Jiangsu Dablood Pharmaceutical CO, LtD.
86-5 Shuanggao Road, Gubai Town,
Gaochun District
Nanjing, China
March 25, 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
CDRH-EUA-Templates@fda.hhs.gov

Re:Manufacturer FDA Emergency Use Authorization (EUA) Notification Letter

To whom it may concern:

Pursuant to the recent FDA Guidance Document (Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health EmergencySection), Jiangsu Dablood Pharmaceutical CO, LtD. is notifying the FDA that it has selected Predictive Laboratories, Inc. (Predictive) as its agent to distribute our validated**"Diagnostic Kit for the Detection of IgM/IgG Antibody to SARS-CoV-2 Test"**that will be distributed in the United States under the brand name of **"Assurance AB™ COVID-19 IgM/IgG Rapid Antibody Test".**

Assurance AB™ COVID-19 IgM/IgG Rapid Antibody Test is a SARS-CoV-2 specific IgM/IgG rapid antibody test intended for the qualitative detection of the presence of IgM/IgG antibodies in human serum, plasma and/or whole blood specimens collected from individuals who display signs and symptoms of COVID-19, were exposed to an infected individual with COVID-19 or want qualitative information of their IgM or IgG SARS-CoV-2 antibodies.

It is our understanding that Predictive Laboratories, Inc. is CLIA certified and CAP accredited, and as our representative, Predictive has notified the FDA of its intent to distribute the Assurance AB test,direct to patients for in-home use. In order to meet the requirements under the FDA guidance, Predictive Laboratories is submitting the Emergency Use Authorization (EUA) on behalf of the manufacturer.

As the manufacturer, we are notifying the FDA that we have completed validation of the assay utilizing cross-reactivity/analytical specificity, class specificity and clinical agreement with positive human specimens to determine sensitivity/PPA and specificity/NPA.

Additionally, we understand that Predictive is aware of the FDA Guidance and is appropriately distributing this product for in-home use with the following restrictions:

- This test has not been reviewed by the FDA.

- 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.
- 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.
- 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.

If you have any additional questions, please feel free to contact our representative at the following address:

Predictive Laboratories, Inc.
2749 East Parleys Way, Suite 100
Salt Lake City, Utah 84109
1-888-585-1551
Attn: Lesa Nelson, Chief Laboratory Officer

Sincerely yours,

Vice General Manager

Jiangsu Dablood Pharmaceutical CO, LtD.