SARS-CoV-2 Antibody Test (Lateral Flow Method)

Manual

【Product name】

Common name: SARS-CoV-2 Antibody Detection Kit (colloidal gold method)

【Packing specifications】

Card type: 1 test / bag, 10 tests / box, 20 tests / box, 50 tests / box.

【Expected usage】

SARS-CoV-2 Antibody Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgM & IgG antibody in human whole blood, serum or plasma sample. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.

The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.

For in vitro diagnostic use only. For professional use only.

【Inspection principle】

This kit is based on the principle of capture immunoassay for determination of SARS-CoV-2 IgG/IgM antibodies in human whole blood, serum and plasma. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the SARS-CoV-2 antigen-dye conjugate and flows across the pre-coated membrane. When the SARS-CoV-2 antibodies level in the specimen is at or above the target cutoff (the detection limit of the test), the antibodies bound to the antigen-dye conjugate are captured by anti-human IgG antibody and anti-human μ chain antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the SARS-CoV-2 antibody level in the specimen is zero or below the target cutoff, there is not a visible colored band in the Test Region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

【PRECAUTION】

1. This kit is for *in vitro* diagnostic use only.

2. All specimens should be treated as capable of transmitting diseases. Use appropriate precautions in the collection, handling, storage and disposal of patient samples and used kit contents. And follow biosafety level 2 or higher guidelines. *whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (containing EDTA, Heparin or Citrated sodium).* ***Other anticoagulants have not been validated and may give incorrect result.***

3. Centrifuge whole blood and separate the plasma from red blood cell as soon as possible to avoid hemolysis.

4. Test should be performed within 8 hours after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum or plasma specimens may be stored at 2ºC～8ºC for up to 3 days prior to testing. Serum or plasma specimens may be stored at -20ºC for up to 9 days.

Note: Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Severe hemolytic or heat-inactivated specimens are not recommended.

【Main composition】

Test card, sample diluent (drop bottle).

1. Test card: The test card consists of a SARS-CoV-2 antibody test strip and a plastic box; the test strip consists of a nitrocellulose membrane, a sample pad, a binding pad, absorbent paper, and a PVC board. Among them, the nitrocellulose membrane is coated with anti-μ chain antibody, anti-human IgG antibody and anti-rabbit IgG polyclonal antibody, and the binding pad contains SARS-CoV-2 recombinant antigen and rabbit IgG.

2. Sample Diluent (Drop Bottle)

Note: The components in different batches of the kit cannot be mixed to avoid erroneous results.

【Storage conditions and validity】

Store at 2 ℃ ～ 30 ℃, the validity period is tentatively set for 12 months.

After opening the aluminum foil bag, the test card should be used as soon as possible within 30 minutes. The sample diluent should be capped immediately after opening and placed in a cool place. Please use it within the validity period.

Production date: See product label.

Expiration date: See product label.

【Sample requirements】

Serum, plasma, and venous whole blood samples.

Serum / plasma sample collection: Serum and plasma should be separated as soon as possible after blood collection to avoid hemolysis. The separated serum and plasma should be tested as soon as possible within 8 hours. If it cannot be used in a timely manner, it should be stored at 2 ° C to 8 ° C for 3 days. If it is more than 3 days, it should be stored at -20 ° C and stored for 9 days, pay attention to return to room temperature before testing to avoid repeated freezing and thawing. Severe hemolytic and heat-inactivated samples are not recommended.

Collection of venous whole blood: Use anticoagulation tube to collect blood, or add anticoagulant in the blood collection tube (recommended to use heparin, EDTA salt, sodium citrate for anticoagulation). It can be stored at room temperature for 8 hours. If it cannot be detected immediately, it can be stored at 2 ~ 8 ℃ for 7 days. Venous whole blood samples over 7 days are not suitable for this reagent.

【Testing method】

Please read the instruction manual carefully before testing. The samples to be tested, detection reagents and other materials used for testing need to be equilibrated to room temperature. The test should be performed at room temperature.

1. Remove the test card by opening it along the tear of the aluminum foil bag and lay it flat.

2. Add **10 μL** of serum / plasma OR **20 μL** of whole blood sample to the sample well (the end near the membrane) of the test card, and then add about 120 μL (about 3 drops) dilution buffer card sample well to the sample well (the end far away from the membrane).

3. 15 minutes observation showed the results, and the results shown after 20 minutes had no clinical significance.

