

## Novel Coronavirus Antigen Detection Kit (Colloidal Gold)

### Package Insert

**Cat:** COVID-19-NG02 **Specimens:** Stool/Sputum  
**Version:** 04 **Effective Date:** 2020-10

*For professional and in vitro diagnostic use only.*

#### PRODUCT NAME

Novel Coronavirus Antigen Detection Kit (Colloidal Gold)

#### PACKING

1 piece/bag, 25pieces/box.

#### INTENDED USE

This product is suitable for the qualitative detection of novel coronavirus in stool or sputum sample. It provides an aid in the diagnosis of infection with novel coronavirus.

#### SUMMARY

The novel coronaviruses belong to the  $\beta$  genus. COVID-19 is an acute respiratory infectious 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.

#### PRINCIPLE

The Novel Coronavirus Antigen Detection Kit (Colloidal Gold) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in throat swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control a red line will always appear in

the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

#### COMPOSITION

1. Disposable test card
2. Disposable sample extraction tube
3. Cotton swab
4. Disposable paper cup

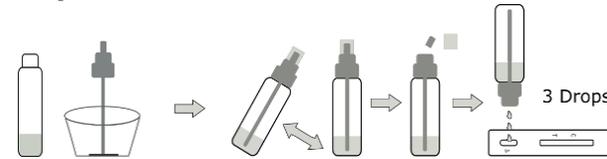
#### STORAGE AND STABILITY

1. Store as packaged in the hermetic bag at the temperature (2-30°C or 38-86°F) and avoid direct sunshine. The kit is stable within the expiration date printed on the labeling.
2. Once open the hermetic bag, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
3. The lot number and the expiration date are printed on the labeling.

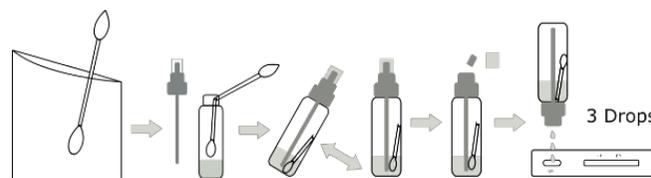
#### TEST PROCEDURE

Allow the test device and specimens to restore to room temperature (15-30°C or 59-86°F) prior to testing.

##### Stool Sample:



##### Sputum Sample:



1. **Stool Sample:** Unscrew the sampling bottle, use the sampling rod to pick up 10-50mg of fresh stool samples (equivalent to the size of a match head). Put them into the tube and shake to mix the sample completely.
2. **Sputum Sample:** Use the cotton swab to pick up 10-50mg sputum samples (equivalent to the size of a match head). Open the cap of sample extraction tube, break the swab tip into the tube. Close the disposable sample extraction tube and shake to mix the sample completely. Leave the swab in the extraction tube for one minute.

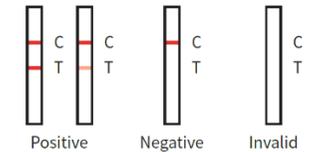
3. Take the test card from the packaging bag, place it on a table, cut off the protrusion of the collection tube, and add 3 drops of the sample solution into the sample loading hole vertically.
4. Read the result in 15 minutes. The result is considered inaccurate and invalid after 30 minutes.

#### RESULTS OF INTERPRETATION

**Positive(+):** Both of T and C lines are appeared in 15minutes.

**Negative(-):** C line is appeared while no T line appeared in 15 minutes after the sample is loaded.

**Invalid:** As long as the C line does not appear, it indicates that the test result is invalid, and should retest the sample with another test card.



#### NOTES

1. The Novel Coronavirus Antigen Detection Kit (Colloidal Gold) is applicable to stool or sputum samples. Blood, serum, plasma, urine and other samples may cause abnormal results.
2. Please make sure that a proper amount of sample is added for testing. Too much or too little sample amount may cause deviations in results.
3. For positive judgement, it can be confirmed as soon as both T and C line appeared. That may take 3-15 minutes after the sample is loading. For negative judgement, please wait for 15 minutes after sample loading. The result is invalid after 30 minutes after sample loading.
4. This product is disposable. DO NOT recycle.
5. Dispose of used products, samples, and other consumables as medical wastes under relevant regulations.
6. If the test line or control line is out of the test window, do not use the test card. The test result is invalid and retest the sample with another one.

#### INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalogue number

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