

SLINTEC DEVELOPS A COST EFFECTIVE LOOP MEDIATED ISOTHERMAL AMPLIFICATION KIT (LAMP-PCR) TO ENHANCE THE NATIONAL COVID-19 TESTING CAPACITY



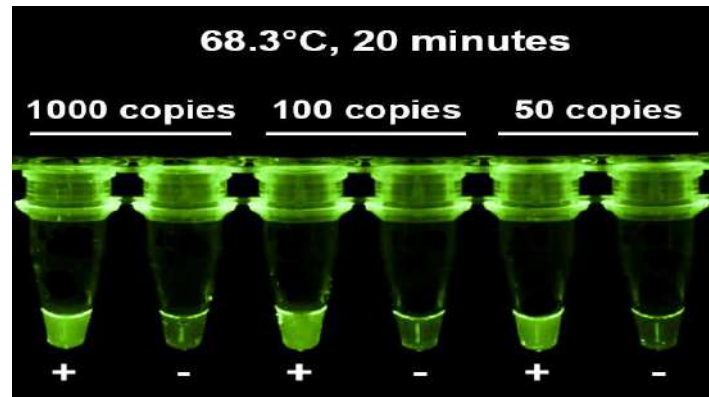
SLINTEC - USJ TEAM

The COVID19 pandemic is devastating the world, with millions infected and tens of thousands dead already. As of 2nd August 2020, 2,815 confirmed cases have been reported in Sri Lanka with 11 deaths. Social distancing, using facemasks and general lockdowns are helping to flatten the curves of the first wave of outbreaks around the world, but at significant humanitarian and economic cost. However, when these measures are relaxed, outbreaks will recur. Until effective antivirals and vaccines for SARS-CoV-2 are developed and administered around the world, ubiquitous testing and contact tracing will be required to detect and suppress COVID-19 outbreaks before they overwhelm healthcare systems and force the reintroduction of mass social and economic lockdowns.

Detection of SARS-CoV-2 mainly relies on RT-qPCR testing programs requiring specialized laboratory equipment and reagents, which are expensive. Although the actual testing takes about 2-3 hours, it may take about 1-2 days to obtain the final report from the time of sampling. Currently about 1500 RT-qPCR tests are being done daily in the country. So far only suspected persons, persons in isolation units in hospitals and random community samples are being tested but with the opening up of the economy and the airports plans are afoot to start sample testing of all incoming passengers.

In an effort to increase the diagnostic capacity for Covid-19 virus in the country, Sri Lanka Institute of Nanotechnology (SLINTEC), a pioneer in nano and advanced technology and research coming under the purview of the Ministry of Higher Education, Technology and Innovation, rapidly repurposed its staff and facilities in late March 2020 to develop cost-

effective Covid-19 diagnostic test kits, including gold nanoparticles and graphene based strips or electrodes to detect viral antigen, and RT-LAMP PCR to detect viral RNA.



After several months of dedicated and intense work, SLINTEC has successfully demonstrated the use of loop mediated isothermal amplification PCR coupled with reverse transcription (RT-LAMP) as a robust method for SARS-CoV-2 detection in clinical specimens. After demonstrating the proof of concept, SLINTEC RT-LAMP assay was validated against the existing RT-qPCR test at University of Sri Jayewardenepura (USJ), by analyzing RNA extracted from patient specimens supplied by USJ using GELDOC at SLINTEC. This was followed by analyzing virus samples isolated from positive patients supplied by National Institute of Infectious Diseases (NIID) using RT-qPCR available at USJ. Further studies are continuing to determine the specificity and sensitivity of the SLINTEC RT-LAMP assay followed by NMRA registration before transferring the technology for commercialization.

In this regard, SLINTEC, through Aravinth Panch of DreamSpace Academy, was able to partner with Guy Aidelberg from the Center for Research and Interdisciplinarity (CRI), Paris and the Open Covid19, a Just One Giant Lab (JOGL) program, that develops open-source and low-cost tools and methodologies that are safe and easy to use in response to the COVID-19 pandemic. This link helped us immensely to fast track the development process of the LAMP PCR kit. Professor Neelika Malavige and her team at Centre for Dengue Research, University Sri Jayewardenepura worked closely with SLINTEC and provided us with both positive and negative clinical specimens to demonstrate the proof of concept and to carry out the initial validation trials to compare with the qRT-PCR results. In addition, Ministry of Higher Education, Technology and Innovation, Ministry of Health and Presidential Task force on COVID-19 supported this project throughout.

Our study results demonstrate that RT-LAMP PCR assay developed by SLINTEC can readily replace the current RT-qPCR test as a means for detecting SARS-CoV-2 transcripts within RNA extracted from nasopharyngeal swabs displaying a sensitivity threshold almost equivalent to the gold standard RT-qPCR. Specificity of the RT-LAMP PCR technique is presently being analyzed and the results will be out soon. Switching to RT-LAMP translates into a three-fold decrease in total assay kit cost and a potential four-fold increase in pipeline output. With this intervention by SLINTEC, the country is expected to save nearly Rs. 150 million a month on Covid19 testing. Currently, we are studying the possibility of performing

the test without prior RNA extraction, allowing rapid and cost-effective testing that could potentially be extended to point-of-care.

Although diagnostic tests utilizing LAMP technique have been developed for RNA viruses and other pathogens, and RT-LAMP to detect SARS-CoV-2 is in use in several other countries, the know-how generated by SLINTEC has an intrinsic value, as SLINTEC will be the first in the country to have first-hand knowledge in this area including the development of LAMP system, production of associated reagents/enzymes mix, and validated Standard Operating Procedures (SOPs) for SARS-CoV-2 detection in clinical specimens. This will help SLINTEC to play a key role in commercializing the research output in the coming months and help the nation in managing the pandemic effectively.