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ICMR approves HiMedia-Syngene COVID-19 antibody test kit

09 September 2020 | News

The ELISafe 19 antibody test kit has a sensitivity of 100% and specificity of 99%

HiMedia Laboratories, a bioscience company with expertise in media manufacturing and diagnostics, and Syngene International, an integrated research and development services company, have collaborated to manufacture ELISafe 19™, an IgG based ELISA test kit for COVID-19 now approved by the Indian Council of Medical Research (ICMR). The ELISafe 19™ antibody test kit has a sensitivity of 100% and specificity of 99%.

Commenting on the news, Dr. Vishal G. Warke, Director R&D, Cell Culture and Immunology, HiMedia Laboratories, said, “We appreciate the prompt response of the ICMR in reviewing and approving the ELISafe 19™ kit. The kit is a result of a unique combination of skills: Syngene’s expertise in viral research and HiMedia’s ability to manufacture and commercialise the product. The kit is made in India for the benefit of Indian hospitals and patients and it will play a significant role in testing for SARS-CoV-2 antibodies facilitating tracking of the progression of infection and immunity to future infection.”

Dr. Mahesh Bhalgat, Chief Operating Officer, Syngene International Ltd. added, “Since the declaration of the COVID-19 pandemic, there has been an urgent need for simple and specific testing tools that not only detect the presence of the coronavirus but also contribute to the surveillance of the immune response to the virus. The ELISafe 19™ testing kit fills this gap. This type of serological detection of SARS-CoV-2 antibodies will generate invaluable data and provide the basis for epidemiological studies of immunity in the community: a significant advance in the management of this highly infectious disease in India.”

The use of an IgG antibody test offers the opportunity to study and understand the percentage of population exposed to SARS-CoV-2 infection. The ELISafe19™ kit is intended for qualitative detection of IgG SARS-CoV-2 antibodies using the standard ELISA method on human serum/plasma samples. The kit will also help to identify the IgG immune status of COVID-19 recovered patients so that their plasma can be used for therapeutics.

Syngene developed the IgG based ELISA at its research facility in Bengaluru and partnered with HiMedia to manufacture and commercialise the product. HiMedia is seeking approval from the Central Drugs Standard Control Organisation (CDSCO) and will launch the kits once approval is in place.