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CDSCO approves COVID-19 PCR kit by Mylab

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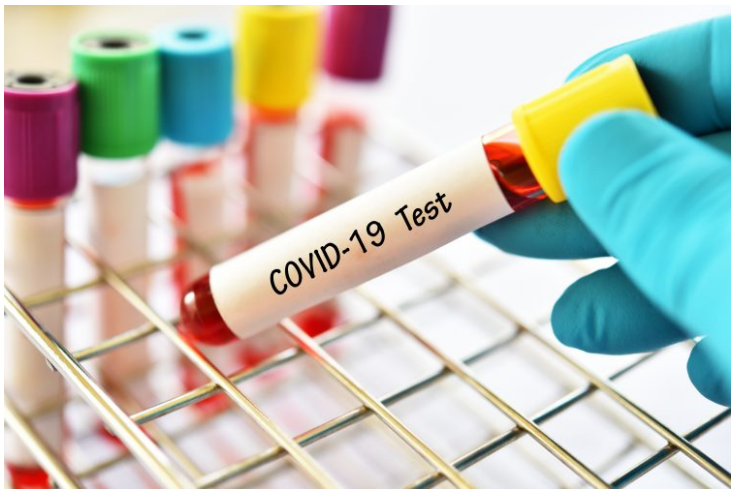
Developed the first made in India test kits for COVID-19 in a record time of six weeks



As India fights back the epidemic COVID-19 (aka Coronavirus), limited testing facilities and expensive testing kits has become the biggest concern for the authorities. In order to combat this challenge, the Pune-based molecular diagnostics company Mylab Discovery Solutions Pvt Ltd which specializes in molecular diagnostic kits has developed the first made in India test kits for COVID-19 in a record time of six weeks. The kit is the first one to receive commercial approval from Indian FDA/ Central Drugs Standard Control Organisation (CDSCO) and is named as Mylab PathoDetect COVID-19 Qualitative PCR kit. Further, Mylab is the only Indian company to have achieved 100% sensitivity and 100% specificity in the ICMR evaluation.

Hasmukh Rawal, Managing Director, Mylab Discovery Solutions, said, “With emphasis on ‘Make in India’ and support from local and central government, the COVID- 19 kit, has been made as per WHO/CDC guidelines. It was developed and evaluated in a record time”. He further added that the support and the immediate action from regulatory bodies (CDSCO/FDA), evaluation centre of ICMR, NIV, Biotechnology Industry Research Assistance Council (BIRAC) and the central and state governments during this national emergency is commendable.

Mylab has an experience of several years in manufacturing of RTPCR kits and manufactures a range of kits at the facility approved by Indian FDA/CDSCO and compliant with MDR 2017 regulation for manufacturing medical devices of Class C and D, the most stringent and regulated products by the government, Mylabcurrently manufactures ID-NAT screening kits for blood banks/hospitals, Quantitative HIV, HBV and HCV kits. Apart from this, Mylab has received clearance from Drugs Controller General of India (DCGI) to manufacture the COVID-19 Qualitative kit, in the same facility. The Mylab COVID-19 kit has been evaluated at Indian Council of Medical Research (ICMR).

“We have been trying hard to make cutting edge technology available to our country at a reasonable and affordable price. Since this test is based on the sensitive PCR technology, even early stage infection can be detected, with highest accuracy as has been seen during tests at ICMR. The ICMR tested, CDSCO approved kit makes detection faster too”, said Mr. Shailendra Kawade, Executive Director at Mylab.

Currently India ranks lowest in terms of testing done per million population. The number is as low as 6.8. Countries like South Korea and Singapore have been able to contain the growing number of Coronavirus cases by doing more and more testing.

So far the Indian government is sourcing millions of testing kits from Germany to facilitate testing to diagnose Coronavirus patients PAN India. However, the dependency on foreign kits has been troublesome and supply is getting blocked due to grounded airlines. This can change with the approval for made in India kits.

Mylab promised that it can manufacture up to 1 lakh tests in a week which can be further scaled up if needed. Further, the company claims that its test kits can test about 100 patients with one kit. An average lab with automated PCR can test more than 1000 patients a day.

With local sourcing of test kits it will be a major breakthrough for India as the testing kit by Mylab would cost nearly one fourth of the current procurement cost. Moreover, Mylab PathoDetect COVID-19 Qualitative PCR kit screens and detects the infection within 2.5 hours, compared to 7+ hours taken by current protocols. This means that laboratories will be able to do twice the number of reactions in the same time on one machine.

The Mylab manufacturing facility, approved by FDA/CDSCO is compliant with MDR 2017 regulation for Manufacturing Medical Device of Class A,B,C and D and ISO 13485: 2016 certification