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

Human SARS-CoV-2 & Influenza Antigen Combo Lateral Flow Assay Kit

Catalog No: E-HD-C101

20T/40T

Version Number:	V2.2.2
Replace version:	V2.2.1
Revision Date:	2022.08.26

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 Flu A & B Antigen Rapid Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in oropharyngeal swab, nasal swab and nasopharyngeal swab samples. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against Influenza virus A and B; the reaction membrane contains the secondary antibodies either for virus A or for B. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If influenza A presents in the sample, a complex formed between the anti-influenza A conjugate and the virus will be captured by the specific anti-influenza A monoclonal antibodies coated on the A region (A). If the sample contains influenza B, a complex formed between the anti-influenza B conjugate and the virus will be captured by the specific anti-influenza B monoclonal antibodies coated on the B region (B).

Results appear at 10 minutes in the form of a red line that develops on the membrane. To serve as a procedural control, a red line will always appear in the control region(C) indicating that proper volume of sample has been added and membrane wicking has occurred.

The SARS-CoV-2 Antigen Rapid Test Cassette is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in nasopharyngeal (NP) swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

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. The test device should remain in the sealed pouch until use.
2. Do not use kit past its expiration date.
3. Swabs, tubes and test devices are for single use only.
4. The extraction buffer contains a solution with a preservative (0.05% Proclin 300). If solution comes in contact with the skin or eyes, flush with ample volumes of water.
5. Do not interchange or mix components from different kit lots.
6. When collecting an oropharyngeal swab, nasal swab or nasopharyngeal swab sample, use the suitable swab supplied in the kit.
7. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
8. Specimens must be processed as indicated in the SPECIMEN COLLECTION and SAMPLE TREATMENT sections of this Product Insert. Failure to follow the instructions for use can result in inaccurate results.
9. To obtain accurate results, do not use visually bloody or overly viscous samples.
10. Proper laboratory safety techniques should be followed at all times. Proper handling and disposal methods should be established by the laboratory in accordance with local regulatory requirements.
11. Humidity and temperature can adversely affect results.
12. Used testing materials should be discarded in accordance with local regulation.

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

It is recommended to use a rayon/flocking swab with a PP (polypropylene) rod as a sterile swab for sample collection.

Samples should be treated as soon as possible after collection. If samples cannot be treated immediately, it should be stored in a dry, sterilized and tightly sealed plastic tube, which can be stored within 12 hours at 2-8 ℃.

Sample collection

1. Oropharyngeal swab: The head of the person is slightly tilted, with mouth wide open, exposing the pharyngeal tonsils on both sides. Use the swab to gently wipe the tonsils on both sides for at least 3 times, and then wipe the posterior pharyngeal wall up and down at least 3 times.
2. Nasal swab: Prior to collecting the nasal swab, the patient should be instructed to blow their nose. Carefully insert the swab into the nostril with 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), and rotate the swab against the nasal wall several times and then remove it from the nostril.

3. Nasopharyngeal swab: Carefully insert the swab into the nostril with the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx (in case of reflex cough, stop for 1 minute).

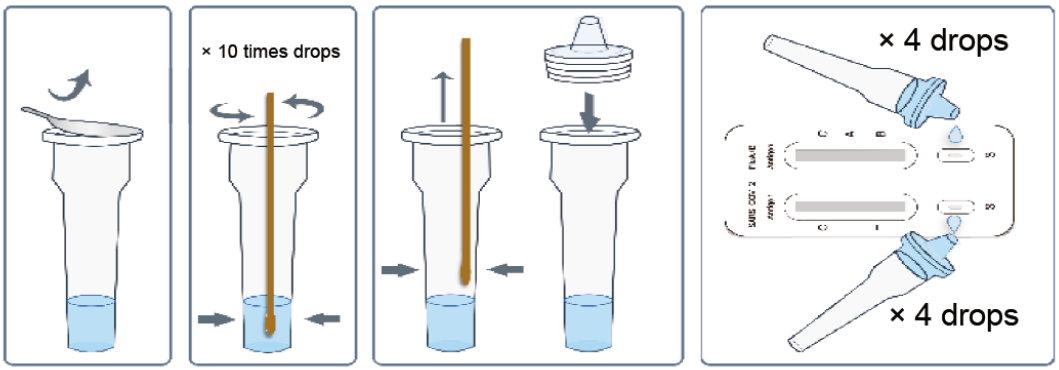
Sample treatment

1. Uncover the sealing membrane of the sample treatment solution.
2. Put the swab into sampling tube, make sure the swab soaked in the solution.
3. 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.
4. Remove the swab and cover the tube cap. It is recommended to test immediately after sample collectionand processing. If the test cannot be performed timely, the processed samples can be stored at 2-8℃ for 48h.

Assay procedure

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

1. Allow the test device, test sample and buffer to equilibrate to room temperature (15-30 ℃) prior to testing.
2. Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
3. Insert a nozzle with filter into the sample extraction tube tightly.
4. Reverse the sample extraction tube, and add 4 drops (about 100 μL) of test sample by squeezing the extracted.
5. Solution tube into the each sample well (s).
6. Wait for the colored band(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 30 minutes.

