COVID-19 Ag Detection Kit
(Colloidal Gold Immunochromatography)
Catalog Number 41A254

(Please read this instruction manual before use.)
WARNING! Wear appropriate protective eyewear, clothing and gloves.

INTENDED USE

COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography) is a lateral flow antigen rapid diagnostic test that uses highly specific monoclonal antibodies to qualitatively detect SARS-CoV-2 Nucleocapsid protein (NP) from nasopharyngeal/nasal or oropharyngeal secretions of individuals suspected of COVID-19 within the first seven days of symptom onset, which can be used by healthcare professionals. This test is intended for a Point-of-Care setting.

SUMMARY

The spread of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) has caused a worldwide COVID-19 pandemic. Rapid identification and isolation of COVID-19 patients is the main strategy to contain this pandemic.
COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography) is a rapid flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2 from nasopharyngeal/nasal or oropharyngeal swab.

ASSAY PRINCIPLE

This assay is based on the specific antibody-antigen reaction with colloidal gold immunochromatography. A monoclonal antibody against SARS-CoV-2 NP conjugated with colloidal gold particles is pre-coated on the conjugation pad together with colloidal gold conjugated goat anti-chicken IgY as the control particles. Another monoclonal antibody against SARS-CoV-2 NP is immobilized on the membrane, while the chicken IgY is pre-coated as the control line.
During testing, SARS-CoV-2 NP present in the samples bind to the monoclonal antibody conjugated colloidal gold. The complex migrates upward by the capillary effect and is captured by the anti-SARS-CoV-2 NP monoclonal antibodies immobilized on the membrane forming a test line (T). The remaining conjugate continues to migrate until it binds to the chicken IgY and forms a control line (C). The result is visible within 15 minutes.

REAGENTS AND MATERIALS

1. COVID-19 Ag strip (20 tests/kit)
2. Sample lysis buffer (500 µL/tube)
3. Extraction tube (20 tubes/kit)
4. Swabs (20 nasal swabs/kit)
5. Product Insert

OTHER MATERIALS REQUIRED, BUT NOT PROVIDED

1. Timer or other equipment for time recording.
2. If clinical samples other than nasal secretions need to be measured, other kinds of swab may be required (such as throat swabs).

PRECAUTIONS

- All reagents are for *in vitro* diagnostics use only.
- All operations linked to the use of the test must be performed following Good Laboratory Practices.
-All reagents should be equilibrated to room temperature before use.
- Avoid touching nitrocellulose membrane with your fingers.
- Wears gloves, FFP2 or FFP3 mask, and lab glasses when handling samples. Otherwise, run the test under a Laminar Air Flow cabinet.
- Strips are sensitive to temperature and humidity. The reaction temperature should be at 15 °C ~30 °C and the humidity should be below 70%.
- Reagents cannot be mixed from different kits.
-The quality of expired reagents cannot be guaranteed or if reagents are not stored under required conditions as indicated in the manual.
- Do not use the strip if the pouch is damaged or the seal is broken.
-The used reagents should be discarded according to local regulations.

STORAGE

- The kit needs to be stored at 4 °C ~30 °C and in a dry environment.
- Avoiding freezing strips and buffer.
- The test strip is stable until the expiry date only if it has not been opened and kept in the sealed aluminum pouch.
- Production date and expiration date are shown in the package label.
- Do not open the sealed pouch until use. Once opened, the strip should be used within 1 hour.

SPECIMEN COLLECTION AND STORAGE

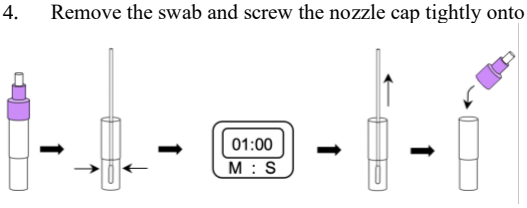
Anterior nasal (front nose) swab
1. Carefully insert the swab into the user's nostril. The swab tip should inserted up to 2.5 cm (1inch) form the edge of the nostril.
2. Dab along the lining of the nostril and roll the swab several times.
3. Remove the swab from the nasal cavity.

Specimen Transport and Storage
Do not return the nasal swab to the original package.
For the best performance, direct nasal swabs should be tested preferably as soon as possible after collection. Based on data generated with SARS-CoV-2 COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography), specimens are stable for up to 48-hours at 2~8°C. For long term storage, specimens can be stored at -60~-80°C up to 1 year.

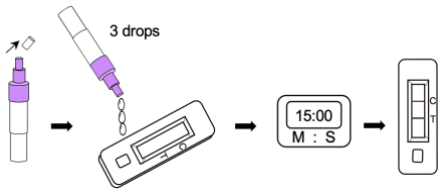
TEST PROCEDURE

Preparation of the test:
Equilibrate kit components in unopened packaging to room temperature (15-30 °C) before starting the test.
Clearly label the extraction tube with patient's information.

Assay procedure:
1. Open the extraction tube.
2. Insert the swab into an extraction tube. While squeezing the tube, stir the swab more than 5 times and wait for 1 minute.
3. Squeeze the wall of the tube to extract the liquid from the swab.
4. Remove the swab and screw the nozzle cap tightly onto the tube.

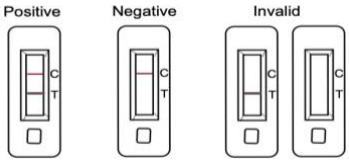


Analysis of Specimen:
5. Open the pouch and remove the strip.
6. Invert the extraction tube and add 3 drops (~80 µL) of the extracted specimen to the specimen well (S).
7. Read the test result at 15 minutes.



Do not interpret the result after 20 minutes.

