

Co-Diagnostics, Inc Receives CE Mark for Novel Coronavirus Test

Logix Smart™ COVID-19 Test now available for export from the United States as a CE-marked IVD

Salt Lake City, Utah - February 24, 2020 - Co-Diagnostics, Inc. (Nasdaq:CODX), a molecular diagnostics company with a unique, patented platform for the development of diagnostic tests, announced today that its Logix Smart™ Coronavirus COVID-19 Test has obtained regulatory clearance to be sold as an *in vitro* diagnostic (“IVD”) for the diagnosis of SARS-CoV-2 (COVID-19) in markets that accept CE-marking as valid regulatory approval, and is now available for purchase from the Company’s Utah-based ISO-13485:2016 certified facility.

The Declaration of Conformity for the Logix Smart COVID-19 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. Co-Diagnostics shipped samples of the Research Use Only version of its test to distributors in Italy and Germany last week, which allowed future customers to confirm the quality and sensitivity of the product prior to the IVD being available, and the Company to accelerate the sales efforts of its diagnostic. 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.

Dwight Egan, Chief Executive Officer of Co-Diagnostics, remarked, “Co-Diagnostics has received overwhelming interest in our novel coronavirus diagnostic from all over the world since first announcing its development a month ago. As the disease has spread from China, so have concerns about the global health community’s ability to contain and control it. The first step in containment is a prompt, accurate diagnosis, and we are pleased to provide this product to those areas that are able to utilize a CE-marked IVD to protect their residents and visitors from a disease that has already affected millions.

“We believe Co-Diagnostics is the first U.S. company to receive a CE-marking for a coronavirus IVD, which is a testament to the quality of our platform. The rapid development of our COVID-19 test was made possible thanks to our proprietary design process and patented CoPrimer™ technology platform. We look forward to scaling up production to meet global demand with this regulatory clearance in place, and to obtaining approvals from other bodies that will allow us to further increase the reach of this invaluable diagnostic tool.”

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.

Company Contact:

Andrew Benson
Co-Diagnostics Investor Relations
801-438-1036
investors@codiagnostics.com

or

Media Contact:

Jennifer Webb
Coltrin & Associates, Inc
+1.267.912.1173
jennifer_webb@coltrin.com

<https://news.codiagnosics.com/2020-02-24-Co-Diagnostics-Inc-Receives-CE-Mark-for-Novel-Coronavirus-Test>