FDA Grants Hardy Diagnostics Emergency Use Authorization (EUA) for a Rapid Antibody Test Kit for COVID-19

Strategic partnership with Autobio Diagnostics Co., Ltd enables Hardy Diagnostics to become exclusive U.S. supplier of a new rapid, one-step lateral flow assay that detects IgM and IgG antibodies to the SARS-CoV-2 virus

SANTA MARIA, Calif., April 28, 2020 (Newswire.com) - Hardy Diagnostics, a medical device manufacturer based in Santa Maria, California, announced FDA EUA approval on April 24th for a new in vitro diagnostic medical device: Anti-SARS-CoV-2 Rapid Test (Cat. No. RTA0203).

This immunoassay is intended for qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human plasma or serum. This test was developed by Autobio Diagnostics Co., Ltd (603658, Shanghai), a publicly-traded, major microbiology medical device manufacturer, based in Zhengzhou, China. Through this partnership, Hardy Diagnostics and Autobio have begun to open supply chains to exclusively deliver this rapid test to the United States. This rapid market deployment of a new in vitro diagnostic medical device was made possible through the FDA Emergency Use Authorization (EUA) program. This program is used in times of crisis, such as the current COVID-19 pandemic.

IgM antibodies are generated initially by the body as a result of infection at about the time symptoms appear. IgM antibodies will dissipate within approximately one month. IgG antibodies are generated by the body about one week after symptoms appear and last for an extended amount of time.

By using a patient’s serum or plasma specimen, the Anti-SARS-CoV-2 Rapid Test offers a turnaround time of only 15 minutes. This simple to use test requires no equipment or special expertise or training to implement.

“We are incredibly proud of the work our partners in China have accomplished,” said Andre Hsiung, Director of Technical Services at Hardy Diagnostics. “Because Autobio quickly developed this technology and because the FDA allowed Emergency Use Authorization, we will be able to more effectively leverage our sales network to get this product out to where it is needed the most.”

The Anti-SARS-CoV-2 Rapid Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human plasma from anticoagulated
blood (Heparin/ EDTA/ sodium citrate) or serum from individuals with signs and symptoms of infection who are suspected of COVID-19 infection. The Anti-SARS-CoV-2 Rapid Test is also intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform moderate or high complexity tests. The Anti-SARS-CoV-2 Rapid Test is intended for use by clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures.

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in recent contact with the virus, due to the lag time between exposure and the patient's antibody response.

This test should not be used as the sole basis for patient management decisions. Test results must be combined with clinical observations, patient history, and epidemiological information.

Follow-up testing with a molecular diagnostic test should be considered to confirm the infection status. This test is not intended for the screening of donated blood.

This test will be useful in identifying asymptomatic and mildly symptomatic carriers of the SARS-CoV-2 virus. It will also be helpful in identifying persons who were infected by the virus previously, but may not have been properly diagnosed.

Studies suggest that antibody testing for COVID-19 may provide useful information in managing the infected patient, making determinations as to immune status, and preventing the future spreading of the disease.

About Hardy Diagnostics:

Hardy Diagnostics is an FDA-licensed manufacturer of medical devices for microbiological testing with an ISO 13485 certified Quality Management System. The company manufactures over 2,700 products for the culture and identification of bacteria and fungi from its California and Ohio manufacturing facilities. Hardy Diagnostics is headquartered in Santa Maria, California, and services over 10,000 laboratories across the nation. In 2015, the company became 100% employee-owned. The company was founded in 1980 by Jay Hardy, a Clinical Laboratory Scientist from Santa Barbara, California. Hardy Diagnostics maintains nine distribution centers nationwide and exports products to over 80 foreign distributors. Hardy Diagnostics’ mission is to produce and distribute the finest products for the detection of microorganisms and partner with its laboratory customers to diagnose and prevent disease. For more information on products and services and a complete profile on the company’s
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About Hardy Diagnostics

At Hardy Diagnostics, a 100% employee owned ISO 13485 certified and FDA licensed medical device manufacturer; every team member has a personal interest in ensuring only the highest quality service and products are provided for its valued customers.

http://hardydiagnostics.com/our-company/

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