COVID-19 Antigen Rapid Test

Colloidal Gold

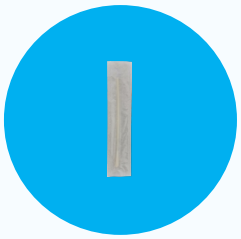
- Instant results within 15 minutes
- Easy to use, no equipment required
- Room temperature storage (2-30℃)
- Non-invasive sampling
- Cost-effective solution for large-scale testing
- High sensitivity and specificity

PRODUCT SPECIFICATIONS

Product Components

Test cassette

Extraction tube



Nasal swab

Order Information

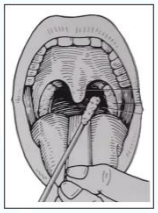
Catalog No.	00013C
Product Name	COVID-19 Antigen Rapid Test (Colloidal gold)
Packing Size	20T
Sample Type	Nasal/oropharyngeal swab
Storage Condition	2-30℃
Shelf Life	18 months
Contents	20x Test cassettes (individually packed) 20x Extration tubes with extraction buffer inside 20x Nasal swabs 1x Instruction for use
Qualification	CE

Specimen Collection

For Nasal Swab Sample

1. Take out the Nasal Swab supplied in the kit, be careful not to touch the head end of the swab with your hand.
2. Gently insert the swab into the nostril. The insertion depth should not exceed 1.5cm (about 3/4 of the white fiber part of the head end of the swab enters the nostril)
3. Slowly rotate the swab along the inside of nostril for 15 seconds.
4. Gently pull out the swab.
5. Repeat steps 2-4 on the other nostril with the swab.

For Oropharyngeal Swab Sample



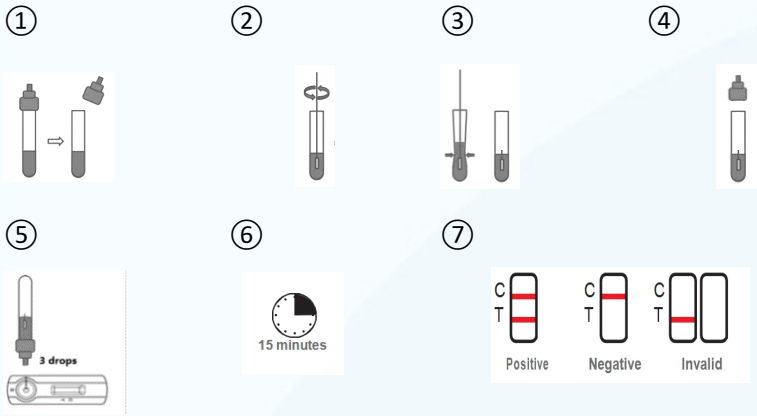
1. Take out the Nasal Swab supplied in the kit, be careful not to touch the head end of the swab with your hand.
2. Let the patient open his mouth and pronounce "ah"to expose the throat, and use tongue depressor if necessary.
3. Gently insert the swab into the posterior pharynx and tonsillar areas.
4. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.
5. Gently pull out the swab.

Note:

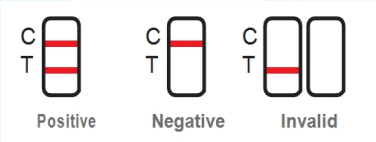
Specimens should be tested as soon as possible after collection. If immediate testing is not possible, specimen collected may be stored at 2-8℃ for no more than 24 hours. All clinical specimens must be returned to room temperature before beginning the assay.

Test Procedure

1. Open the upper cap of the Extraction Tube.
2. Place the swab sample into the Tube (contains Extraction Buffer). Vigorously rotate and twist the swab against the side of the tube at least 10 times.
3. Squeeze the sides of the extraction tube to obtain as much liquid as possible and take out the swab. Break the swab, leave the sampling head in the tube, discard the handle properly.
4. Close the upper cap of the Extraction Tube.
5. Add 3 drops (approximately 100μL) extracted sample from the Extraction Tube to the specimen well of the test device.
6. Waiting for 15 minutes.
7. Read the results.



Result Interpretation



Positive

Two red lines appear, the control line (C) and the test line (T). The result is positive.

Negative

Only the red control line (C) appears. The result is negative.

Invalid

If no red line appears in the position of control line (C), the test result is invalid regardless of color on the test line (T). Insufficient specimen volume or incorrect procedures are the most common reasons for control line (C) failure. Review the procedure and repeat the test with a new test device.

Performance

For Nasal Swab Sample

The clinical performance of the device was established with a study using 415 Nasal swabs.

COVID-19 Antigen Rapid Test	Clinical diagnosis	
	Positive	Negative
Positive	106	4
Negative	9	296

The assay demonstrated clinical sensitivity 92.17% (95% CI: 85.26%-96.13%) and clinical specificity 98.67% (95% CI: 96.39%-99.57%).

For Oropharyngeal Swab Sample

The clinical performance of the device was established with a study using 415 Oropharyngeal swabs.

COVID-19 Antigen Rapid Test	Clinical diagnosis	
	Positive	Negative
Positive	107	3
Negative	8	297

The assay demonstrated clinical sensitivity 93.04% (95% CI: 86.33%-96.73%) and clinical specificity 99% (95% CI: 96.86%-99.74%).

1. Limit of Detection

The Limit of Detection (LoD) of the kit was 6.20 x10^2 per mL.

2. Hook Effect

As part of the LoD study the highest concentration of heat-inactivated SARS-CoV-2 stock available (TCID50 of 6.20 x10^6 per mL) was tested. There was no Hook effect detected.

3. Cross Reactivity

Specimens which tested positive with following various agents from patients were investigated with the kit. The results showed no cross reactivity.

No.	Virus/Bacteria	No.	Virus/Bacteria
1	Parainfluenza virus	10	TP
2	Influenza A	11	HIV 1/2
3	Influenza B	12	EB virus
4	Chlamydia pneumonia	13	Hepatitis A
5	Mycoplasma pneumoniae	14	Hepatitis B
6	Respiratory syncytial virus	15	Adenovirus
7	Coronavirus (229E)	16	SARS
8	Coronavirus (OC43)	17	MERS
9	Coronavirus (NL63)		

4. Interference

The following potential interference substances were evaluated with the kit at the concentrations listed below and were found not to affect test performance.

No.	Substance	Concentration
1	Oxymetazoline	5%
2	Blood	5%
3	Benzocaine	0.7 g/mL
4	Fluticasone	5%
5	Menthol	0.8 g/mL
6	Triamcinolone	5.00%
7	Phenylephrine hydrochloride	5%
8	Mucin protein	2.5 mg/mL
9	Budesonide	5%
10	Saline	15%