INTERPRETATION OF TEST RESULT



- ✧ **Positive:**
  The presence of two lines as the control line (C) and the test line (T) in the result window.
- ✧ **Negative:**
  The presence of a single line as the control line (C) in the result window.
- ✧ **Invalid:**
  If the control line (C) is not visible within the result window after performing the test, the result is invalid.

LIMITATIONS OF TEST

- A negative test result may occur if the level of the extracted antigen in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained.
- Negative test results do not rule out the possibility of SARS-CoV-2 infection, which should be further confirmed by RT-PCR.
- The test result must always be evaluated with other data available to the physician.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.

WASTE DISPOSAL

- Dispose of gloves, swabs, extraction tubes, used strips in accordance with GLP.
- Each user is responsible for the management of any waste produced and must ensure that it is disposed of in accordance with the applicable legislation.

ASSAY PERFORMANCE

Sensitivity and specificity:

The COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography) has been evaluated with specimens obtained from 105 COVID-19 patients and 425 non-infected negative controls. Tests were conducted within 7 days of symptom onset. Two nasal swabs were collected and tested using COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography). An FDA Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was utilized as the comparator method for this study.

Reagents		RT-PCR		Total
		Positive	Negative	
COVID-19 Ag Detection Kit	Positive	97	11	107
	Negative	8	414	423
Total		105	425	530
Positive Agreement: 95/105 92.38% (95%CI: 87.44%-98.07%)				
Negative Agreement: 414/425 97.41% (95%CI: 95.47%-99.21%)				

Analytical Performance

Analytical Sensitivity

The LOD of COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography) was confirmed as $2.8x10^2$ $TCID_{50}$/ml.

$TCID_{50}$/ml	Number Positive/Total	% Detected
2.8×10^2	19/20	95
pg/ml	Number Positive/Total	% Detected
75	19/20	95

High Dose Hook Effect

No high dose hook effect was noted when tested with up to a concentration of $2.8x10^6$ $TCID_{50}$/ml of inactivated SARS-CoV-2 virus with COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography).

Endogenous Substances Interference Test

The following substances with test concentration in the table do not affect the performance of COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography).

Substance	Concentration	Substance	Active Ingredient	Concentration
Mucin	2% w/v	OTC Nasal Drop	Phenylephrine	12% v/v
Benzocaine	5 mg/ml	OTC Nasal Spray 1	Cromolyn	15% v/v
Tobramycin	5 ug/ml	OTC Nasal Spray 2	Oxymetazoline	15% v/v
Oseltamivir phosphate	10 mg/ml	OTC Nasal Spray 3	Fluconazole	5% w/v
Arbidol	5 mg/ml	OTC Homeopathic Nasal Spray 1	Zincum gluconium	5% w/v
Triamcinolone	10 mg/ml			
Mupirocin	10 mg/ml	OTC Homeopathic Nasal Spray 2	Alkalol	10% v/v
Zanamivir	5 mg/ml			
Ribavirin	5 mg/ml	OTC Homeopathic Nasal Spray 3	Fluticasone Propionate	5% v/v
Dexamethasone	5 mg/ml			

Cross Reactivity and Microbial Interference

Cross reactivity and potential interference of COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography) was tested in microorganisms listed in the table that may be present in the nasal cavity. No cross reactivity or interference was noted when tested at the concentration presented in the table below.

Type	Human Cross Reactant	Test Concentration
Coronavirus	Human coronavirus HKU1	1×10^5 $TCID_{50}$/ml
	Human coronavirus OC43	1×10^5 $TCID_{50}$/ml
	Human coronavirus NL63	1×10^5 $TCID_{50}$/ml
	Human coronavirus 229E	1×10^5 $TCID_{50}$/ml
	SARS-coronavirus	10 μg/ml
	MERS-coronavirus	10 μg/ml
Virus	Rhinovirus	1×10^5 PFU/ml
	Adenovirus	1×10^5 $TCID_{50}$/ml
	Human Metapneumovirus	1×10^5 $TCID_{50}$/ml
	Parainfluenza 1	1×10^5 $TCID_{50}$/ml
	Parainfluenza 2	1×10^5 $TCID_{50}$/ml
	Parainfluenza 3	1×10^5 $TCID_{50}$/ml
	Parainfluenza 4	1×10^5 $TCID_{50}$/ml
	Influenza A	1×10^5 $TCID_{50}$/ml
	Influenza B	1×10^5 $TCID_{50}$/ml
	Enterovirus	1×10^5 $TCID_{50}$/ml
	Respiratory syncytial virus	1×10^5 PFU/ml
Bacteria	Bordetella pertussis	1×10^6 cells/ml
	Chlamydia pneumoniae	1×10^6 IFU/ml
	Haemophilus influenzae	1×10^6 cells/ml
	Legionella pneumoniae	1×10^6 cells/ml
	Mycoblasma pneumoniae	1×10^6 U/ml
	Streptococcus pneumoniae	1×10^6 cells/ml
	Streptococcus pyogenes	1×10^6 cells/ml
	Mycobacterium tuberculosis	1×10^6 cells/ml
	Staphylococcus aureus	1×10^6 org/ml
	Staphylococcus epidermidis	1×10^6 cells/ml
Yeast	Candida albicans	1×10^6 cells/ml
Pooled human nasal wash		-

Note: $TCID_{50}$ -Median Tissue Culture Infectious Dose; PFU-Plaque Forming Unit

SYMBOLS

	Manufacturer	CE	EC Declaration of Conformity
	Expiry date		Consult Instruction
LOT	Lot number		Store
REF	Catalog number		Caution
IVD	In Vitro Diagnostic Device	EC REP	Name and Address of EU REP

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