

Co-Diagnostics JV CoSara Receives Clearance from Indian FDA for COVID-19 2-Gene Multiplex Test

SALT LAKE CITY, Nov. 25, 2020 /PRNewswire/ -- Co-Diagnostics, Inc. (Nasdaq: CODX) (the "Company"), a molecular diagnostics company with a unique, patented platform for the development of molecular diagnostic tests, announced today that CoSara Diagnostics Pvt Ltd ("CoSara," or the "JV"), its joint venture for manufacturing and sales in India, has received clearance by the Central Drugs Standard Control Organization ("CDSCO") in India 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 of 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."

CoSara Director Mohal Sarabhai remarked "Our honorable Prime Minister Shri Narendra Modi has endorsed the hike in number of available RT-PCR tests to keep the COVID-19 positivity rate under 5%. 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.

About Co-Diagnostics, Inc.:

Co-Diagnostics, Inc., a Utah corporation, is a molecular diagnostics company that develops, manufactures and markets a new, state-of-the-art diagnostics technology. The Company's technology is utilized for tests that are designed using the detection and/or analysis of nucleic acid molecules (DNA or RNA). The Company also uses its proprietary technology to design specific tests to locate genetic markers for use in industries other than infectious disease and license the use of those tests to specific customers.

Forward-Looking Statements:

This press release contains forward-looking statements. Forward-looking statements can be identified by words such as "believes," "expects," "estimates," "intends," "may," "plans," "will" and similar expressions, or the negative of these words. Such forward-looking statements are based on facts and conditions as they exist at the time such statements are made and predictions as to future facts and conditions. Forward-looking statements in this release include statements regarding the (i) use of funding proceeds, (ii) expansion of product distribution, (iii) acceleration of initiatives in liquid biopsy and SNP detection, (iv) use of the Company's liquid biopsy tests by laboratories, (v) capital resources and runway needed to advance the Company's products and markets, (vi) increased sales in the near-term, (vii) flexibility in managing the Company's balance sheet, (viii) anticipation of business expansion, and (ix) benefits in research and worldwide accessibility of the CoPrimer technology and its cost-saving and scientific advantages. Forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances. Actual results may differ materially from those contemplated or anticipated by such forward-looking statements. Readers of this press release are cautioned not to rely on any forward-looking statements. Any forward-looking statement made by the Company in this press release is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company does not undertake any obligation to update any forward-looking statement relating to matters discussed in this press release, except as may be required by applicable securities laws.

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