PathoCatch™ COVID-19 NAb Detection Lateral Flow Test Device

(Qualitative detection of neutralizing antibody (NAb) of SARS CoV-2 in human serum/plasma)

Mylab Discovery solutions | ACCELBIO

Version 1.0
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INTENDED USE.

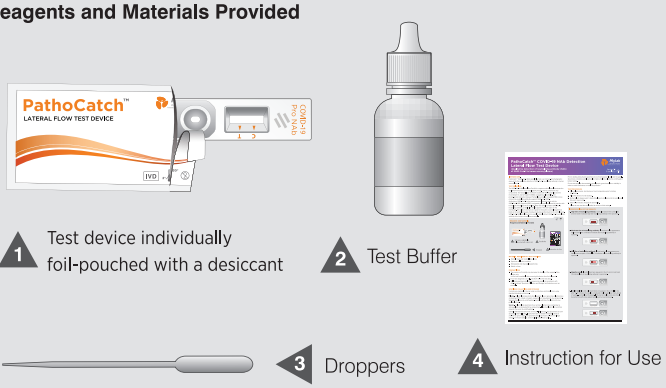
PathoCatch™ SARS-CoV-2 NAb Lateral Flow Test is an immune-chromatographic assay kit for the qualitative detection of SARS-CoV-2 neutralizing antibody in human serum/plasma.

TEST PRINCIPLE

The SARS-CoV-2 NAb lateral flow Test Kit is a capture method lateral flow detection tool, which mimics the virus neutralization process. The kit contains two key components: the nitrocellulose membrane coated with Anti-human IgG and the recombinant S1 and S2 fragment (RBD) conjugated gold particles. The protein-protein interaction between Human IgG and gold conjugated RBD can be mimiced by neutralizing antibodies against SARS-CoV-2 RBD.
Antibodies of SARS-CoV-2 in the specimens are allowed to react with the SARS-CoV-2 RBD fragment (RBD) conjugated gold particle followed by reaction with human IgG immobilized in the test line. When the sample contains SARS-CoV-2 neutralizing antibody, a visible line should appear in the test region on the membrane. The solution continues to migrate to encounter a control reagent that binds to the control conjugate, thereby producing another band in the control region. SARS-CoV-2 NAb lateral flow Test is useful to directly detect SARS-CoV-2 neutralizing antibody from human serum/plasma samples.

REAGENT AND MATERIAL

Reagents and Materials Provided



MATERIAL REQUIRED BUT NOT PROVIDED:

1. Medical mask and medical latex gloves
2. Specimen collection container
3. Micropipette and disposable pipette tips
4. Watch or timer

PRECAUTIONS

1. The presence of humidity may decrease the stability of the reagents. Thus, please carry
   out the test immediately after removing the device from the foil pouch.
2. For in vitro diagnostic use only. DO NOT re-use the test device.
3. Collected specimen should be prepared as sample in accordance with after-mentioned "Specimen Collection and Storage" and tested as soon as possible.

SPECIMEN COLLECTION AND STORAGE

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

Plasma:- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer) by venipuncture. 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 venipuncture. Allow the blood to clot, and then separate the serum by centrifugation.

Carefully withdraw the serum into a new pre-labeled tube. Test specimens as soon as possible after collecting. If specimens are not tested immediately store at 2°C-8°C for up to 5 days. The specimens should be frozen at - 20°C for longer storage. For frozen samples, 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

TEST PROCEDURE

1. Place all specimens, test devices at room temperature prior to testing (15-30min).
2. Place the device on a flat surface.
3. By the help of dropper add 1 drops (25 μl) serum or plasma into the sample well [S] and 2 drops buffer.
4. After 10-20 minutes, interpret the test results.

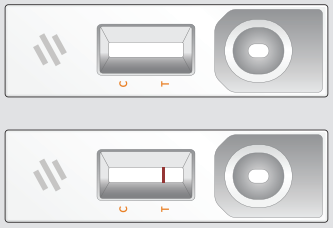
   Please do not read the results after 30 minutes of this testing.

INTERPRETATION OF THE RESULTS

1. **Detection of Neutralizing Antibodies:** Both Colour Bands in the Control & Test region Indicate 'detection of Neutralizing Antibodies.

4. **Negative result:** Absence of Colour Band in Test region while presence of Colour band in the Control region Indicate 'non-detection of Neutralizing Antibodies.

5. **Invalid result:** If a red color band does not appear in the control line (C) after 10-20 minutes, the result is considered invalid regardless of any shade of a pink-to-red test line (T) appears. If the test is invalid, a new test should be performed with a new patient sample and a new test device.



STORAGE & EXPIRATION

1. PathoCatch™ SARS-CoV-2 NAb Lateral Flow Test kit should be stored between 2 to 30 °C.
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity

- Detection limits: 10 ng/ml
- Cross-reactivity: A low titer sample was diluted 1:100 to a serum or plasma sample containing antibodies reactive to one of following pathogens were tested along with unspiked samples in duplicate. No false positivity or false negativity was found: HBV, HCV, HIV-1&2, Syphilis Dengue Ag&Ab However, there were no cross-reactivities of MERS-coronavirus, Human coronavirus (NL63), Human coronavirus (229E), Human coronavirus (OC43), Adeno virus type 1, Adeno virus type 2, Influenza A (H1N1), Influenza A (H3N2), Influenza B, Respiratory syncytial virus type A, Respiratory syncytial virus type B, Streptococcus group A, Streptococcus group B.

GLOSSARY OF SYMBOL

EC REP	Authorized Representative in the European Community	CE	CE mark European Conformity		Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Use By or Expiration Date		Tests per Kit		Manufacturer
	Store between 2-30 °C	IVD	For in vitro Diagnostic use only		Do not reuse		Do Not Use If Damaged

LIMITATIONS OF THE TEST

1. This test is designed for qualitative detection. Test result should not be the sole basis for clinical diagnosis and treatment.
2. The user of this kit is advised to carefully read and understand the package insert. Strict adherence to the manual is necessary to obtain reliable test results.
3. A negative result can occur if the titer of antibodies against the SARS-CoV-2 virus present in the specimen is below the sensitivity of the kit.
4. If symptoms persist and the result from the SARS-CoV-2 neutralization test is negative, it is recommended to collect a new sample from the patient a few days later and test it again.
5. PathoCatch™ SARS-CoV-2 NAb Lateral Flow Test is designed for the primary test of Neutralising Antibodies against the SARS-CoV-2 Virus and is provided for use by clinical laboratories or healthcare workers for point-of-care testing, and also to track immunity after vaccinations.

Mylab Discovery solutions Translating Discovery to Delivery

Manufactured by

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