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Co-Diagnostics receives CDSCO clearance for Influenza Multiplex PCR test

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Designed using Co-Dx Co-Primers and licensed by the CDSCO for use in diagnostic procedures



US-based Co-Diagnostics, Inc. has announced that CoSara Diagnostics, 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 utilise 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.

CoSara Director Mohal Sarabhai commented, "This test marks the 15th 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."

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.