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

Human SARS-CoV-2 Antigen Lateral Flow Assay Kit (Nasal swab)

Catalog No: E-HD-C098

20T/40T

Version Number:	V6.3.5
Replace version:	V6.3.4
Revision Date:	2022.05.40

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

This kit adopts the sandwich method and the technical principle of colloidal gold immunochromatography to qualitatively determine the SARS-CoV-2 antigen (nucleocapsid (N) protein antigen). During the test, the sample is dropped into the sample well, and chromatography is performed under the capillary effect. The SARS-CoV-2 antigen in the sample combined with the colloidal gold-labeled SARS-CoV-2 monoclonal antibody I, and then spread to the test area. It is captured by another coated antibody (SARS-CoV-2 monoclonal antibody II), to form a complex and gather in the test area (T line). The quality control area is coated with the goat anti-mouse antibody, and the colloidal gold-labeled antibody 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 Treatment Solution	20/40 vials
Swab	20/40 pieces
Manual	1 copy

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

Notes

1. Please read the instruction carefully before test, and should operate in strict accordance with the instruction. Different batches of reagents and treatment solution should not be mixed.
2. Sample collection, storage and testing should be in strict accordance with the novel coronavirus related testing technical guide and biosafety guide etc.; the remaining sample disposal solution, swabs, test cassette and all wastes must be disposed of laboratory biosafety requirements.
3. It is recommended to use ethyl ether, 75% ethanol, chlorine-containing disinfectant, peracetic acid, chloroform and other solvents to soak the waste generated during the detection process, inactivate the virus, and treat the waste as the infectious material.
4. The test cassette is ready to use, valid within 1 hour after opening, and the test cassette cannot be reused.
5. The test results are for reference only.
6. If you have any questions or suggestions during use, please contact the manufacturer.

Storage and expiry date

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

Expiry date: expiration date is on the packing box.

Requirements of sample

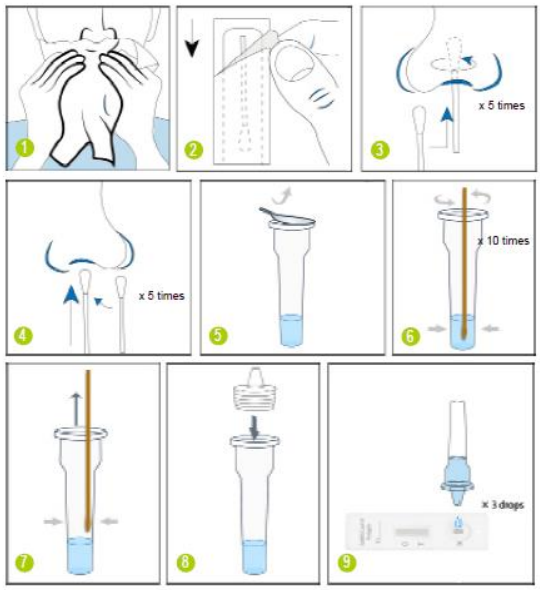
Before use, please read the instructions carefully and operate in strict accordance with the instructions:

1. Fig. 1: Thoroughly blow and wipe your nose to clear thick mucus (snot).
2. Fig. 2: Open the package with the swab. Be careful not to touch the swab head.
3. Fig. 3: Insert the swab into one nostril just until the soft tip is no longer visible (up to 2.5cm). Rotate it in a circle around the inside edge of your nostril 5 times.
4. Fig. 4: Then Use the same soft tip to repeat the previous step in the second nostril 5 times.
5. Fig. 5: Uncover the sealing membrane of the sample treatment solution.
6. Fig. 6: Put the swab into sampling tube, make sure the swab soaked in the solution. Rotate and squeeze the swab on the wall and bottom of the tube 10 times, squeeze the swab tip along the inner wall of the sample tube to keep solution in the tube as much as possible.
7. Fig. 7: Remove the swab and put it into biohazard bag.
8. Fig. 8: Cover the dropper tip on the tube.

   It is recommended to test immediately after sample collection and processing. If the test cannot be performed timely, the processed samples can be stored at 2-8℃ for 48h.

Assay procedure

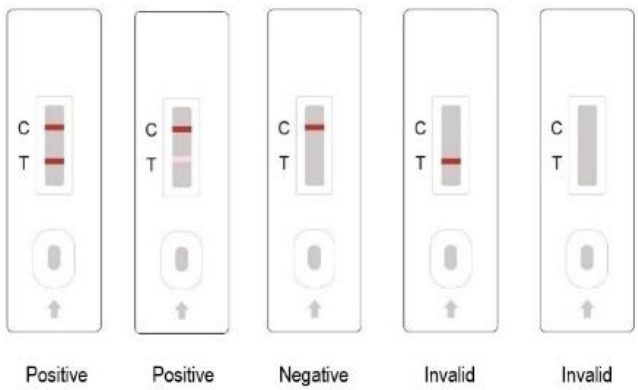
1. Bring the pouch to room temperature before use, the test package should only be opened before the test is performed.
2. Take out the cassette, put it on a horizontal table.
3. Fig. 9: Add 3 drops of the processed sample vertically into the sample well and start the timer.
4. Observe the result after 15 minutes, the result is valid within 30 minutes, read results after 30 minutes is invalid.



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. Read the instructions carefully.
2. Do not use the product after the expiry date.
3. Do not use the product if the bag is damaged or the seal is broken.
4. Store the test kit between 2℃ -30℃ in the original sealed bag. Do not freeze.

5. The product should be used at room temperature (15℃ to 30℃). If the product has been stored in a cooler area (less than 15℃), leave it 30 minutes at normal room temperature before use.
6. Treat all samples as potentially infective agent.
7. Slice the nose several times before sampling.
8. Insufficient or inaccurate sampling, storage and transport may lead to inaccurate test results.
9. Correct sampling is the most important step in the test process. Make sure collect enough sample material (nasal secretion) with the swab.
10. Samples should be test as soon as possible after sampling.
11. Do not replace the components in this kit with components in other kits.
12. Too many or too few drops of the treatment solution may result in an invalid or incorrect test result.
13. Warning: If the extraction solution comes into contact with the skin or eyes, wash the affected area with plenty of water. If irritation is found, contact your doctor.
14. Wash hands thoroughly after handling.
15. The test kit can be disposed of the normal household waste in accordance with local regulations.
16. The SARS-CoV-2 antigen test should not be used as a sole measure to diagnose, rule out or assess the status of infection.
17. This test does not determine the etiology of the respiratory infection caused by micro-organisms other than the SARSCoV-2 virus.