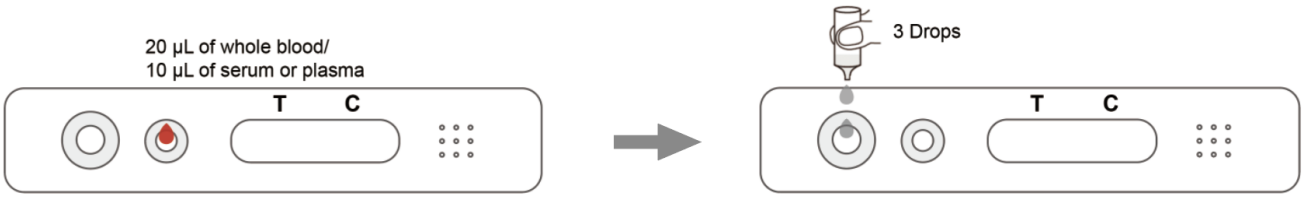

Figure 1

(The pattern is for reference only, the actual product shall prevail)

【Interpretation of test results】

Positive result:

Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the SARS-CoV-2 antibodies in the specimen.

Negative result:

Colored band appears at control line (C) only. It indicates that the concentration of the SARS-CoV-2 antibodies is zero or below the detection limit of the test.

Invalid result:

No colored band appear at control line (C) no matter whether there is a colored band appear at test line (T) or not. It indicates an invalid result for the SARS-CoV-2 antibodies in the specimen.

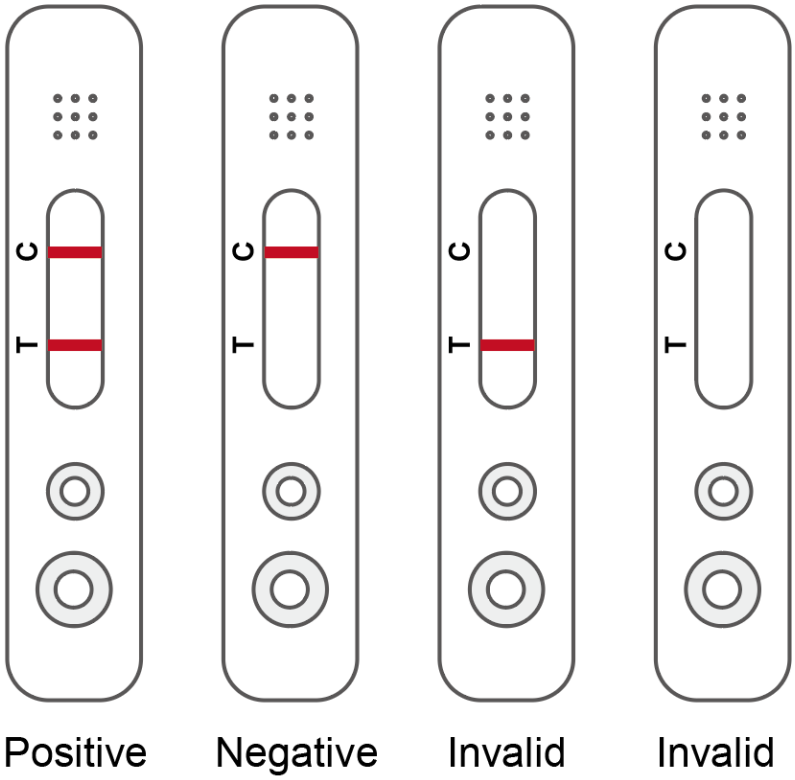

Figure 2

(The pattern is for reference only, the actual product shall prevail)

【Sensitivity and Specificity】

596 clinical case samples which include 361 confirmed case samples* and 235 confirmed excluded case samples*, were obtained for testing, and then compared the test results between SARS-CoV-2 Antibody Test (Lateral Flow Method) and the confirmed case samples.

Sensitivity: 86.43% (95% CI:82.51%-89.58%)

Specificity:99.57% (95% CI:97.63%-99.92%)

Total agreement: 91.61% (95% CI:89.10%-93.58%)

Cross reactivity: No cross reaction with the following targets.

Parainfluenza virus antibody
Influenza A antibody
Influenza B antibody
Chlamydia pneumonia antibody
Mycoplasma pneumoniae antibody
Adenovirus antibody
Respiratory syncytial virus antibody
Hepatitis B surface antibody
Hepatitis C virus antibody
Treponema pallidum antibody
HIV antibody
EB virus antibody
Measles virus antibody
Cytomegalovirus antibody
Enterovirus type 71 antibody
Mumps antibody
Varicella-zoster virus positive sample