dAb ImmunoTech
COVID-19 IgG/IgM Dual Antibody Test
(Immunochromatographic Assay)

For Emergency Use Authorization (EUA) use only

Please carefully read the instructions before testing
Do not open sealed foil pouch before using

PROTOCOL FOR COVID-19 (SARS-COV-2) IgG/IgM DUAL ANTIBODY TEST

(Code: dAb-LFI-P01)

The dAb ImmunoTech COVID-19 IgG/IgM Dual Antibody Test Kit based on the principle of Lateral Flow ImmunoAssay (LFIA), also known as the immunochromatographic assay, or strip test to detect the COVID-19 IgG/IgM antibodies in human serum, plasma and whole blood specimens. The whole workflow is shown in Figure 1 below.

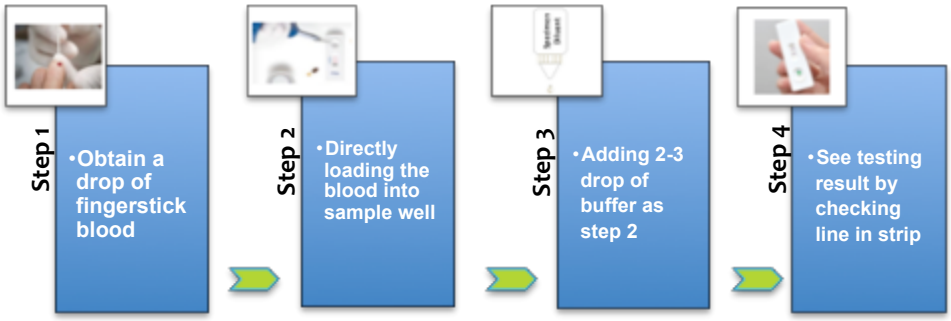

Fig.1. Schematic illustration of testing procedure for COVID19 IgG/IgM Dual Antibody Kit

Here describes all simple test steps in detail in order to do test correctly.

1. Bring kit and specimens to room temperature (20-30°C) before beginning testing. It is essential that all kit components are at room temperature before use.

2. The Test Card should be used in 1 hour after remove from foil pouch. The kit does not need to be installed, can be ready for use. Using capillary sampler, obtain 20μL of fingerstick whole blood specimen.
3. Label a test tube for each specimen or control to be tested.
4. Place the required number of Test Cards on a flat surface with the patient ID label facing toward the operator. Peel away the foil seals and discard them. Label the Card to correspond with the test tubes and the specimens to be tested.
5. Quickly invert the Specimen Diluent bottle to thoroughly mix just prior to loading the assay buffer.
6. Take 10μL of serum or plasma or whole blood specimen and load to the specimen well of Test cassette. Note: Use of this test kit with specimens other than those specifically approved for use with this test kit may result in inaccurate test results.
7. Then immediately add two full eyedroppers of Specimen Diluent (80 μL) to specimen well as above. Note: With the eyedropper in the Specimen Diluent, hold vertically and squeeze the bulb completely, draw Specimen Diluent up into the eyedropper, and gently expel all of the Specimen Diluent into the test well. Repeat this sequence to deliver the second full eyedropper for more tests. Note: Do not allow the tip of the pipet to touch any part of the tube or the Specimen Diluent in the tube. Discard the used pipet tip or Transfer Pipet into the biohazardous waste.
8. Wait for 5-10 minutes for reactive line appearances.
9. Carefully read and analyze the results by viewing the detection window (See also Fig.2).
10. If no color C line develops in the Stripe, regardless of color development and intensity anywhere else on the membrane, the results are INVALID (See

examples 3A-3D in Fig.2). Repeat the assay, and if results are still invalid collect a fresh sample or test by another method. Do not report any results.

11. If color C line develops in the Stripe, the results are VALID (See examples 1A-1C and 2A in Fig.2).

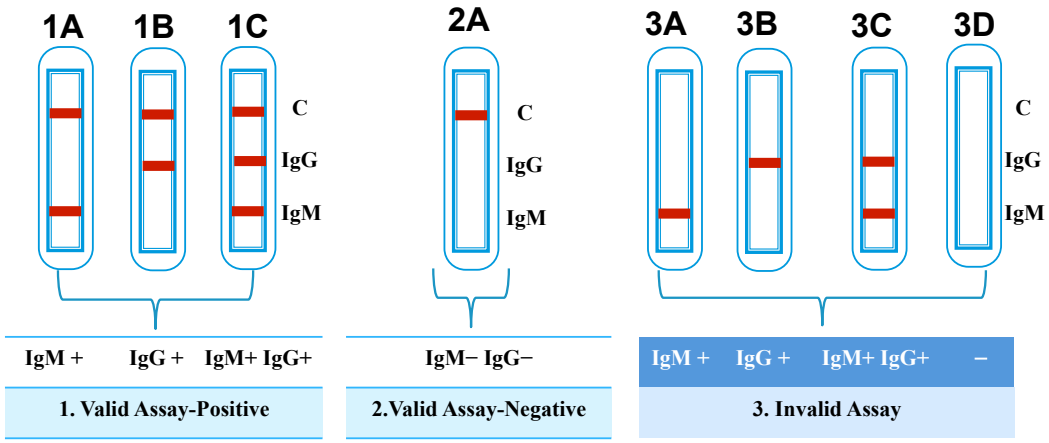

Fig.2. The three type of typical results are shown throughout assay

12. Record all results and Report any results.
13. All wastes should be treated as potential infectious materials.

For any technical questions and concerns:

- Please visit website www.dabimmunotech.com
- Please reach us for technical questions and concerns via email, technical@dabimmunotech.com or by phone, 470-566-1748.

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(Immunochromatographic Assay)

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Solution For Immunoassay and In Vitro Immunodiagnostics

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