5%	+	+	-	+
Mupirocin	10 mg/mL	+	+	-	+
Nasal Drops (Phenylephrine)	15% v/v	+	+	-	+
Naso GEL (NeilMed)	5% v/v	+	+	-	+
Nasal Throat drop (Halls)	15%	+	+	-	+
Nasal spray (Afrin)	15%	+	+	-	+
Nasal Spray (Cromolyn)	15% v/v	+	+	-	+
Oseltamivir phosphate	15.0 mg/L	+	+	-	+
Oxymetazoline	15% v/v	+	+	-	+
Palamivir	600 mg/L	+	+	-	+
Phenylephrine	5 mg/ml	+	+	-	+
Rheumatoid factor	300 IU/mL	+	+	-	+
Ribavirin	600 mg/L	+	+	-	+
Ritonavir	100 mg/L	+	+	-	+
Sodium citrate	7.6%	+	+	-	+
Sodium chloride	30%	+	+	-	+
Tobramycin	4 mg/mL	+	+	-	+
Triamcinolone	30 mg/L	+	+	-	+
Triglyceride	60 g/L	+	+	-	+
Whole Blood	4%	+	+	-	+
Vitamin C	1000 µg/mL	+	+	-	+
Zanamivir	5.0 mg/L	+	+	-	+
Zicam	5% v/v	+	+	-	+

5. High-dose Hook Effect:

High-dose hook effect was evaluated by testing the following serial dilutions of the chemically inactivated SARS-CoV-2. No high dose hook effect was observed when tested with up to a concentration of 4×10^5 $TCID_{50}$/mL of inactivated SARS-CoV-2 virus (see table 7 below).

Table 7. High-dose hook effect

SARS-CoV-2 Concentration	Test Result (positive/replicate)
4×10^5 $TCID_{50}$/mL	3/3
4×10^4 $TCID_{50}$/mL	3/3
4×10^3 $TCID_{50}$/mL	3/3
4×10^2 $TCID_{50}$/mL	3/3

6. Clinical Performance

In an US certified laboratory, which meets the requirements to perform moderate to high complexity, 75 nasopharyngeal swab specimens, including 36 negative specimens and 39 PCR positive specimens, were evaluated with both the AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold) and a comparator EUA QuantiVirus SARS-CoV-2 Test Kit from DiaCarta, Inc.

The COVID-19 antigen assays were positive in 37/39 confirmed PCR positive samples (94.87% positive agreement). The COVID-19 antigen was not detected in any of the confirmed PCR negative specimens (100% negative agreement). Results are summarized in the table 8 below.

Table 8, Statistical analysis of 75 clinical specimens used in our study

COVID-19 antigen tested	Nucleic Acid Tested		Total
	RNA positive	RNA negative	
Ag positive	37	0	37
Ag negative	2	36	38
Total	39	36	75
Positive agreement (PPA): 37/39 = 94.87% [95% CI: 83.11% - 98.58%]			
Negative agreement (NPA): 36/36 = 100.00% [95% CI: 90.36% - 100.00%]			

Positive agreement (PPA) and negative agreement (NPA) between the tested reagent and the comparison nucleic acid reagent were PPA 37/39 = 94.87% [95% CI: 83.11% - 98.58%] and NPA 36/36 = 100.00% [95% CI: 90.36% - 100.00%]. In summary, the AMPER COVID-19 antigen Rapid Testing kit (Colloidal Gold) is in good agreement with the results of nucleic acid tests. Compared to the corresponding patients' available FDA EUA approved PCR assay results, the AMPER COVID-19 antigen Rapid Testing kit (Colloidal Gold) demonstrated a positive percent agreement of 94.87% and negative percent agreement of 100%, which is consistent with the manufacturer's intended to label clinical performance values.

PRECAUTIONS

The reagent card should be sealed and kept away from moisture. Check the tightness of the aluminum film pouch before use.

Do not use damage or air leakage pouches.

Do not use expired reagents.

Before testing, each component of the kit should be balanced at room temperature before opening. The test should be carried out as soon as possible after unsealing, so as to avoid being exposed to the air for a long time, which may cause damp.

In order to avoid any potential biological hazards in the specimens, the test specimens should be regarded as infectious substances. Please operate according to the laboratory procedures of infectious diseases to avoid contact with skin and mucous membrane.

Please handle the used reagent properly and do not discard it at will.

When using this kit, it is necessary to follow the precautions of all laboratory reagent operation, and all wastes must be disposed according to local regulations.

Negative results can not completely exclude the infection of SARS-CoV-2, especially in those specimens with a history of contact with infectious sources. It is suggested that subsequent nucleic acid testing should be carried out to exclude the infected individuals.

Antigen test results should not be used as a basis for diagnosing or excluding SARS-CoV-2 infection or reporting the epidemic to the health administration.

