IISc start-up gets regulatory approvals for COVID-19 test

New Delhi, May 19 (India Science Wire): PathShodh Healthcare, a start-up incubated at the Society for Innovation and Development (SID), Indian Institute of Science (IISc), has made a significant breakthrough in developing a first-of-its-kind, semi-quantitative electrochemical ELISA test for COVID-19 IgM and IgG antibodies. PathShodh has received the license to manufacture the test for sale from the Central Drugs Standard Control Organisation (CDSCO), after due diligence validation at the Translational Health Science and Technology Institute (THSTI), Faridabad, as per the requirements of the Indian Council of Medical Research (ICMR).

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

“The capability to quantify the COVID-19 antibody concentration will be crucial in estimating the declining antibody response over time 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 programmes in the future,” says Navakanta Bhat, Dean, Division of Interdisciplinary Sciences and Professor, Centre for Nano Science and Engineering (CeNSE), IISc, who is also the co-founder of PathShodh Healthcare.

This test has been developed by leveraging PathShodh’s Lab-on-Palm platform “anuPath™”, which interfaces with disposable test strips functionalised with an immunoreceptor specific to COVID-19 antibodies. The results are automatically displayed by the handheld reader. Therefore, there are no subjective errors due to manual readout of test results, as in the current lateral flow assay test kits. The other unique features of this technology include on-board 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.

According to Vinay Kumar, CEO and co-founder of PathShodh, “This novel technology can detect COVID-19 antibodies all the way down to the 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 Healthcare is an ISO 13485 certified company, the first start-up from IISc to get this certification. Its current product offering – the multi-analyte Lab-on-Palm platform “anuPathTM” – is capable of early diagnosis and management of diabetes, liver disease, anaemia and malnutrition. With
the new COVID-19 diagnostic test, PathShodh 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. PathShodh is also developing a COVID-19 rapid antigen test on the same platform. This could become a first-of-its-kind COVID-19 diagnostics solution with the capability to perform both rapid antibody and rapid antigen tests on a single platform.

The funds for developing and commercialising this technology were provided 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 technology development was also supported by SINE at IIT Bombay and IKP Knowledge Park, Hyderabad. The Society for Innovation and Development at IISc provided the seed funding for this development. (India Science Wire)

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