CE IVD COVID-19 Neutralizing Antibody Rapid Test Cassette（Colloidal Gold）

For professional use only.

SPECIFICATION

1Test/Kit, 20Tests/Kit， 25Tests/Kit, 40Tests/Kit

INTENDED USE

The COVID-19 Neutralizing Antibody Rapid Test Cassette（Colloidal Gold） is a rapid chromatographic immunoassay for the qualitative detection of neutralizing antibodies to COVID-19 in human whole blood, serum, or plasma as an aid in the diagnosis of the presence of neutralizing antibodies to COVID-19 .

INTRODUCTION

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.

The COVID-19 Neutralizing Antibody Rapid Test Cassette（Colloidal Gold） is a rapid test that utilizes a combination of S-RBD antigen coated colored particles for the detection of neutralizing antibodies to COVID-19 in human whole blood, serum, or plasma.

PRINCIPLE

The COVID-19 Neutralizing Antibody Rapid Test Cassette（Colloidal Gold） is a qualitative membrane based immunoassay for the detection of neutralizing antibodies to COVID-19 in whole blood, serum or plasma. The membrane is pre-coated with Angiotensin I Converting Enzyme 2 (ACE2) on the test line region of the strip. During testing, the whole blood, serum or plasma specimen reacts with S-RBD conjugated colloid gold. The mixture migrates upward on the membrane chromatographically by capillary action to react with ACE2 on the membrane and generate a colored line. Presence of this colored line indicates a negative result, while its absence indicates a positive result. To serve as a procedural control, a colored line will always change from Blue to Red in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions
Disposable pipettes	For adding specimens use
Buffer	Phosphate buffered saline and preservative
Package insert	For operation instruction

MATERIALS

Materials Provided

- Test devices
- Droppers
- Buffer
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Timer
- Centrifuge

PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
3. The extraction reagent solution contains a salt solution if the solution contacts the skin or eye, flush with copious amounts of water.
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. Read the entire procedure carefully prior to testing.
6. Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. If infection with a novel coronaviruses is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel coronaviruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ is available to receive and culture specimens.
8. Do not interchange or mix reagents from different lots.
9. Humidity and temperature can adversely affect results.
10. Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

1. The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Capillary Whole Blood

Wash the patient's hand then allow to dry. Massage the hand without touching the puncture. Puncture the skin with a sterile lancet. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site. Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube or hanging drops.

venous Whole Blood:

Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.

Plasma

Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture. Separate the plasma by centrifugation. Carefully withdraw the plasma into new pre-labeled tube.

Serum

Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture. Allow the blood to clot. Separate the serum by centrifugation. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

ASSAY PROCEDURE

Bring the specimen and test components to room temperature Mix the specimen well prior to assay once thawed. Place the test device on a clean, flat surface.

For capillary whole blood sample:

To use a capillary tube: Fill the capillary tube and **transfer approximately 50μL (or 2 drops) of fingerstick whole blood** specimen to the specimen well (S) of the test device, then add **1 drop (about 30 μL) of Sample Diluent** immediately into the sample well.

For whole blood sample:

Fill the dropper with the specimen then **transfer 2 drops (about 50 μL)** of specimen into the sample well. Making sure that there are no air bubbles. Then **transfer 1 drop (about 30 μL)** of Sample Diluent immediately into the sample well.

For Plasma/ Serum sample:

Fill the dropper with the specimen then **transfer 1 drop (about 25 μL)** of specimen into the sample well. Making sure that there are no air bubbles. Then **transfer 1 drop (about 30 μL)** of Sample Diluent immediately into the sample well.

Set up a timer. Read the result at 15 minutes. ***Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result***

INTERPRETATION OF ASSAY RESULT

POSITIVE RESULT:

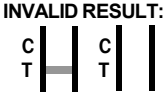
Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE RESULT:

Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

*NOTE: The intensity of the color in the test line region will vary depending on the concentration of neutralizing antibodies to COVID-19 in the specimen. Therefore, any shade of color in the test line region should be considered negative.

INVALID RESULT:



Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be disgarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.
2. **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative (provided upon request), to assure the proper performing of the assay.

PERFORMANCE CHARACTERISTICS

Twenty five samples confirmed positive for neutralization antibody with Microneutralization Assay from convalescent patients were evaluated with the COVID-19 Neutralizing Antibody Rapid Test Cassette（Colloidal Gold）.

One hundred and fifteen samples confirmed negative for neutralization antibody with Microneutralization Assay from the healthy population were evaluated with the COVID-19 Neutralizing Antibody Rapid Test Cassette（Colloidal Gold）.

Relative Sensitivity: 96.00% (88.32%~100.0%)
Relative Specificity: 99.13% (97.43%~100%)
Overall Agreement: 98.57% (96.61%~100%)
***95% Confidence**

		COVID-19 Neutralizing Antibody Rapid Test		
		+	-	**Total**
Microneutralization Assay	+	24	1	25

Interval	**(MNA)**	-	1	114	115
			25	115	140

Cross-reactivity

The COVID-19 Neutralizing Antibody Rapid Test Cassette（Colloidal Gold） has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAb, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV and HAMA positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to COVID-19 neutralizing antibody negative and spiked positive specimens.

Analytes	Conc.	Result	
		Negative Specimen	Spiked Positive Specimen
Acetaminophen	20 mg/dL	Negative	Positive
Acetylsalicylic Acid	20 mg/dL	Negative	Positive
Albumin	2 g/dL	Negative	Positive
Ascorbic Acid	2g/dL	Negative	Positive
Bilirubin	1g/dL	Negative	Positive
Caffeine	20 mg/dL	Negative	Positive
Creatine	200mg/dl	Negative	Positive
Ethanol	1%	Negative	Positive
Gentisic Acid	20 mg/dL	Negative	Positive
Hemoglobin	1000mg/dl	Negative	Positive
Oxalic Acid	60mg/dL	Negative	Positive
Uric acid	20mg/ml	Negative	Positive

None of the substances at the concentration tested interfered in the assay.

LIMITATIONS OF TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of COVID-19 vaccination. Failure to follow the procedure may give inaccurate results.
2. The COVID-19 Neutralizing antibody Rapid Test is limited to the qualitative detection of antibodies to COVID-19 Vaccine in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative or non-reactive result for an individual subject indicates absence of detectable COVID-19 Vaccine antibodies. However, a negative or non-reactive test result does not preclude the possibility of COVID-19 vaccination.
4. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
6. The continued presence or absence of neutralizing antibodies cannot be used to determine the success or failure of the vaccine.
7. Results from immunosuppressed patients should be interpreted with caution.
8. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
9. Not for the screening of donated blood.

Hangzhou Heo Technology Co.,Ltd.
Address:Room201，Building 3, No.2073 Jinchang Road,
Liangzhu Street, Yuhang District, Hangzhou, China ,
Postcode：311113
Tel:0086-571-87352763 E-mail:52558565@qq.com

EC REP Lotus NL B. V. Address:
Koningin Julianaplein 10, l e Verd, 2595AA, The Hague
, Netherlands.
E-mail: Peter@lotusnl.com Tel：+31644168999

Index of Symbol

	Consult instructions for use	4℃ 30℃	Store between 4-30°C		Use by
IVD	For in vitro Diagnostic use only		Do not reuse	LOT	Lot Number
	Manufacturer	Σ	Tests per kit	REF	Catalog No
EC REP	European union authorized		Keep dry		Don't use the product when the package
	Biological risks	CE	The product meets the basic requirements of European in vitro. diagnostic medical devices directive 98/79/EC		

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