# Co-Diagnostics, Inc. JV CoSara Receives Clearance from Indian Regulators for Influenza Multiplex PCR Test

***The clinical laboratory real-time PCR multiplex test was designed using Co-Dx Co-Primers™ and licensed by the CDSCO for use in diagnostic procedures***

SALT LAKE CITY, March 7, 2024 /PRNewswire/ -- Co-Diagnostics, Inc. (Nasdaq: CODX) (the "Company" or "Co-Dx"), 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 SARAPLEX™ Influenza Multiplex (IFM) Test Kit to clinical laboratories as an *in vitro* diagnostic ("IVD") for the detection and differentiation of Influenza A and Influenza B.

CoSara's new real-time multiplex PCR test is built on the Company's patented Co-Primers™ technology and designed to simultaneously detect influenza A (H1N1, H3N2, H7N9, H1N2, H5N1, H2N2, H9N2, H10N8, H5N6, H7N7, H7N4, H7N2 and H2N1), influenza B (Yamagata and Victoria strains) and to differentiate between H1N1 and H3N2. Co-Primers utilize a unique design architecture to combat common issues with real-time PCR that can lead to inaccurate results, specifically primer dimer propagation, and which are magnified in multiplex reactions.

"The importance of accurate, reliable PCR testing at the high-throughput clinical laboratory level remains critical," remarked Dwight Egan, CEO of Co-Diagnostics. "We are pleased that our Co-Primers technology will help to combat respiratory illnesses in India as the world continues to adjust in the wake of the pandemic, and while we work with CoSara in preparation for playing an important role in the next stage of our Company's growth with the upcoming launch of our Co-Dx™ PCR Pro™ instrument*."

CoSara Director Mohal Sarabhai commented, "This test marks the 15$^{th}$ of CoSara's clinical lab tests to receive IVD clearance by the CDSCO, and adds to our expanding menu of valuable diagnostic tools available to our growing distributor and laboratory customer base. It strengthens our foundation for future growth as CoSara also assists in the progress of point-of-care testing across India, and prepares to provide manufacturing, distribution, and regulatory support for the forthcoming Co-Dx PCR platform."

CoSara has previously received CDSCO clearance for RT-PCR tests for Mycobacterium tuberculosis, malaria, hepatitis B, hepatitis B viral load, hepatitis C, hepatitis C viral load, HPV types 16 and 18 and HPV-HR, two COVID-19 assays, chikungunya, dengue, a dengue/chikungunya duplex test, and a Flu A/Flu B/COVID-19 ("ABC") multiplex test, all designed using the Company's patented Co-Primers technology and cleared to be manufactured and sold to clinical laboratories in the Indian market as IVDs.

**The Co-Dx PCR platform (including the PCR Home™, PCR Pro™, mobile app, and all associated tests) is subject to review by the FDA and/or other regulatory bodies and is not yet available for sale. The Co-Dx PCR Pro instrument and Co-Dx COVID-19 Test are currently under review by the FDA.*

**About Co-Diagnostics, Inc.:**
Co-Diagnostics, Inc., a Utah corporation, is a molecular diagnostics company that develops, manufactures and markets state-of-the-art diagnostics technologies. The Company's technologies are 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 for its Co-Dx PCR at-home and point-of-care platform and to locate genetic markers for use in applications other than infectious disease.

**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 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 place undue reliance on any forward-looking statements. There can be no assurance that any of the anticipated results will occur on a timely basis or at all due to certain risks and uncertainties, a***

***discussion of which can be found in our Risk Factors disclosure in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 16, 2023, and in our other filings with the SEC. 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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