Co-Diagnostics, Inc Receives CE Marking for Direct Saliva SARS-CoV-2 Test

SALT LAKE CITY, June 18, 2021 /PRNewswire/ -- Co-Diagnostics, Inc. **(Nasdaq: CODX)**, a molecular diagnostics company with a unique, patented platform for the development of molecular diagnostic tests, announced today that its Logix Smart™ SARS-CoV-2 DS (Direct Saliva) has obtained regulatory authorization to be sold as an *in vitro* diagnostic ("IVD") for the diagnosis of COVID-19 in markets that accept CE markings, and is now available for purchase from the Company's Utah-based ISO-13485:2016 certified facility.

Co-Diagnostics' Logix Smart DS test kit is designed to detect the presence of the *RdRp* and *E* genes of SARS-CoV-2 directly from minimally processed human saliva samples while eliminating RNA extraction of the samples, a costly and time-consuming process required by most PCR tests. Co-Diagnostics believes that eliminating the extraction process has the potential to increase throughput and lower costs of not only COVID-19 testing, but also any other pathogen for which the Company develops a direct saliva test.

Dwight Egan, Chief Executive Officer of Co-Diagnostics, commented, "We are pleased to announce that this new, simplified PCR testing method is now available as an IVD in any country that accepts a CE marking as valid regulatory approval to aid in the ongoing battle against the COVID-19 pandemic, which we anticipate will drive demand for diagnostics as normalization testing protocols are established. We believe that the need for testing will especially persist in countries where vaccination rates lag substantially behind those of the United States.

"The direct saliva technical advance represents one of the important innovations that the Company has developed since the pandemic began. Our unique CoPrimer™ technology utilized in this test design received initial patent protection in 2018, which was further strengthened by an additional patent last year. In combination with this technology, direct saliva testing will play a key role in our ongoing centralized lab initiative, as well as our forthcoming at home and point of care testing strategies. As a Company, we are particularly pleased with the dedication and hard work performed by our scientific, laboratory and regulatory staff that has culminated in this significant achievement.

"The quality of our tests and technology have been consistently borne out both here in the United States and in over 50 countries internationally as Co-Diagnostics has been chosen by prestigious laboratories who specialize in providing highly accurate PCR testing. We believe this CE marking is a critical indicator of our goal to bring high quality, affordable molecular diagnostics to nations across the world, where our distributors and customers have come to depend on the quality, accuracy, and affordability of our diagnostic products, and of our commitment since the earliest days of the pandemic to remain on the forefront of the fight against COVID-19."

The CE Marking for the Logix Smart DS CE-IVD Test confirms that it meets the Essential Requirements of the European Community's In-Vitro Diagnostic Medical Device Directive (IVDD 98/79/EC), permitting export and sales of the product as an IVD to commence immediately in the European Community. Many other global markets also accept a CE marking as valid regulatory approval following routine local product registration, which allows sales of the Company's IVD into these areas as well.

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, (ix) benefits in research and worldwide accessibility of the CoPrimer

technology and its cost-saving and scientific advantages, and (x) the impact that known and unknown COVID-19 variants may have on us and our products, our customers and suppliers, including disruptions and inefficiencies in the supply chain. 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. 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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