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CoSara receives CDSCO approval for COVID-19 2- gene multiplex test

26 November 2020 | News

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Co-Diagnostics Inc, a US based molecular diagnostics company with a unique, patented platform for the development of molecular diagnostic tests, has announced that CoSara Diagnostics Pvt Ltd (CoSara), its joint venture for manufacturing and sales in Vadodara, has received clearance by the Central Drugs Standard Control Organisation (CDSCO) to manufacture and sell its Saragene™ COVID-19 2-gene multiplex RT-PCR test as an *in vitro* diagnostic (IVD), intended for the qualitative detection of the SARS-CoV-2 virus.

The Saragene test kit approved by the CDSCO uses the Company's patented CoPrimer™ technology and is based on a test originally designed by Co-Diagnostics, who also recently announced receipt of a CE marking for its Logix Smart™ SARS-CoV-2 (*genes RdRp/E*) multiplex test. Both the CoSara and Co-Diagnostics test target two gene markers of the SARS-CoV-2 genome, *RdRp* and *E-gene*, to identify the presence of the virus, and were designed to meet the needs of those markets where government or regulatory bodies recommend a multi-target coronavirus diagnostic.

Dwight Egan, CEO, Co-Diagnostics, commented, "Tests built on our CoPrimer technology have several advantages over other platforms, including the enhanced multiplex capabilities. We believe that the highly specific nature of the new Saragene test which follows World Health Organization guidance will help CoSara be able to play an even more active role in the battle against this pandemic."

Mohal Sarabhai, Director, CoSara remarked, "Our honourable Prime Minister has endorsed the hike in number of available RT-PCR tests to keep the COVID-19 positivity rate under 5 per cent. With this clearance in place, CoSara is geared up for this challenge by providing affordable, high quality, 'Made in India' 2-gene multiplex COVID-19 RT-PCR tests across the country."

CoSara has previously received CDSCO clearance for RT-PCR tests for Mycobacterium tuberculosis, malaria, hepatitis B,

hepatitis C and human papillomavirus (HPV) to be manufactured and sold as IVDs in the Indian market.