Fingerstick Antibody Test

LIMITATIONS

1. This product is only used for qualitative testing.
2. Limited by the amount of detection, the negative result may be caused by the antibody concentration lower than the detection limit of the product.
3. Due to the limit of methodology, when the sample contains higher triglyceride, bilirubin or hemolysis, it will affect the chromatogram of the sample on the nitrocellulose membrane, resulting in erroneous detection results. Therefore, samples containing any of the factor should not be used for testing:

⊖Severe lipemia: the concentration of triglycerides exceeds 4000mg/dl;
⊜Jaundice: the concentration of bilirubin exceeds 40mg/dl;
⊛Severe hemolysis: the concentration of hemoglobin exceeds 600mg/dl;

4. Human Anti-Mouse antibodies (HAMA) may be produced in human blood who had been treated with Mouse-derived monoclonal antibody immunotherapy. This assay has been developed in a special way to minimize the impact of these antibodies. However, care must be taken when patients are known to contain these antibodies.

PRECAUTIONS

1. Do not test samples with severe hemolysis, lipemia and jaundice.
2. Do not use the reagent that is damaged in single package and out of expiration date.
3. Please strictly follow the instructions. When the test start, it cannot be terminated. If not, it must be retested.
4. Invalid results must be retested.
5. All samples and various wastes should be treated as biological contaminated material.
6. The desiccant in the aluminum foil bag should not be taken orally.
7. Use a clean dropper for each sample. After use, please treat it as biological contaminated material.
8. This test has not been reviewed by the FDA.
9. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
10. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
11. Positive results may be due to past or present infection with non- SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

For a reliable result, the rapid test must be performed by (care) emergency services.