# DST funded start-up’s Electrochemical ELISA test would help rapid & accurate estimation of total antibody concentration of COVID 19

Posted On: 22 MAY 2021 9:39AM by PIB Delhi

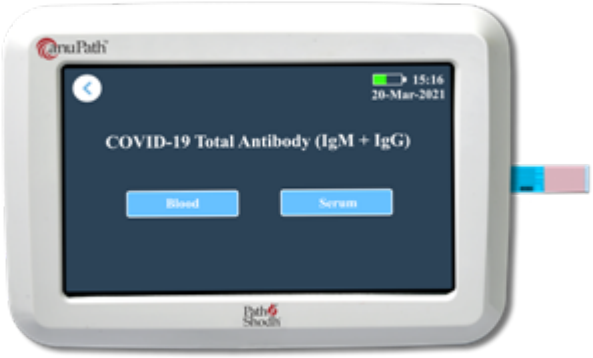
A Bangalore-based start-up has developed a novel, point-of-care Electrochemical ELISA test that enables fast and accurate estimation of total antibody concentration of COVID 19 in clinical samples.

PathShodh Healthcare, the start-up incubated at the Society for Innovation and Development (SID), Indian Institute of Science (IISc), has made a very significant breakthrough to develop the first of its kind, semi-quantitative Electrochemical ELISA test for COVID-19 IgM and IgG antibodies. While *Qualitative* analysis detects constituent elements in the sample, *semiquantitative* analysis gives an approximate *estimation* of their concentrations. PathShodh has received the license to manufacture for sale from the Central Drugs Standard Control Organisation (CDSCO), after validation at Translational Health Science and Technology Institute (THSTI), Faridabad, as per the requirements of Indian Council of Medical Research (ICMR).

This novel technology and product was supported by the Department of Science and Technology (DST), Government of India, under its initiative on Centre for Augmenting WAR with COVID-19 Health Crisis (CAWACH). The effort was coordinated through SINE at IIT Bombay and IKP Knowledge Park, Hyderabad.

The novelty of the technology is based on the measurement of electrochemical redox activity of IgM and IgG antibodies specific to SARS-CoV-2 Spike Glycoprotein (S1). The S1 protein hosts the Receptor Binding Domain (RBD), which latches to the ACE2 receptors on the cells before infection. Hence the antibody tests targeting S1 spike protein are more representative of an immune response against infection compared to other antibody tests targeting Nucleocapcid (N) protein. PathShodh’s technique is also a major departure from the qualitative rapid antibody tests in the market, which are primarily based on lateral flow ELISA technique. The technology has been protected through US and Indian patent applications.

“The capability to quantify the COVID-19 antibody concentration will be very crucial in estimating the temporal decay of antibodies, and hence its possible impact on immunity against recurrence of infection. On a related note, this technique will also play a very big role in elucidating seroconversion response to COVID-19 vaccines, and thereby play a supporting role in vaccination programs in future,” said Prof. Navakanta Bhat, Dean, Division of Interdisciplinary Sciences and Professor, Centre for Nano Science and Engineering, IISc, who is also the co-founder of PathShodh Healthcare.




The test kit come in two parts. One is the handheld analyser which reads the blood sample and gives a detailed report. The other is a test strip where a drop of blood from one's fingertip is inserted into the device. The handheld device provides the results within five minutes, the results of which can be downloaded on your mobile phone. It has been developed, leveraging PathShodh's *Lab-on-Palm* platform "anuPath$^{TM}$", which interfaces with disposable test strips functionalized with immunoreceptors specific to COVID-19 antibodies. As the results are automatically displayed by the handheld reader, there are no subjective errors due to the manual readout of test results. The other unique features of this technology include onboard memory to store more than 1 lakh real-time test results, touch screen display, rechargeable battery, Bluetooth connectivity to smart phone and cloud storage, capabilities to map the patient data to Aadhar number, and the possibility of connecting test data through APIs to Aarogya Setu.

"The test is not only useful as a routine sero-survey tool to establish a previous infection, but even more importantly, as a quantifier of antibodies to address such critical questions as the rate of fading of antibodies, and in general, understanding of biological responses that depend on the quantity of antibodies, such as the efficacy of vaccines in generating antibodies and vaccine breakthroughs," said Prof Ashutosh Sharma, Secretary, DST.

According to Dr. Vinay Kumar, CEO, and co-founder of PathShodh, "This novel technology can detect the COVID-19 antibodies all the way down to nanomolar concentration. It can work with venous or capillary (finger prick) whole blood sample as well as serum sample. We plan to deploy the product in the market in the next couple of weeks. PathShodh's current production capacity is about 1 lakh tests per month, and we can scale this up further by augmenting the manufacturing infrastructure."

PathShodh's multi-analyte *Lab-on-Palm* platform "anuPath$^{TM}$", is capable of performing early diagnosis and management of diabetes, liver disease, anaemia, and malnutrition. With COVID-19 serology test development, the start-up has expanded its product line beyond Non-Communicable Diseases (NCD) and plans to offer a new line of diagnostics solutions for infectious diseases as well.

More technical information on this technology can be found in the following preprint available on the Medical Archive (medRxiv): https://doi.org/10.1101/2021.05.04.21256472

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(Release ID: 1720795)