ClearEpi™ SARS-CoV-2 Neutralising Antibody Rapid Test

Product Insert

Product Name

ClearEpi™ SARS-CoV-2 Neutralising Antibody Rapid Test

Packaging Specifications

20 Tests / Box, 50 Tests / Box

Intended Use

The ClearEpi™ SARS-CoV-2 Neutralising Antibody Rapid Test is intended for qualitative detection of circulating human IgG neutralising antibodies in serum or plasma that are capable of binding to SARS-CoV-2 spike protein and blocking ACE2 binding.

The ClearEpi™ SARS-CoV-2 Neutralising Antibody Rapid Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2 and should not be used to diagnose or exclude acute SARS-CoV-2 infection.

At this time, it is unknown for how long antibodies persist following infection and if the presence of neutralising antibodies confers protective immunity. Testing is limited to professional use and is not intended for at home testing.

Background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a Betacoronavirus that is enveloped, non-segmented and positive sense RNA virus that is the causative agent of coronavirus disease 2019 (COVID-19). The first outbreak was reported in December 2019 and spread rapidly worldwide having been designated as a pandemic by the World Health Organization (WHO) in March 2020.

SARS-CoV-2 consist of the genome and proteins required for its structure and replication. The spike protein (S) contains a receptor binding domain (RBD) that binds to its receptor human angiotensin-converting enzyme 2 (ACE2) on the surface of cells resulting in membrane fusion, viral entry and infection. Infection with SARS-CoV-2 stimulates an immune response resulting in production of SARS-CoV-2 specific antibodies. A subset of these antibodies can block cell entry and replication of the virus and are termed neutralising antibodies.

Principle of Test

The ClearEpi™ SARS-CoV-2 Neutralising Antibody Rapid Test is a competitive lateral flow assay that uses the principles of colloidal gold immunochromatography for qualitative detection of neutralising antibody against SARS-CoV-2. The principle of the test is to mimic viral neutralization. In the absence of neutralising antibodies, colloidal gold (Au) conjugated recombinant SARS-CoV-2 RBD fragment (Au-RBD) binds with the human ACE2 receptor protein (ACE2) to generate a red colored line (red test line). If neutralising antibodies are present in the patient sample, the protein-protein interaction between Au-RBD and ACE2 can be blocked.

Kit Components

Component Name	Description
Test Cassette	Aluminum foil bag, desiccant, test strip and PVC plate. The test strip consists of absorbent pad, nitrocellulose membrane, sample pad, colloidal gold marker pad and PVC plate. The nitrocellulose membrane neutralising antibody test line (nAb Test line) is coated with recombinant ACE2. The C line (Control line) is coated with goat anti-chicken antibody, and the conjugate pad contains colloidal gold conjugated recombinant RBD and chicken IgY antibody.
Pipette Dropper	Packaged in aluminum foil bag along with test cassette.

Note: The components in the kit with different lots cannot be used interchangeably.

Storage Conditions and Validity Period

The kit should be stored at 4 – 30 ˚C in its sealed aluminum foil packaging. The validity is for 12 months from the date of manufacturing (refer to packaging for expiration information).

It is recommended that the individual test kit is opened in an environment of 22 – 26 ˚C with a relative humidity of 54 – 58%. Once opened, use test cassette within 1 hour.

Specimen Collection and Handling

1. The kit is intended for testing of human serum or plasma.
2. Specimens should be collected by standard protocols.
3. Hemolyzed, or hyperlipidemic blood samples should not be tested.
4. Collect plasma samples using a EDTA anticoagulant blood tube. Samples should be run on the same day as collection. If not, serum/plasma samples can be stored at 2 — 8 ˚C for 7 days, or at – 20 ˚C or lower for 24 days. Avoid repeated freezing and thawing of samples.

5. Bring the sample to room temperature (18 – 28 ˚C) before processing. Frozen samples must be completely thawed, and mixed well before testing. Avoid repeated freezing and thawing. Specimens containing visible particulate matter should be clarified by centrifugation at 3,000g x 10 min before testing.

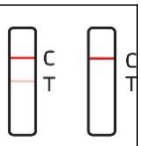
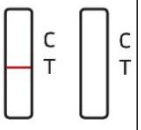
Test Procedure

Please read instructions carefully before use.

