Co-Diagnostics, Inc. Receives CE Markings for "ABC" and SARS-CoV-2 2-Gene Multiplex Tests

New tests expand global reach of Company COVID-19 test menu

SALT LAKE CITY, Nov. 17, 2020 /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™ ABC (Influenza A/B, SARS-CoV-2) and its Logix Smart™ SARS-CoV-2 (*genes RdRp/E*) multiplex test for multiple targets of the SARS-CoV-2 genome have both obtained regulatory authorization to be sold as *in vitro* diagnostics ("IVD") for the diagnosis of COVID-19 in markets that accept CE-markings, and are now available for purchase from the Company's Utah-based ISO-13485:2016 certified facility.

Co-Diagnostics' Logix Smart ABC test kit allows for simultaneous detection of and differentiation between influenza A, influenza B, and SARS-CoV-2, the virus that causes COVID-19. The Company's SARS-CoV-2 multi-gene test uses two gene markers, *RdRp* and *E-gene* to identify the presence SARS-CoV-2, and was designed to meet the demand for tests in regions that prefer multiple targets to confirm a positive diagnosis. Both multiplex tests use the Company's patented CoPrimer™ technology and are designed for use with saliva and other respiratory tract samples, such as nasal swabs or sputum.

Due to the similarity in symptoms between the common cold, the flu, and COVID-19, even vaccinated patients exhibiting any of these related symptoms will still require testing for differentiation. For this reason, the Company believes a durable market will persist for its ABC test long after a COVID-19 vaccine is widely available, and that the test marks the Company's entrance into the high-demand upper respiratory diagnostic space, independent of COVID-19.

Dwight Egan, Chief Executive Officer of Co-Diagnostics, commented, "Since announcing that we were the first American company to receive a CE marking for a COVID-19 diagnostic, Co-Diagnostics has continued to provide high-quality molecular diagnostic solutions for the coronavirus worldwide. We are pleased to now announce additional tools in the ongoing battle against the pandemic, especially for those regions where government or regulatory bodies recommend a multi-target coronavirus diagnostic, such as in India.

"Our CoPrimer technology is ideally suited for multiplexed PCR tests, as it dramatically reduces the possibility of 'primer-dimers,' a common phenomenon in PCR reactions that leads to false positive results, and allowing for assays with much higher specificity. With up to 56 million flu cases in the US alone in the last flu season, and with symptoms that are often similar to those of COVID-19, we believe that the need for a high-quality diagnostic tool capable of accurately detecting and differentiating between flu A/B and COVID-19 while also delivering true-negative results will remain strong.

"Both tests were designed and created in response to demand from our target markets, domestic and abroad. With these CE markings in place, we look forward to continuing our mandate to bring high quality, affordable molecular diagnostics to nations across the world, and to remaining in the forefront of the fight against COVID-19."

The CE Markings for both the Logix Smart ABC Test and the Logix Smart SARS-CoV-2 (*genes RdRp/E*) test confirm that they meet the Essential Requirements of the European Community's In-Vitro Diagnostic Medical Device Directive (IVDD 98/79/EC), permitting export and sales of the products as IVDs 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 IVDs into these areas.

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, and (ix) 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 rely on any forward-looking statements. Any forward-looking statement made by the Company in this press release is based only on information currently available to the Company and speaks only as of the date on which it is made. 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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For further information: Company Contact: Andrew Benson, Head of Investor Relations, +1 801-438-1036, investors@codiagnostics.com; Media Contact: Jennifer Webb, Coltrin & Associates, Inc, +1.267.912.1173, jennifer_webb@coltrin.com

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