

RT-PCR kits by iGenetics, Biogenomics get ICMR-NIV approval

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The indigenous test kit has been designed by Mumbai-based iGenetic Diagnostics and will be produced and marketed by Thane-based Biogenomics



Adding to the arsenal of indigenous testing kits in India's fight against COVID-19, Mumbai-based speciality diagnostic major iGenetic Diagnostics and Thane-based Biogenomics have jointly developed RT-PCR testing kits with 100 per cent concordance to true positives and true negatives and have received approval from the Indian Council of Medical Research (ICMR) and the National Institute of Virology (NIV).

The RT-PCR kit, considered to be gold standard for diagnosis of COVID-19, has been jointly developed by iGenetic & Biogenomics and Biogenomics is working on manufacturing and distribution across the country. The kits are expected to be available in the market within a few weeks.

"India has already began testing 1 lakh people a day and our kits will offer a boost to the efforts of ramping up the testing capability further. The RT-PCR test kits have been approved after satisfying the stringent guidelines of ICMR and NIV that squeeze the chances of a false positive or a false negative to zero. These kits are better than global kits in terms of quality, adaptability, and price. Having a dependable kit developed in the country is crucial in these days of restricted movement, when global kits may not be easily available, to cater to the increasing demand, need to scale up production, and can be custom-made to suit the mutation of the virus in the Indian setting. We partnered with Biogenomics due to their extensive experience and expertise in manufacturing and marketing of biotechnology products, We have already received overwhelming interest and are exploring areas for ramping up," said Arunima Patel, Founder & CEO, iGenetic Diagnostics.

The availability of the kits will boost testing capabilities in the Bangalore which has 2283 of confirmed cases of coronavirus that has claimed 44 lives.

iGenetic Diagnostics is a pioneer in developing in-house testing for various complex infections, including PCR tests for

community-acquired pneumonia, TB, septicaemia, meningitis, and various CNS infections while Biogenomics is a young, rapidly-growing biopharmaceutical firm in Chennai with independent, high-quality research and manufacturing capabilities adhering to Current Good Manufacturing Practice (cGMP) regulations.

As a partner to iGenetic, it will conduct further validation and testing of such kits in-house, and Biogenomics will exclusively obtain all licenses towards manufacturing and marketing this kit and manufacture, distribute, market, sell, recover dues, and conduct all commercial activities of the diagnostic kit.

“We are proud to be able to join forces with iGenetic in this fight against a raging pandemic. As research-minded professionals, we recognise the value of iGenetic contribution and its importance. The production of the kits is going on with full steam ahead and these will be available for use in next few weeks,” said Dr Archana Krishnan, founder director of BioGenomics.

iGenetic will continue to perform validations and/or testing of various batches of the kit as may be necessary and as per regulations or market requirements and will also support BioGenomics in any additional development work including but not limited to validations, testing of live samples and such other activities. “We have done extensive validation in-house while developing the kit – the design and development is an intricate process that requires significant expertise and resources. iGenetic successfully harnessed its expertise and deep knowledge base to design this test in-house with the highest degree of concordance. We are a leading name in the field of clinically relevant differential diagnosis and has been catering to patients across India for the last several years. All our laboratory facilities are NABL-approved and are spread out across the country in Maharashtra, Karnataka, Andhra Pradesh, Telangana, Delhi/NCR, Kerala, Tamil Nadu, Madhya Pradesh and Rajasthan,” added Patel.