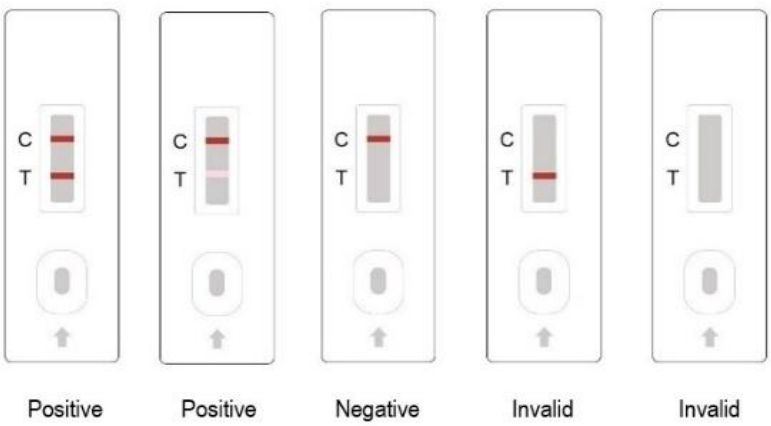


NOTE: This figure is only used as a reference.

Interpretation of results

For SARS-CoV-2 Antigen Rapid Test

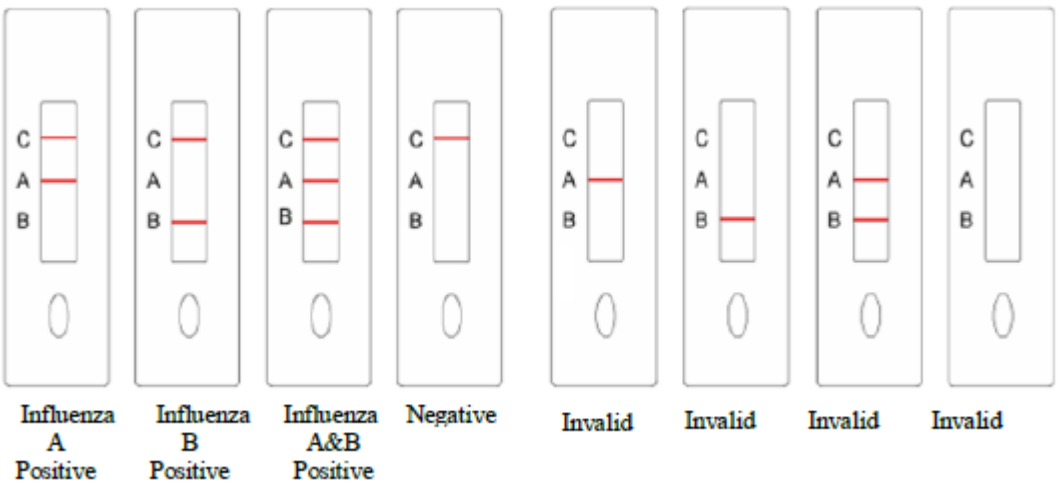
1. Positive: The presence of two lines as control line (C) and test line (T) within the result window indicates a positive result.
2. Negative: The presence of only control line (C) within the result window indicates a negative result.
3. Invalid: If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.



For Flu A&B Antigen Rapid Test

1. Influenza virus A antigen Positive: Two lines appear colors, one in test line (A line) and the other in quality control line (C line).
2. Influenza virus B antigen Positive: Two lines appear colors, one in test line (B line) and the other in quality control line (C line).
3. Influenza virus A&B antigen Positive: Three lines appear colors, two in test line (A line and B line), and one in quality control line (C line).

4. Negative: The test line (A line and B line) does not appear color, only the quality control line (C line) appears color.
5. Invalid: The quality control line (C line) does not appear color, which means that the test is invalid and the test should be repeated.



Note:

a) The intensity of the color in the A and/or B test line region(s) will vary depending on the concentration of Influenza virus A and/or B antigen in the sample. Therefore, any shade of color in the A and/or B test line region(s) should be considered positive.

b) This reagent contains a quality control process. When C line appears color, it indicates that the operation is correct and effective, otherwise is invalid.

c) Standard Laboratory Practice (GLP) laboratories are recommended to conduct quality control in accordance with laboratory operating procedures under the guidance of national or local regulations.

d) The figure above is only used as a reference.

Limitations of this test method

1. SARS-CoV-2 & Influenza Antigen Combo Test Kit should only be used for the qualitative detection of influenza A, B and/or SARS-CoV-2 in oropharyngeal swab, nasal swab and nasopharyngeal swab specimens.
2. The etiology of respiratory infection caused by microorganisms other than influenza A, B or SARS-CoV-2 will not be established with this test.
3. The SARS-CoV-2 & Influenza Antigen Combo Test Kit is capable of detecting both viable and non-viable influenza and SARS-CoV-2 particles. The performance of the SARS-CoV-2 & Influenza Antigen Combo Rapid Test Kit depends on antigen load and may not correlate with cell culture performed on the same specimen.
4. If the test result is negative and symptoms persist, additional testing using other methods is recommended. A negative result does not at anytime rule out the presence of influenza A, B or SARS-

CoV-2 viral antigens in specimen, as they may be present below the minimum detection level of the test.

5. Inadequate or inappropriate specimen collection, storage, and transport may yield false negative test result.
6. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
7. Although this test has been shown to detect cultured avian influenza viruses, including avian influenza A subtype H5N1 virus, the performance characteristics of this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown.
8. Performance characteristics for influenza A were established when influenza A/H3 and A/H1 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.
9. Positive and negative predictive values are highly dependent on prevalence. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.
10. Positive test results do not rule out co-infections with other pathogens.
11. The substance the kit detected was SARS-CoV-2 nucleocapsid protein (NP). The variation of new coronavirus mutant B.1.1.7 (SARS-CoV-2 VOC 202012/01) is mainly in spike protein receptor binding domain (RBD). There was no affection for diagnostic after mutation. So this kit could be used to detect the SARS-CoV-2 mutant, but could NOT distinguish the mutant from SARS.