

## **From Relia Biotechnologies LTD.**

Relia has been engaged in the manufacture of POCT immunochromatographic products for 19 years. We were established in the United States in 2001 and are currently manufacture in China. We have the registration certificate required by China and CE certificate.

The COVID-19 IgM / IgG joint detection kit is produced using an immunochromatographic method. The development and production of this reagent occurred during the urgent period of China's coronavirus outbreak. The R&D period was extremely short (within 1 month) as you may understand the reason. The mass manufacture and marketing took 3 weeks. Overall the product came out in a very short period of time. (compare with our other products, the overall time is 3-5 years.)

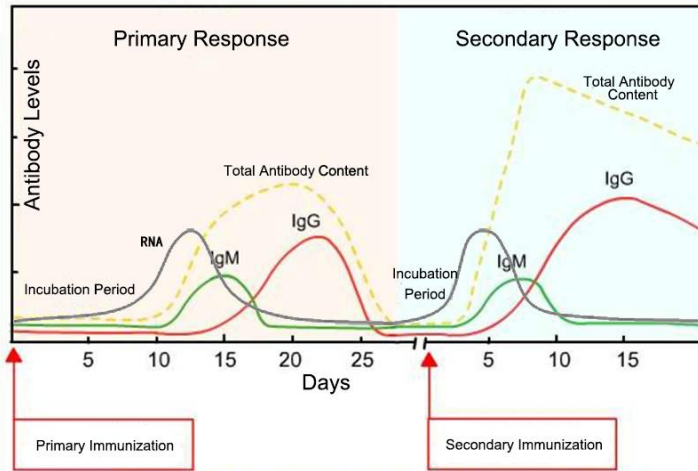
For the product design: The ACE2 binding region (RBD) of the SARS-CoV-2 Spike Protein expressed by human embryonic kidney cells (HEK293) is used as a labeled antigen to ensure that the glycosylation of the recombinant antigen is closer to the actual state of the SARS-CoV-2 Spike Protein to keep the immunoassay will run with good performance.

### **Product advantages: (The purposes we designed this product)**

Our product is fast and easy to operate. The result is about 15 minutes. It can be used for screening of a large number of people ( vs. nucleic acid detection >2 hours and complex operation) with visual observation. In order to prevent personal various in result reading, we can provide the Reader&Timer-this is an optional item to control the experiment accuracy with extra cost. Most of customers won't pick the Reader&Timer because they just want the easy operation. The Reader has been on market over 10 years with CE.

### **Based on the detection of the two results of antibody IgG / IgM, our goals are:**

- Crowd screening and finding a certain percentage of recessive infections to further isolate and do therapy.
  - Supplementary testing for nucleic acid "empty window period" in infected populations. (See graph below)
  - Can perform some joint screening such as body temperature, CBC, etc. before other urgent surgeries (e.g. the outbreak in one neurosurgery in China) or other important events.
- Etc.



\*Remark: common antigen-antibody conversion diagram

### **Product limitations**

- The rapid detection reagent is based on a very short incubation time, and the sensitivity of the reaction is theoretically weaker than the general reaction reagent over 2 hours.
- Whole blood, which we designed as above, is available. However there might be the minor variation from serum / plasma due to hemolysis interference.
- Visual reading may be different for early infected samples. The instrument reading will be more accurate. The instrument is just an optional item. The suspected early samples can be confirmed by nucleic acid tests.
- Our product was developed under emergency time. Our clinical analysis data has limited

In this emergency period, the birth of our products is the one of the limited tools that can be applied for Coronavirus detection. Although the birth process of the reagent does not conform to our usual R & D process, our efforts are to help humanity overcome this terrible disease. The price that our factory sells to Channels is also reasonable based on cost. We also required that the dealers should not make huge profits. After all, the purpose of the birth of the reagent is to help humans control the Coronavirus spreading.