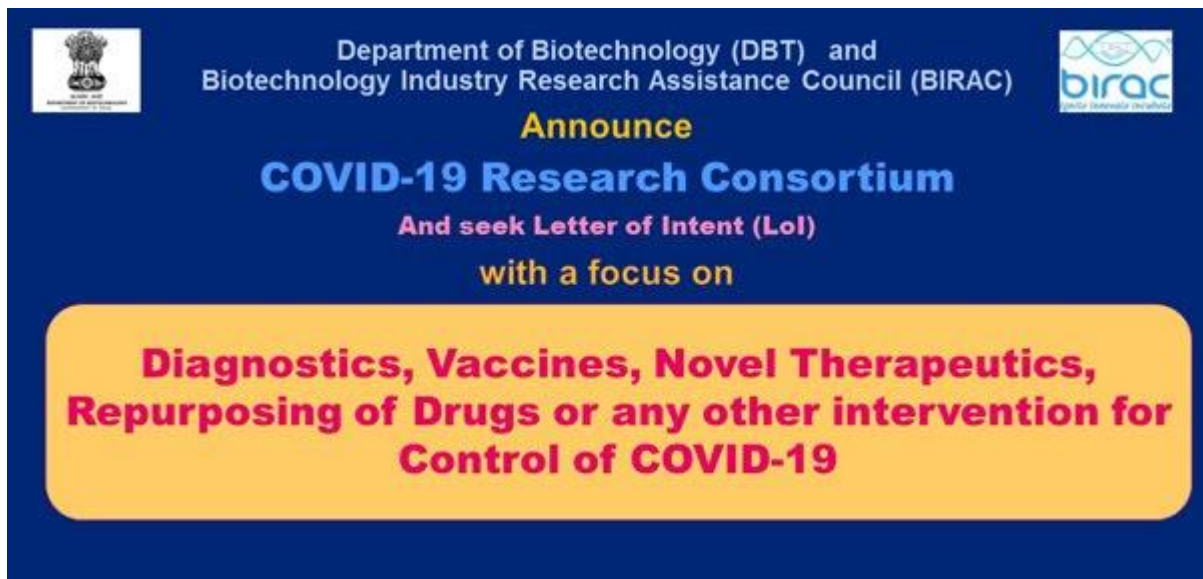


DBT-BIRAC clears proposal for a COVID-19 diagnostic Kit



The banner features the Government of India emblem on the left and the BIRAC logo on the right. The text is centered and reads: 'Department of Biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC) Announce COVID-19 Research Consortium And seek Letter of Intent (LoI) with a focus on Diagnostics, Vaccines, Novel Therapeutics, Repurposing of Drugs or any other intervention for Control of COVID-19'. The focus areas are highlighted in a yellow rounded rectangle.

New Delhi, March 26: The Department of Biotechnology and its public sector undertaking Biotechnology Research Industry Research Council have selected Yaathum Biotech Pvt Ltd for funding support under DBT's National Biopharma Mission for indigenous development and validation of a real-time RT-PCR based molecular test for COVID-19 diagnosis. The company has been selected for funding under the COVID-19 Research consortium call given by DBT and BIRAC to support Diagnostics, Vaccines, Novel Therapeutics, Repurposing of Drugs or any other intervention for control of the coronavirus pandemic.

There is immense need for expansion in testing because epidemiologists estimate that for every case identified three unidentified cases might be at large and it has become evident worldwide that effective and prompt COVID-19 control demands aggressive and extensive testing in hotspots, contact tracing and focus on high-risk target groups alongside lockdown measures.

Yaathum's test is based on quantitative reverse transcription polymerase chain reaction (qRT-PCR) technology which is recommended as the gold standard confirmatory test by WHO for COVID-19 diagnosis. It can rapidly and promptly detect the virus from the early stage of infection itself unlike alternate technologies used for testing which can detect only after 8 days of infection making them less reliable for diagnostic settings and requiring an additional confirmatory test.

The test assay is designed for detection of nucleic acid (RNA) specific to SARS-CoV-2 virus in patients' respiratory specimens in two hours and at a fraction of current cost of testing. It is a nucleic acid amplification test (NAAT). The technical highlight of the test is that it targets three independent regions or genes in the SARS-CoV-2 viral genome while most commercial tests available globally target one or two regions only. This is significant for avoiding false results due to non-specific interference or detection of other SARS 2003 and Bat SARS-like virus strains.

It will be possible to incorporate more assays into this test for predicting drug response simultaneously in future. Viral RNA isolated from any of the respiratory specimens such as nasopharyngeal swabs, sputum, lower respiratory tract aspirates and nasopharyngeal wash/aspirate can be a sample for the test.

Viral RNA is reverse transcribed to cDNA and subsequently amplified and detected using RT mastermix and qPCR assays and any qPCR platform. Fluorescence intensity is monitored by the instrument in real-time and fluorescent signal crossing the threshold confirms detection of nucleic acid and in turn positive result for the virus. The absence of signal is interpreted as a negative result. It must always be interpreted alongside clinical observations and patient epidemiological data. It is highly sensitive with the ability to detect less than 10 copies of the genome in a reaction.

Most of the components have been developed indigenously which has made the test highly cost effective. The test is being offered at Rs.1,000 per patient and can be further brought down to less than Rs.800 on large scale production. After validation it can be readily deployed in all the government authorized RT-PCR testing labs for COVID-19 across the country. This can significantly help ramp up COVID-19 testing in India and in meeting the huge demand for test kits especially indigenous ones.

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