

ICMR validates a West Bengal based Bio-tech Company for launching cheapest COVID-19 Detection Kit

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Success Story
Feature

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Indian Council of Medical Research (ICMR) has validated Department of Scientific & Industrial Research (DSIR) accredited an ISO 13485 certified biotech reagent manufacturing organisation based in West Bengal for producing SARS-Cov-2 viral RNA detection kit named *DiAGSure nCOV-19 Detection Assay* to meet the diagnostic testing challenges the country is facing right now. The kit was validated by ICMR on May 1, 2020 (last Friday) and is mentioned in the website of ICMR. ICMR approved the kit possessing the Batch Number 20115K1278 & 20115K1251 developed by GCC Biotech (India) Pvt Ltd, the company based in Bakrahat, South 24 Parganas, West Bengal. The price tag of the kit is Rs 500 and has demonstrated a near about 100% sensitivity as well as specificity in detecting the virus within a short span of 90 minutes (testing time). This apart, the strategically designed primers used for detecting the viral nucleic acid, the test promises to cover for possible variations in viral strain character limiting the chances of false-negative results. The kit is capable of detecting the virus at an extremely low viral load or titer even at the very early stages of the viral infection.

This has become possible largely due to the unflinching efforts of a young group of scientists who toiled day and night to ensure that every component of this kit is indigenously developed. This not only helped to bring down its cost and ensure its affordability for the millions who need the test today but also to do without the dependence on import of kit components (which are also costly) during these uncertain times.

The kit is made without depending upon imported reagents and the scientists developed indigenously all reagents including the polymerase enzymes and primers composing this kit, much in consonance with Union Government's 'Make in India' doctrine. However, the quality of the kit remains uncompromised with respect to the quality-assurance guidelines issued by WHO and the Centre for Disease Control and Prevention (CDC), USA. The kit developed indigenously using cutting-edge technology through almost two months of tireless labour by a young team of Indian scientists can help fulfil the goal of 'Test for Everyone'. In fact, the company has already developed the capability of providing 1 crore kits per month to the country. Moreover, the test kits can cover about 160 patients with one kit. An average lab with automated Polymerase Chain Reaction (PCR) can thus easily test more than 1000 patients a day using this kit with its one-step testing protocol.

The actual development of the kit through rigorous testing and problem shooting was technically guided by Prof. Samit Adhya, former renowned Scientist of CSIR, Govt. of India, Kolkata with validation and logistic support coming from Prof. Koustubh Panda, Professor & Head of the Department of Biotechnology and Dr. B.C. Guha Centre for Genetic Engineering and Biotechnology, University of Calcutta. Lastly, when the entire country was under lockdown with people confined in the safety of their homes this dedicated team of young scientists was working round the clock in their labs. Their only goal was to help their country combat this invisible enemy with indigenously developed weapons. The names of these young soldiers are - Dr. Avijit Ghosh (Head of R&D), Mr. Joydeep Mitra, Mohd. Nadeem Khan, Mr. Surajit Maiti, Dr. Gairik Mukherjee, Mr. Pinaki Chatterjee and many more.

Amidst the widespread efforts to develop dependable testing kits for the virus in our country the this organisation's new *DiAGSure nCOV-19 Detection Assay* is a commendable success story which emerged out of completely indigenous components. It is also perhaps the first of such kit developed in Eastern India. Let us now pray for an evolution of an effective vaccine or medicine so as to emerge victorious against deadly virus called COVID-19.

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This makes University of Calcutta very proud.

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