The test results of this product cannot be used for blood source screening.

Cartridges are not reusable.

INQUIRIES AND GENERAL INFORMATION	INQUIRY AND QUESTIONS
Please visit website www.amperbio.com	Via email: info@amperbio.com

SYMBOLS EXPLANATIONS

SYMBOL	EXPLANATION	SYMBOL	EXPLANATION
	Manufacturer		Keep dry
EC REP	Authorized representative in the European Community		Do not re-use
	Date of manufacture		Attention. See Instructions For Use
	Expiry date (Use by date)		Caution
LOT	Lot number	IVD	In vitro diagnostic medical device
REF	Catalogue Code		Keep upright

	Temperature limitation (store at 2-30°C)	CONT	Contents of kit
	Do not use if package is damaged	CONTROL	Control
	Keep away from sunlight		Contains sufficient for <n> tests
EC REP **Lotus NL B.V.** Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands		 **AMPER, INC** 2500 Gateway Centre Blvd, Suite 400 Morrisville, NC 27560, USA Website: www.amperbio.com email: info@amperbio.com	
		Distributor: **NeoGeneStar LLC** 100 Randolph Road, Suite 2B, Somerset, NJ 08873 USA Contact information: Phone: (732) 421-4567 Fax: (908) 756-4483 Website: www.NeoGeneStar.com email: info@NeoGeneStar.com	

AMPER *AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)* External Control Kit

For Emergency Use Authorization only
For prescription use only
For in vitro diagnostic use only

【INTENDED USE】

The *AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)* External Control Kit is intended to use as quality controls for the performance of the *AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)* device. The performance of the *AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)* External Control Kit has not been established for any other assays or instrument platforms.

【MATERIALS】

1 Positive swab SC2: a swab contains un-infectious inactivated SARS-CoV-2 (500 $TCID_{50}$/swab).
1 Negative swab: a swab contains un-infectious inactivated adenovirus (500 $TCID_{50}$/swab).

【PRECAUTIONS】

1. For Emergency Use Authorization only.
2. For in vitro diagnostic use only.
3. This product has not been FDA cleared or approved.
4. This product has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
5. This product has been authorized for use with the COVID-19 Antigen Rapid Testing Kit (Colloidal Gold) for the presence of antigens of SARS-CoV-2, not for any other viruses or pathogens.
6. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
7. The controls are intended for professional use only.
8. Please read through the instructions for use before performing the test. Failure of following the IFU will give inaccurate test results. If the result is not as expected, do not proceed the testing and contact manufacturer immediately.
9. Do not use after expiration date.
10.This product contains human source and/or potential infectious ingredients. Use the Centers for Disease Control (CDC) recommended universal precautions for handling this product and human blood. Do not pipette by mouth; do not eat or drink in areas where specimens are being handled. Treat the controls as potential biological hazardous materials.
11. Wear protective clothing and disposable gloves while handling the control reagents.

12. Wash hands thoroughly after performing the test.

【STORAGE】

UNOPENED COVID-19 Antigen Rapid Testing Kit (Colloidal Gold) External Control Kit can be stored at -20°C until expiration date. Once opened, the COVID-19 Antigen Rapid Testing Kit (Colloidal Gold) External Control Kit is stable at 2-8°C for 30 days or by the expiration date, whichever comes first. Avoid freeze-thaw cycles. Do not use after expiration date.

【TEST PROCEDURE】

Take a test device to room temperature and allow it sitting for at least 20 minutes if stored in a colder place. Equilibrate all components of the test kit to room temperature.

1. Add whole sample extraction buffer into 1 sample tube for use.
2. Label the tubes with an External Control ID number.
3. Put the External Control swab in a tube containing sample extraction buffer, fully stir, squeeze the swab head along the inner wall of the tube. Then take out and disinfect the swab.
4. Tear off the pouch bag at the notch.
5. Remove the test device and microdropper.
6. Place the test device horizontally on a clean workbench.
7. Label the device with an External Control ID number.
8. Transfer 4 drops (about 80μL) of the External Control specimens directly into the sample hole of the test device.
9. Wait 15 minutes to record a test result. Do not record any result after 30 minutes.
10. The Negative swab Control should yield a negative result.
11. The Positive swab SC2 Control should yield an SC2 positive result.
12. Discard the test device and disinfect the table after interpreting each result.
13. Record the result.

【LIMITATION】

The *AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)* External Control Kit is designed for use only with the *AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)*. The validity of the reaction produced in another rapid test cannot be guaranteed. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

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	Catalogue Code		Keep upright
	Temperature limitation (store at 2-30°C)		Contents of kit
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	Keep away from sunlight		Contains sufficient for <n> tests

Lotus NL B.V.
Koningin Julianaplein 10,1e Verd,2595AA,
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