Goldsite Diagnostics Inc.

SARS-CoV-2 Antigen Kit (Colloidal Gold)

Catalog No.	CG123001, CG123005, CG123025

1. Intended Use

This SARS-CoV-2 Antigen Kit (Colloidal Gold) is a lateral flow rapid chromatographic immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid (N) antigen in nasopharyngeal swab specimens from individuals who are suspected of COVID-19.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but correlation with patient history and other diagnostic information is necessary to determine the infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

The SARS-CoV-2 Antigen Kit (Colloidal Gold) is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

2. Background Information of COVID-19

The novel coronaviruses belong to the β 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.

3. Test Principle

Immunochromatography is applied. Briefly, the SARS-CoV-2 antigen in the sample binds with the colloidal gold labeled anti-SARS-CoV-2 nucleocapsid antibodies in the cartridge to form the immunocomplexes. When the complexes migrate to the T line (coated with anti-SARS-CoV-2 nucleocapsid antibodies), the complexes that contain the SARS-CoV-2 antigen will be captured. Similarly, the colloidal gold labeled chicken IgY antibody will be captured in the control line (coated with goat anti-chicken IgY). The complexes containing SARS-CoV-2 antigen will produce a colored line in the T line region, indicating the sample is positive for SARS-CoV-2 antigen. Similarly, a colored line will also appear in the control line region indicating the correct operation procedure has been taken and the assay is providing reliable results. A negative sample will produce a single line at the control line region indicating no SARS-CoV-2 antigen was detected.

4. Materials Provided

Component	Figure	1T CG123001	5T CG123005	25T CG123025
Test cartridge		1	5	25
Sampling Swab		1	5	25
Extraction Tube		1	5	25
Instructions For Use		1	1	1

5. Material Required but Not Supplied

5.1 Timer

5.2 Any necessary personal protective equipment

6. Storage and Stability

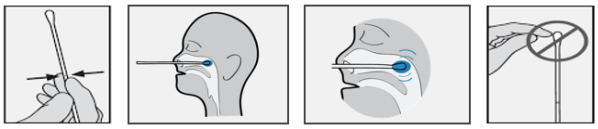
Store the kits at 2 – 30°C in a dry place and avoid direct sunlight. The unopened cartridges are stable until the expiry date printed on the labels. Once opened, they should be used immediately.

7. Sample Collection

7.1 Nasopharyngeal swab specimens are acceptable for testing with this kit.

7.2 Sample collection: insert swab through the nares perpendicular to the nose (face) until resistance is encountered and the fingers touch the nose. Leave the swab in place for 15 – 30 seconds. Rotate the swab 3 times and remove it from the nasopharynx.

7.3 Treat all specimens as potentially infectious. Be cautious and follow universal precautions in sample collection, storage and transport.



8. Test Procedure

8.1 Remove the cartridge from its package. Place the cartridge on a clean, flat and dry surface. Label the cartridge with patient ID.

8.2 Remove the Dropper Lid from the Extraction Tube with the prefilled Extraction Buffer. Place and soak the patient swab into the Extraction Buffer.

8.3 Rotate the swab 5 – 6 times while squeezing the sides of the tube. Insert the tube into the hole indicated on the kit box (operational) or a tube holder. Make sure the tube is standing upright and reaches the bottom. Leave the swab in the Extraction Tube for 1 minute.

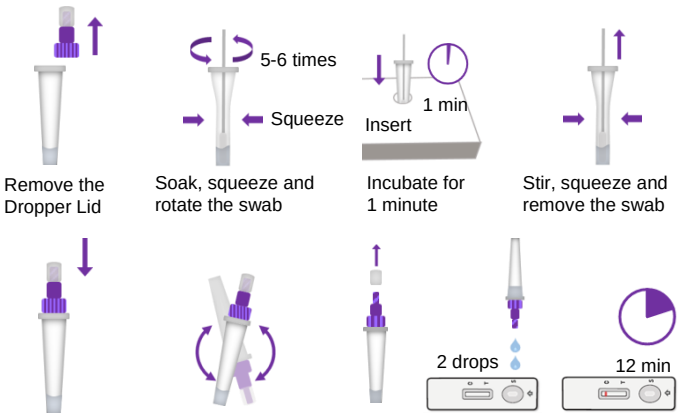
8.4 Stir to mix the contents well. Remove the swab while squeezing the sides of the tube.

8.5 Replace and tighten the Dropper Lid to the top of the Extraction Tube. Mix the contents thoroughly (by inverting the tube several times).

8.6 Remove the cap on top of the Dropper Lid, invert the extraction tube, and then add two drops (around 70 uL) of the well-mixed sample into the sample well of the cartridge.

8.7 Leave the sample-loaded cartridge at room temperature for **12 minutes**.

8.8 After the 12-minute incubation, read the results. Do not interpret the results after 15 minutes (from addition of the sample).



