CE IVD

One Step Test for SARS-CoV-2 Antigen

(Colloidal Gold)

User Manual REF CG2061

BACKGROUND

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.

As it is a novel disease diagnosis of which are being explored, please refer to the latest guidelines for diagnosis and treatment of COVID-19.

INTENDED USE

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab samples from patients suspected of COVID-19 infection by a healthcare provider.

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. This test is only intended for professional and laboratory use, not for home testing. Results from the test should not be used as the sole basis for diagnosis and exclusion of SARS-CoV-2 infection.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

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

PRINCIPLE

The test uses recombinant SARS-CoV-2 nucleocapsid protein (N protein) monoclonal antibody Ⅰ conjugated with colloidal gold coated on the sample pad, and another N protein monoclonal antibody Ⅱ coated on test line. After the samples has been applied to the test strip, the colloidal gold-labelled recombinant N protein monoclonal antibody Ⅰ bind with SARS-CoV-2 antigens in sample and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on test line by N protein monoclonal antibody Ⅱ. The color intensity of each test line increases in proportion to the amount of SARS-CoV-2 antigen in sample.

CONTENTS

1. A kit contains:

Package specifications: 25 tests/box.

1) Getein SARS-CoV-2 antigen test card in a sealed pouch with desiccant
2) Sample extraction solution: 25 tubes/box
3) Sampling swab: 25 pieces/box
4) Disposable pipette: 25 pieces/box
5) User manual: 1 piece/box

Note: Do not mix or interchange different batches of kits.

2. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad (coated with recombinant SARS-CoV-2 N protein monoclonal antibody Ⅰ), nitrocellulose membrane with test line (coated with SARS-CoV-2 N protein monoclonal antibody Ⅱ), the control line (coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

3. Sample extraction solution composition (400 μL/tube):

Phosphate buffered saline, protein stabilizer and surfactant.

STORAGE AND STABILITY

Store the test card at 4- 30°C with a valid period of 24 months.
Use the test card within 1 hour once the foil pouch is opened.
Store the sample extraction solution at 0-30°C with a valid period of 24 months.
Store the sample extraction solution at 2-8°C for better results.

PRECAUTIONS

1. Do not open pouches until ready to perform the test to protect the test cards from getting damp exposing in air for too long.
2. The test cards can be stored in room temperature with sealed pouches. And the test cards shored in low temperature should reach room temperature before testing.
3. There should be appropriate bio-safety assurance procedure for infectious sources or potential infectious sources. Some relevant precautions are showed below:

1) Wear disposable gloves to deal with samples, or sterilize reagents.
2) Sterilize spilled samples or reagents with sanitizer.
3) Sterilize and cope with all of samples, reagents and potential contaminant with relevant local regulations.

SPECIMEN COLLECTION AND PREPARATION

1. Sample should be ***human nasal swab sample***. Test samples immediately after collection for optimal test performance. Inadequate sample collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) .
https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.htm
2. It is recommended to use a flocked swab with a PP (polypropylene) rod as a sterile swab for sample collection.
3. Sample collection:

Carefully insert a sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Keep the swab in the nasal cavity for 15-30s, rotate the swab 3 times against the nasal wall then remove it from the nostril. If taking samples from two nostrils, use one swab each.

4. Nasal swab sample should be processed with sample diluent after collection. If testing is delayed, the sample should be stored in a dry, sterilized and strictly sealed plastic tube immediately, it can be stored up to 8 h at 2-8°C before testing.

TEST PROCEDURE

Read the manual carefully before using and operate according to the manual to avoid incorrect results.

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature (15-30°C) before test.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Sample pretreatment:

1) Take one tube of sample extraction solution, insert the nasal swab sample into the tube, and rotate the swab 10 times in the

solution to make the sample dissolve in the sample extraction solution as much as possible.

2) Squeeze the swab tip along the inner wall of the sample extraction tube 3 times to keep the liquid in the tube as much as possible before taking it out of the tube.

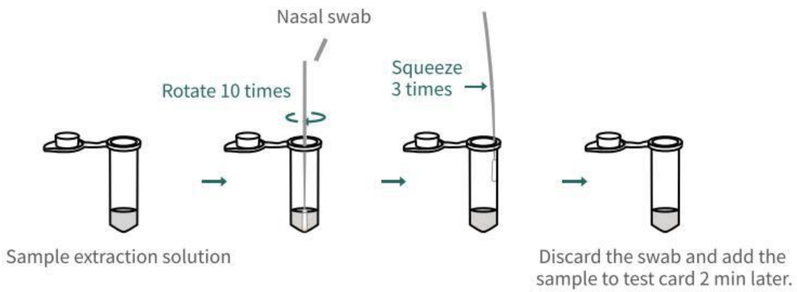
3) Discard the swab and add the sample to test card 2 min later.

6. Using sample transfer pipette, deliver ***100 uL*** of sample into the sample port on the test card.

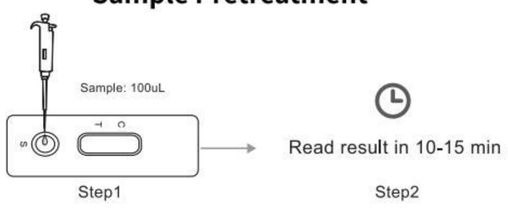
7. Read the result visually in ***10-15 min***.

Note:

Don't read results after ***20 min***. To avoid confusion, discard the test card after interpreting the result.



Sample Pretreatment



Test

TEST RESULTS

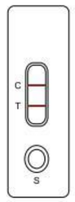
1. Valid Test

Positive (+):

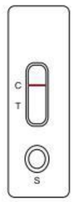
Two bands appear, one at the control area (C) and the other at the test line (T). The result indicates the presence of SARS-CoV-2 antigen.

Negative (-):

A single band appears at the control area (C) and no other band at test line. The result indicates that the sample does not contain SARS-CoV-2 antigen.



Positive



Negative

2. Invalid Test

If no band appears in the control area (C), the test result is invalid. The test should be repeated with a new test card and if the same situation reappears, please stop using this batch of products and contact your supplier.

Note:

1. Positive results indicate the presence of SARS-CoV-2 antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. A positive result does not rule out co-infections with other pathogens.
2. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management.

LIMITATIONS

1. The test is for in vitro diagnostic use only.
2. The test results of this kit are for clinical reference only. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment response.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980: 2008 and International Standard ISO 15223-1: 2016.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing One Step Test for SARS-CoV-2 Antigen (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

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