

# FDA Policy Change to Allow Rapid Domestic Expansion of Co-Diagnostics COVID-19 Test

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**Salt Lake City, Utah - March 17, 2020** - Co-Diagnostics, Inc. (Nasdaq:CODX), a molecular diagnostics company with a unique, patented platform for the development of diagnostic tests, announced today that a new FDA policy released last night aimed at expediting the availability of COVID-19 diagnostics will allow the Company to aggressively expand its presence in the U.S. market.

Co-Diagnostics was the first U.S. company to obtain a CE marking for a COVID-19 test, and international shipments have continued to escalate. In the past month, the Company has shipped its CE marked and research use Logix Smart™ COVID-19 test kits to countries all over the world. These include Italy, Germany, the United Kingdom, Turkey, Greece, the Philippines, Thailand, Australia, Paraguay, Ecuador, Israel, South Africa, and Canada, in addition to numerous shipments to customers and research institutions in the United States.

Previous domestic shipments to date have been in accordance with the FDA's policy change on February 29, 2020 that allows U.S. CLIA laboratories to use the Company's COVID-19, under certain conditions. Now, as a result of the change announced last night by the FDA, the Company's test kit will soon be available for use by and marketed to a wide array of U.S. laboratories, without first requiring Emergency Use Authorization.

Co-Diagnostics CEO Dwight Egan remarked "The ramifications of this new FDA policy are significant for our Company. This change will quickly afford Co-Diagnostics even more opportunities to serve the needs of laboratories nationwide, as we play an even larger role in responding to this pandemic. We applaud the FDA's decision to recognize the dire need for increased access to high-quality COVID-19 tests, and to adapt as the situation demands in light of a public health emergency.

"With no known treatment or approved vaccine for the highly-infectious COVID-19, the need for accurate and rapid diagnoses has never been greater. Our cost-effective Logix Smart COVID-19 test has been designed to run on a variety of commercially available platforms, with easy-to-interpret results in under two hours. We are confident in our ability to meet the growing demand for this diagnostic."

See the original press release from the Food and Drug Administration [here](#).

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 may include statements regarding the (i) use of funding proceeds, (ii) expansion of product distribution, (iii) acceleration of initiatives in certain verticals or markets, (iv) capital resources and runway needed to advance the Company's products and markets, (v) increased sales in the near-term, (vi) flexibility in managing the Company's balance sheet, (vii) anticipation of business expansion, and (viii) 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 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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