
(FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSIS !)

Human Anti-SARS-CoV-2 Neutralization Antibody Lateral Flow Assay Kit

Catalog No: E-HD-C104

20T/40T

Version Number:	V3.0
Replace version:	V2.0
Revision Date:	2021.09.03

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help.

Toll-free: 1-888-852-8623 Tel: 1-832-243-6086 Fax: 1-832-243-6017

Email: techsupport@elabscience.com

Website: www.vetassay-elab.com

Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.

Test principle

The Anti-SARS-CoV-2 Neutralization Antibody Test Kit is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 neutralizing antibodies in serum, plasma and whole blood. The sample is dropped into the sample well, and chromatography is performed under the capillary effect. The SARS-CoV-2 neutralizing antibodies in the sample combined with the colloidal gold-labeled SARS-CoV-2 spike protein (SP), then spread to the test area. It is captured by coated SP subunit RBD-NTD-CTD, to form a complex and gather in the test area (T line). The quality control area is coated with mouse anti-chicken IgY, and the colloidal gold-labeled chicken IgY is captured to form a complex and aggregate in the quality control area (C line). If the C line does not show color, it indicates that the result is invalid, and this sample needs to be tested again.

Kit components

Item	Specification
Detection Card	20T/40T
Sample Diluent	20/40 vials
Dropper	20/40 pieces
Manual	1 copy

Note: All reagent bottle caps must be tightened to prevent evaporation and microbial pollution.

Notes

1. Do not reuse.
2. Handle all samples cautiously as if they may contain infectious agents. Observe established precautions against microbiological hazards throughout the process and properly handle samples in accordance with standard procedures.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
4. The used tests, samples and potentially contaminated should be discarded according to the local regulation.
5. Unreasonable sampling, transportation and handling, or low virus content in the sample will lead to false negative

Storage and expiry date

Storage: Store at 4-30°C. With cool and dry environment.

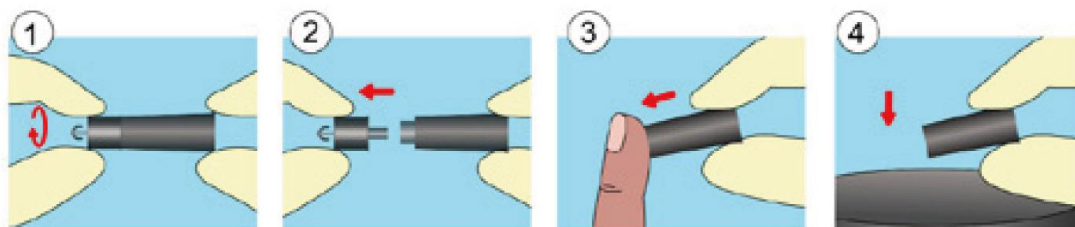
Expiry date: expiration date is on the packing box.

Requirements of sample

1. Rotate the twisting cap slightly.
2. Pull out the twisting cap.

3. Place the device on the puncture site and push to start.
4. Discard lancet into a sharps container.
5. Press lightly on the finger towards the puncture site to obtain adequate blood sample.

NOTE: the lancet is for single use only.



NOTE: This figure is only used as a reference.

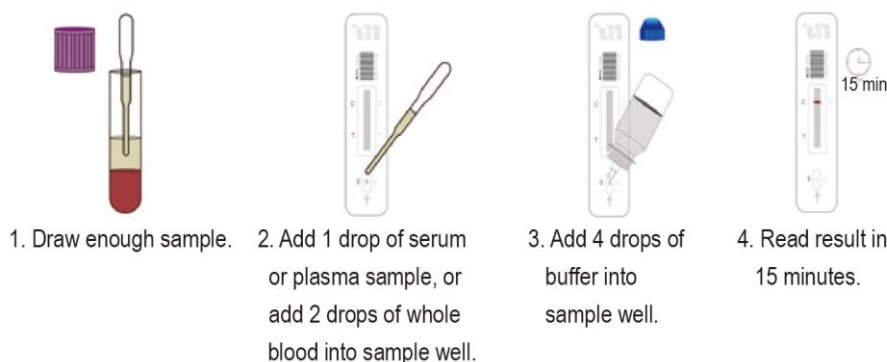
Assay procedure

Bring the pouch to room temperature before opening. Take the cassette from the sealed pouch and use it within ONE hour.

1. Place the cassette on a clean and flat surface.
2. For Serum or Plasma samples: add 1 drop (approximately 30 μ L) of sample into sample well, then add 4 drops of buffer and start the timer. Avoid trapping air bubbles into the sample well.
3. For Whole Blood samples: add 2 drops (approximately 50 μ L) of whole blood sample into sample well, then add 4 drops of buffer as soon as possible and start the timer. Avoid trapping air bubbles into the sample well.
4. Note: It's recommended to add 1 more drop of buffer if the liquid flows too slowly.
5. Wait for the colored line(s) to appear. The result shall be read at 15 minutes. The result is valid within 30 minutes.

NOTE: It is recommended to use serum or plasma as the priority sample types for testing.

NOTE: Micropipette is recommended to draw and add sample during the whole procedure.

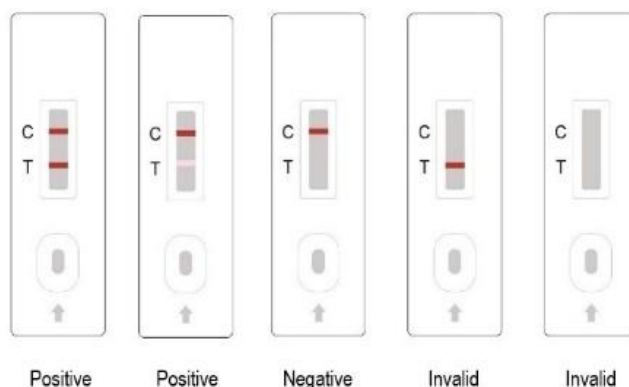


* Micropipette is recommended

NOTE: This figure is only used as a reference.

Interpretation of results

1. Positive: The presence of purple on the test line (T) and the control line (C) indicates positive result (it is also considered positive if the T line is only slightly purple colored).
2. Negative: The presence of purple only on the control line (C) while no color on the test line (T) indicates a negative result.
3. Invalid: The control line (C) is invisible after the test, the result is considered invalid and it is recommended to be repeated after reading the instruction for use again.



Note: this figure is only used as a reference.

Limitations of this test method

1. The test could be performed using serum, plasma samples and whole blood.
2. The presence of binding antibodies does not guarantee the presence of neutralizing antibodies, and the levels can not be consistent.
3. The half-life of binding antibody and neutralizing antibody is different, and the decline rate may be different.
4. Anti-SARS-CoV-2 Neutralization Antibody Test Kit will only indicate the presence of SARS-CoV-2 neutralization antibodies in the sample and should not be used as the sole basis, and should be combined with other test methods, as live virus and pseudovirus neutralizing antibodies assay.
5. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other data.