Remove the Dropper Lid | Soak, squeeze and rotate the swab | Incubate for 1 minute | Stir, squeeze and remove the swab

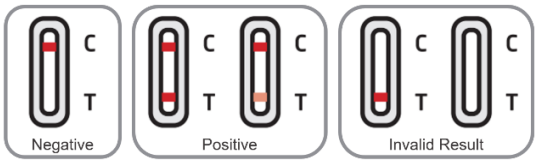
Replace and tighten the Dropper Lid | Invert gently several times | Remove the white cap, add two drops of sample, and read result after 12 minutes

9. Interpretation of Results

The Control (C) line must appear for a test to be valid regardless of the appearance of the T line. Failure to observe the control line indicate the result is not reliable. When this occurs, check the operation procedure carefully, and test again with a new cartridge. If the problem recurs, contact Goldsite.

Result	C line	T line	Test Result Interpretation
Negative	**+**	**-**	Negative. The C line appears indicating a valid test, but no SARS-CoV-2 antigen was detected.
Positive	**+**	**+**	Positive. The C line appears indicating a valid test, the T line also appears indicating SARS-CoV-2 antigen was detected. **Note that any visible T line is positive.**
Invalid	**-**	**Any**	Invalid Test.

			The control line fails to appear indicating an invalid test. The sample must be retested with another device



10. Limitations

10.1 The test is only for qualitative detection of the SARS-CoV-2 antigen in nasopharyngeal swab specimens.

10.2. Results obtained with this kit should not be the sole basis for diagnosis and treatment of SARS-CoV-2 infection. The clinical symptoms, medical history, epidemiological information and other laboratory findings of patients should always be taken into consideration.

11. Performance

11.1 Clinical Performance

The clinical performance of SARS-CoV-2 Antigen Kit (Colloidal Gold) was determined by testing paired nasopharyngeal swab samples from 532 persons suspected of COVID-19 infection. The samples were collected within 7 days post onset of symptoms or suspected exposure. At the collection site, one swab was tested directly with the SARS-CoV-2 Antigen Kit (Colloidal Gold). The second swab were 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	120	0	120
	Negative	8	404	412
	Total	128	404	532

Clinical sensitivity: 93.75% (95% CI: 88.06 – 97.26%)
Clinical specificity: 100.00% (95% CI: 99.09 – 100.0%)
Overall percent agreement: 98.50% (95% CI: 97.06 – 99.35%)

11.2 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.

11.3 Cross Reactivity

The cross-reactivity with the following microorganisms was examined. Samples that tested positive for the following microorganisms were negative when tested with the SARS-CoV-2 Antigen Kit (Colloidal Gold).

The microbial interference study evaluated whether microorganisms possibly contained in clinical samples interfere with the detection capability of the kit which may lead to false negative results. Each microorganism was tested in triplicate in the presence of a fabricated SARS-CoV-2 positive sample (concentration: 3 × LOD). No cross-reactivity or interference with the microorganisms listed in the table below was found.

No.	Microorganism	Final Test Concentration
1	HCoV-OC43	2×10^6 $TCID_{50}$/mL
2	HCoV-229E	2×10^6 $TCID_{50}$/mL
3	HCoV-NL63	2×10^6 $TCID_{50}$/mL
4	RSV	2×10^5 $TCID_{50}$/mL
5	Rotavirus	2×10^6 $TCID_{50}$/mL
6	MERS	1×10^6 $TCID_{50}$/mL
7	Adenovirus	2×10^6 $TCID_{50}$/mL
8	Norovirus	2×10^6 $TCID_{50}$/mL
9	Mycoplasma pneumonia	1.5×10^6 cfu/mL
10	Influenza A virus (H1N1)	2×10^7 $TCID_{50}$/mL
11	Influenza B Virus (Yamagata)	2×10^5 $TCID_{50}$/mL

11.4 Interference

The following interfering substances have no impact on SARS-CoV-2 Antigen Kit (Colloidal Gold).

No.	Interfering substance	Final Test Concentration
1	Phenylephrine	15% v/v
2	Oxymetazoline	15% v/v
3	Sodium chloride	5 mg/mL
4	Beclomethasone	5 ng/mL
5	Dexamethasone	0.5 μg/mL
6	Flunisolide	0.5 μg/mL
7	Triamcinolone acetonide	1 ng/mL
8	Budesonide	2.5 ng/mL
9	Mometasone	1 ng/mL
10	Fluticasone	2 ng/mL

11.5 Hook Effect

There is no hook effect at 600 μg/mL of SARS-CoV-2 nucleocapsid protein antigen.

12. Caution and Warning

12.1 For in vitro diagnostic use only.

12.2 If the package has been damaged, the label cannot be seen clearly or if the cartridge has expired, do not use the cartridge.

12.3 Extraction Buffer of different lots are not interchangeable. The results may not be reliable if reagents from different lots are mixed or used together.

12.4 The test cartridge is for single test and cannot be reused. Do not use expired cartridges.

12.5 Do not eat the desiccant.

12.6 All patient samples and human-sourced materials should be handled as if infectious following national biosafety guidelines.

12.7 The samples, used reagents and consumables are medical waste which are potentially hazardous and should be disposed of in accordance with national and local regulations.

13. Symbols

	Consult instructions for use	LOT	Lot number		Do not reuse
	Use-by date	IVD	In vitro diagnostic medical device		Temperature limit 2 - 30℃
	Manufacturer	Σ	Tests per kit		Avoid sunshine
	Date of manufacture	REF	Catalog number	EC REP	Authorized representative in the European Community
CE	This product complies with the requirements of the European Directive 98/79/EC				

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