

# SARS-CoV-2 Antigen Kit (Colloidal Gold)

## Nasal Covid-19 Lateral Flow Test Kits



### PRODUCT DESCRIPTION

Covid-19 Antigen Kit for self testing for the presence of Covid-19 Antigens.

### INTENDED USE

This SARS-CoV-2 Antigen Kit (Colloidal Gold) is a single use, in vitro visually read rapid immunochromatographic assay for the qualitative detection of SARS-CoV-2 nucleocapsid (N) antigen in human nasal swab specimens. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The agent detected may not be the definite cause of disease.

The SARS-CoV-2 Antigen Kit (Colloidal Gold) is intended to be used manually by Lay users (self-testing) in a private setting to aid in the rapid diagnosis of SARS-CoV-2 infections. Children (at least 2 years old) younger than 15 years old should be tested by an adult. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

### Key Features of Lateral Flow Test Kits

- Clinical Sensitivity 93.04% (EU Common list entry)
- Clinical Specificity 100.0% (EU Common list entry)
- CE 1434 Notified Body
- Multi language CE compliant packaging
- Available in a single pack, a 5 pack as well as bulk 25 packs (on request)
- Shelf Life - 18 months from date of manufacture

### Product Packaging

49409 15.7 x 6.0 x 1.5cm / 23g  
49410 17.5 x 6.5 x 3.5cm / 67g

### Master

49409	480 boxes/480 test kits per master carton	14.6 kg	65.5 x 44 x 34 cm
49410	220 boxes/1100 test kits per master carton	16.9 kg	67.5 x 40 x 36 cm
TBC	40 boxes/1000 test kits per master carton	17.0kg	77 x 36 x 39 cm

### Strax Part Code

49409	6971225931728	Goldsite SARS-CoV-2 Antigen Kit (Colloidal Gold)	x1
49410	6971225931735	Goldsite SARS-CoV-2 Antigen Kit (Colloidal Gold)	x5
TBC	TBC	Goldsite SARS-CoV-2 Antigen Kit (Colloidal Gold)	x25

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### Summary and Explanation

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 of the Procedure

The kit employs lateral flow immunoassay technology. Using this test allows for the rapid detection of nucleocapsid protein from SARS-CoV-2.

To begin the test, a self-collected nasal swab sample is inserted into the Extraction Tube. The pre-filled solution in the tube interacts with the sample and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The extracted sample is then added to the sample well of the Test Cartridge.

If the extracted sample contains SARS-CoV-2 antigens, a pink-to-red line will appear on the test line region (T) and a red line will appear on the procedural control line region (C). Absence of the test line (T) indicates SARS-CoV-2 antigens are not detected, suggesting SARS-CoV-2 is not present, or is present at very low levels.

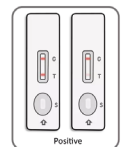
### Interpretation of results

#### Positive Result

Two lines will appear.

One pink-to-red line on the test line region (T) and one red line on the control line region (C).

Note: Look very closely! The test line (T) can be very faint. Any pink/red visible T line should be considered positive.



#### Negative Result

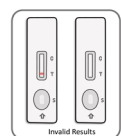
A single line will appear on the control line region (C).



#### Invalid Result

No red line appears on the control line region (C).

Note: Insufficient sample volume, incorrect operating procedure are the most likely reasons for control line failure. If the test result is invalid, a new swab should be collected, and the test should be performed again with a new kit. If the problem persists, discontinue using the kit immediately and contact your local distributor.



### Limitations

- The test is only for qualitative detection of the SARS-CoV-2 antigen in nasal swab samples.
- This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- Failure to follow the Test Procedure, Interpretation of Results may adversely affect test performance and/or invalidate the test results.
- False negative results may occur if a sample is improperly collected or handled.
- Positive test results do not rule out co-infections with other pathogens.
- A negative result does not exclude SARS-CoV-2 infection. Negative results should be treated as presumptive and may need to be confirmed by a molecular assay.
- False negative results are more likely after eight days of symptoms.

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### Clinical Performance

The clinical performance of SARS-CoV-2 Antigen Kit (Colloidal Gold) was determined by testing samples from 267 persons suspected of COVID-19. The samples were collected within 7 days post onset of symptoms or suspected exposure. For each individual, two swabs were collected. The first one was self-sampled nasal swab and was self-tested directly with SARS CoV-2 Antigen Kit (Colloidal Gold) at the site. The second was a healthcare collected nasopharyngeal swab which was placed in virus transport medium, shipped to laboratory, and determined to be positive or negative using an NMPA (National Medical Products Administration, China) approved RT-PCR method, i.e., the comparator method.

		RT-PCR Test Results		
		Positive	Negative	Total
SARS-CoV-2 Antigen Kit Colloidal Gold	Positive	110	1	111
	Negative	9	147	156
Total		119	148	267

Clinical sensitivity:	92.44%	(95% CI: 86.13-96.48%)
Clinical specificity:	99.32%	(95% CI: 96.29- 99.98%)
Overall percent agreement:	96.25%	(95% CI: 93.22-98.13%)

### Limit of Detection (LoD)

SARS-CoV-2 Antigen Kit (Colloidal Gold) was confirmed to detect 2.5 ng/ml of SARS-CoV-2 nucleocapsid protein antigen.

#### Manufacturer

**Goldsite Diagnostics Inc.**

#### Address of Manufacturer

No. 103C, 503C & 5040, Technology Building & No. 3A & 4A, Technology Building Annex, Zhaoshang Sub-District, Nanshan District, Shenzhen, China, 518067

#### Manufacturing Site

No. 103C Technology Building & No. 3A & 4A, Technology Building Annex, Zhaoshang Sub-District, Nanshan District, Shenzhen, China, 518067

#### EC Rep


CMC MEDICAL DEVICES & DRUGS, S.L. C/ Horacio Lengo No 18, CP 29006, Malaga-Spain




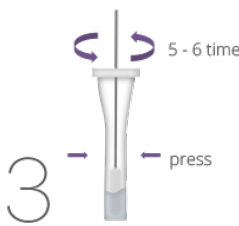
# SARS-CoV-2 Antigen Kit (Colloidal Gold)

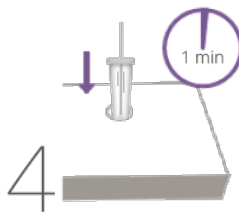
## Nasal Covid-19 Lateral Flow Test Kits


### Step by Step Instructions for Use

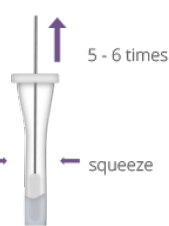
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1 Remove the lid of the dropper
- 


2 Insert and dip the swab in the tube
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3 Stir the swab while pressing 5 - 6 times
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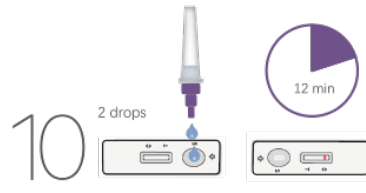
4 Insert the tube into the pre-cut in the kit box. Leave the swab for 1 minute.
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5 Stir to mix well the contents
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6 Remove the swab while squeezing the sides of the tube 5 - 6 times
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7 Attach and tighten the dropper cap
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8 Gently reverse several times
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9 Remove the white cap
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10 Remove the white cap, add two drops of sample and read the result after 12 minutes.