

Co-Diagnostics JV CoSara Receives Clearance from Indian FDA for Chikungunya and Dengue Tests

SALT LAKE CITY, Sept. 16, 2021 /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™ dengue and chikungunya RT-PCR tests as *in vitro* diagnostics ("IVD").

The Saragene test kits approved by the CDSCO use the Company's patented CoPrimer™ technology for the qualitative detection of these mosquito-borne viruses.

According to the [World Health Organization](#), the global incidence of dengue has grown dramatically in recent decades to become a leading cause of death in some Asian and Latin American countries, with 70% of the burden in Asia despite a risk of infection existing in 129 countries. About half of the world's population is now at risk, leading to an estimated 100-400 million infections each year.

While less lethal than dengue, chikungunya has been considered [by the WHO](#) to have serious epidemic potential, due to its potential to cause considerable disability in a proportion of the affected population and ultimately [substantial socioeconomic impact](#) in those areas.

CoSara Director Mohal Sarabhai remarked, "India Today [recently reported](#) that dengue and chikungunya cases are up 110% since January in Gujarat, where CoSara is headquartered. We are pleased to be able to add two more products to our menu of diagnostics that can all be manufactured in India in agreement with the 'Make in India' initiative, as well as exported to help serve the needs of this region of the world which is highly burdened by the effects of these two diseases."

Dwight Egan, CEO of Co-Diagnostics, commented, "The first step in effective treatment of infectious diseases is an accurate diagnosis. Our highly-specific CoPrimer technology is ideally suited to distinguish between similar diseases like dengue and chikungunya, and we believe that these tests have the potential to improve the lives of infected patients through more accessible and accurate diagnoses leading to better treatment."

CoSara has previously received CDSCO clearance for RT-PCR tests for Mycobacterium tuberculosis, malaria, hepatitis B, hepatitis C, human papillomavirus (HPV), and two COVID-19 assays, all 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 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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