1. Bring the Test Cassette and Sample to room temperature before testing. Conduct test at room temperature.
2. Tear off the foil pouch, take out the test cassette and place it on a clean and leveled surface.
3. Add three (3) drops of sample to the sample well of the cassette using the provided dropper.
4. Read results after 15 minutes. DO NOT read the results after 20 minutes. Results read after 20 minutes are invalid.

Interpretation of Test Results

The test results are to be interpreted as the following (Figure 1):

Positive for SARS-CoV-2 neutralising antibody: The Test line (T) is faint or absent and the Control line (C) is colored.	
Negative for SARS-CoV-2 neutralising antibody: The Test line (T) and Control line (C) are colored.	
Invalid: There is no colored Control line (C) that appears. The results are invalid regardless of the Test line (T) coloration.	

Limitations of Test Methods

1. The test is designed for qualitative detection of SARS-CoV-2 neutralising antibodies.
2. A negative result can occur if the titer of the antibodies against SARS-CoV-2 are below the sensitivity of the test kit or do not have neutralising capacity.
3. The test results can only be used to determine the production of neutralising antibodies, and should not be used to diagnose or exclude acute SARS-CoV-2 infection.

Performance Characteristics

1. Clinical performance:

100 samples were tested in the clinical agreement study, including 50 convalescent specimens, and 50 SARS-CoV-2 neutralising antibody negative specimens. The test results of samples from this product were compared with a validated in vitro pseudotyped virus neutralisation assay. This comparison gave the following results:

		Pseudotyped virus neutralisation assay		Total
		Positive	Negative	
ClearEpi™ SARS-CoV-2 Neutralising Antibody Rapid Test	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

Sensitivity: 50/50 x 100% = 100%

Specificity: 50/50 x 100% = 100%

Total Coincidence Rate: (50+50)/100 x 100% = 100%

2. Cross-reactivity: There was no cross-reactivity with specimens containing antibodies to other viruses that may cause symptoms similar to SARS-CoV-2 infection, and to other organisms that may cause respiratory diseases.

Cross-reactant	Specimen number
Anti-Human coronavirus NL63	5
Anti-Human coronavirus HKU1	5
Anti-Human coronavirus 229E	5
Anti-Human coronavirus OC43	5
Anti-MERS-CoV	5
Anti-SARS-CoV	5
Anti-Influenza A virus	5
Anti-Influenza B virus	5
Anti-Adenovirus	5
Anti-Respiratory syncytial virus	5

3. Interfering substances: The concentrations of triglycerides 24 mmol/L, hemoglobin 9 mg/mL, bilirubin 500 μmol/L, and human albumin 46 mg/mL have no effect on the test results.

Precautions

1. Follow universal precautions when handling samples.
2. Proper sample collections, storage and transport are essential for correct results.
3. Do not use kit past its expiration date.
4. Do not use if packaging or foil is damaged. After opening the aluminum foil immediately proceed to performing the test.
5. Ensure the sample and test are at room temperature before initiating the test.
6. Professionally trained operators are required to carry out the test. Before using the kit, please read the instructions carefully and perform the test in accordance.
7. Do not reuse the test cassette.
8. All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.
9. It is essential to ensure that test laboratories adhere to appropriate biosafety practices.
10. National guidelines on the laboratory biosafety should be followed in all circumstances.

Warnings

1. A negative result can occur if the titer of the antibodies against SARS-CoV-2 virus present in the specimen is below the sensitivity of the kit.
2. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
3. Dispose of all specimens and materials used to perform the test as biohazardous waste.
4. Do not perform the test in a room with strong airflow, i.e. an electric fan or strong air-conditioning.

Explanation of labels

IVD	In Vitro Diagnostic Use	REF	Catalog #	LOT	Batch Number
	Expiry Date		Manufacturing Date		Manufacturer
	Do Not Reuse	30°C 4°C	Store Between 4~30°C		Keep Away From Sunlight
	Keep Dry		See Instruction For Use	EC REP	EU Authorized Representative
CE	CE mark				

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Basic Information

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CE IVD

EC	REP

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Company Registration: 200913076M

Production Date and Expiration Date

See the label.

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