

Co-Diagnostics, Inc. Logix Smart™ COVID-19 2-Gene Test Approved for Use in the United Kingdom

Company's validated test available in the UK following implementation of UKHSA CTDA Regulations

SALT LAKE CITY, Nov. 4, 2021 /PRNewswire/ -- 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™ SARS-CoV-2 2-Gene multiplex test has been validated according to the United Kingdom Health Security Agency's ("UKHSA") Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 ("CTDA") and is available for sale in the UK under the Regulation.

The UKHSA is the agency responsible for planning, preventing, and responding to external health threats, replacing Public Health England earlier this year. CTDA amends a previous regulation to require that SARS-CoV-2 test devices must be approved by the Secretary of State before they are placed on market or put into service, and specifies the performance requirements that such devices must meet. Co-Diagnostics' test [has completed](#) the validation required by the CTDA and received approval to be sold according to the amended Regulation, and has been validated for use with several sample types, including saliva.

"We are pleased that our 2-gene multiplex SARS-CoV-2 test has been approved for sale according to the UK's high standard of quality and performance," remarked Dwight Egan, CEO of Co-Diagnostics. "Since the pandemic began, we have been on the forefront of providing gold-standard PCR solutions across the world, including Europe. We believe that each additional validation of our Company's testing technology continues to demonstrate the quality of our patented CoPrimer™ platform, and the valuable role we have been fortunate enough to play in improving the quality of life for people affected by the pandemic through providing accurate, reliable, and cost-effective COVID-19 testing products."

The Company's test is available for sale through [Clent Life Science](#), Co-Diagnostics' authorized distributor in the UK.

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) use of the Company's tests by laboratories, (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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