# COVID-19 Ag Detection Kit

**(Colloidal Gold Immunochromatography)**

**Catalog Numbers 41A254**

*(Please read this instruction manual before use.)*

**WARNING!** Wear appropriate protective eyewear, clothing, and gloves.

## INTENDED USE

COVID-19 Ag Detection Kit is an in vitro rapid test for the detection of SARS-CoV-2 antigen in nasopharyngeal or throat secretions, or other clinal samples.

***For professional use only***

## SUMMARY

The spread of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) has caused a worldwide COVID-19 pandemic. Due to the lack of a vaccine and specific treatment, rapid identification and isolation of COVID-19 patients and asymptomatic carriers is the main strategy to contain this pandemic.

Nucleocapsid protein (NP) is the most abundant protein of SARS-CoV-2, and the detection of NP can be used for the confirmation of SARS-CoV-2 infection.

## 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. Another monoclonal antibody against SARS-CoV-2 NP is immobilized on the membrane.

During testing, SARS-CoV2 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 a control reagent and forms a control line (C). The result is visible within 15 minutes.

## REAGENTS AND MATERIALS

1. COVID-19 Ag strip (20 tests/kit)
   One aluminum pouch with a strip
2. Sample lysis buffer (10 mL)
   Phosphate solution buffered to pH 7.4 containing $NaN_3$ (<0.1%), a detergent, and blocking proteins
3. Extraction Tubes (20 tubes)
   The tubes and nozzle cap come in a zip-locked plastic bag
4. Swabs (20 nasopharyngeal swabs)
   Individually pouched flocked swabs
5. Transfer Pipet (20 transfer pipet)
   Individually pouched plastic transfer pipet

## OTHER MATERIALS REQUIRED, BUT NOT PROVIDED

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

## PRECAUTIONS

- All reagents are for *in vitro* use only.
- All operations linked to the use of the test must be performed following Good Laboratory Practices (GLP).
-All reagents should be equilibrated to room temperature before use.
- Avoid touching nitrocellulose membrane with your fingers.
- Wears gloves, mask FFP2 or FFP3, 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.
-Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.

## LIMITATION 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.

## 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.

## STORAGE

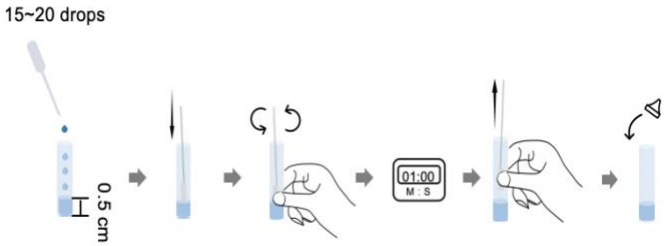
- The kit needs to be stored at 4 °C ~30 °C and in a dry environment.
- Avoiding freezing strips and buffer.
- The test strip is stable until the expiry date only if it has not been opened and kept in the sealed aluminum pouch.
- Production date and expiration date are shown in the package label.
- Do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

## ASSAY PROCEDURE

**Preparation of the test:**
Equilibrate kit components in unopened packaging to room temperature (15-30 °C) before starting the test.
Once opened, run the test immediately.
Label the sample's name clearly on the tube.

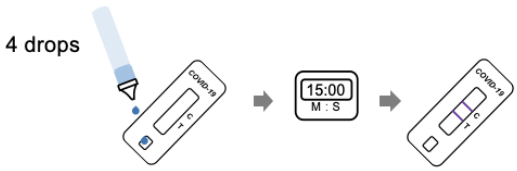
**Specimen preparation procedure:**
(Nasopharyngeal swab)

1. Transfer 200-300 µL (~20 drops) of sample lysis buffer into an extraction tube using a transfer pipet.
2. Insert the swab into an extraction tube. While squeezing the buffer 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. Press the nozzle cap tightly onto the tube.



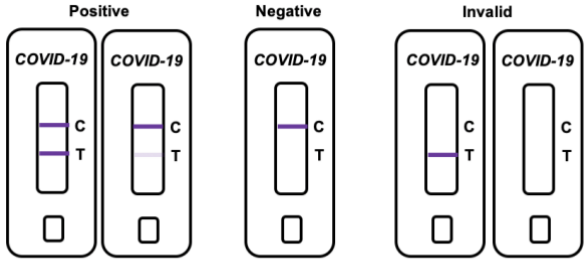

**Analysis of Specimen:**

1. Apply 4 drops (~100 µL) of the extracted specimen to the specimen well of the test strip.
2. Read the test result in 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.

## ASSAY PERFORMANCE

**Sensitivity and specificity:**
The COVID-19 Ag Detection Kit has been evaluated with specimens obtained from COVID19 patients and non-infected negative controls. The results show that the COVID-19 Ag Detection Kit has high sensitivity and specificity.

| Method | COVID-19 Ag Detection Kit | | PCR | |
|---|---|---|---|---|
| | Positive | Negative | Positive | Negative |
| | 72 | 7 | 79 | 0 |
| | 0 | 132 | 0 | 132 |
| Total | 72 | 139 | 79 | 132 |

Relative Sensitivity: 91.14%
Relative Specificity: 100%