



Instructions on the Use and Evaluation of COVID-19(SARS-CoV-2) Ab Test Kit

With the development of COVID-19(SARS-CoV-2) Ab Test Kit and the increase in the number of test samples, the use and evaluation of the product by Anhui Deepblue are summarized as follows for the reference of customers to use and evaluate the test kit correctly.

1. According to the *Covid-19 Diagnosis and Treatment Plan (trial seventh edition)* released by the National Health Commission, serological test showed that "Novel Coronavirus(SARS-CoV-2) specific IgM Antibodies were mostly positive in 3-5 days after onset, and the titer of IgG Antibody in the recovery period was 4 times higher than that in the acute phase." Our company has also proved in a large number of samples that the positive rate of IgM and IgG in Antibody detection of patients in the early stage of infection is low. **Therefore, the test kit is not recommended to be used as the sole diagnostic indicator for patients in the early stage of infection, and the positive detection rate cannot be guaranteed in the early stage of infection.**

2. According to the *Covid-19 Diagnosis and Treatment Plan (trial seventh edition)*, "the titer of IgG Antibody in the recovery stage was 4 times higher than that in the acute stage."Our company failed to collect the serum from the onset of the disease to the recovery period for accurate testing, and could not provide the obvious rule of IgG increased from detection to 4 times. However, the detection rate of IgG increased significantly from the early, middle to recovery periods.

3. According to the information on the approval of IGG/IGM antibody kit by National Medical Products Administration(NMPA), **it is clearly stipulated that this antibody test kit is the supplemental protocol of the PCR based methods, it is not recommended for general healthy population screening at the moment, and it is not a sole diagnostic indicator for new coronavirus infections.**

4. To sum up, **we suggest that the customers should seek a professional laboratory to do the verification evaluation of COVID-19(SARS-CoV-2) Ab Test Kits from Anhui Deepblue, and should test the patients who are confirmed positive by nucleic acid and have symptoms of infection for more than 7 days, so as to count the positive detection rate. If possible, it also can be used to test the patients who has clinical symptoms of infection but the nucleic acid testing is negative, this can effectively make up for the situation of nucleic acid missing inspection.**

5. When using COVID-19(SARS-CoV-2) Ab Test Kit from Anhui Deepblue, it is recommended that the customer should select the patients with symptoms of infection more than 7 days for detection. If either IgM or IgG is positive, it can be confirmed by combining with the nucleic acid detection results

6. Our company collects all user feedbacks and monitors clinical adverse reactions to ensure that the products are safe and effective. The theoretical basis of the products refers to the relevant content of the *Covid-19 Diagnosis and Treatment Plan (trial seventh edition)*.

7. Solemnly remind all partners to accurately and scientifically guide users in the clinical application of products. For any problems during use, please contact the company's corporate



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email Anhui Deepblue<ahslylkj2019@163.com> or the corresponding sales staff in order to ensure professional guidance and assistance in the first place.

8. The COVID-19 Ab rapid test kits from Anhui Deepblue are not yet complete and systematical in testing effectiveness of antibody production after infection in different countries, different populations, and different virus beads. Our company welcomes different users from different countries to provide these tests to different professional institutions for evaluation, trial, and clinical verification reports. We welcome and look forward to scientific discussions, verification and research of these tests with scientists and doctors in different countries and different laboratories in all around the world, in order to look forward to making due contributions to enterprises in the face of the disaster !

9. Attached manuals and interpretation

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