Co-Diagnostics, Inc. Completes Submission to FDA for Co-Dx PCR Pro

The Company's Emergency Use Authorization submission is for the new Co-Dx PCR Pro instrument and COVID-19 test kit, designed for point-of-care and at-home. The menu of tests in development for the platform includes TB, HPV, and a multiplex respiratory panel for flu A/B, COVID-19, and RSV

SALT LAKE CITY, Utah – December 27, 2023 – Co-Diagnostics, Inc. **(Nasdaq-CM: CODX)** (the "Company" or "Co-Dx"), a molecular diagnostics company with a unique, patented platform for the development of molecular diagnostic tests, today announced that it has submitted its Co-Dx™ PCR COVID-19 test with Co-Dx PCR Pro™ instrument for review by the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA). The submission includes the PCR Pro instrument, COVID-19 detection test, and mobile app, all designed for use in point-of-care and at-home settings.

Tests run on the new platform use the Company's patented real-time polymerase chain reaction (PCR) Co-Primers™ technology. The Co-Dx COVID-19 test kit for the PCR Pro instrument included in the Company's FDA submission has been shown in clinical evaluations to detect the presence of COVID-19 in anterior nasal swab samples, with results displayed on the user's smartphone or mobile device in approximately 30 minutes.

The menu of future tests that are currently in development for the new platform includes tuberculosis (TB) and human papillomavirus (HPV), as well as an upper respiratory multiplex panel that will detect influenza A/B, COVID-19, and respiratory syncytial virus (RSV) within a single sample. All three tests have also been the subject of grant support by notable funding bodies over the last half of this year.

"This new platform technology is a significant step towards advancing the Company's mission to increase accessibility of PCR diagnostics," said Dwight Egan, CEO of Co-Diagnostics. "In addition to the development of new technologies from the ground-up by a world-class team to decentralize PCR diagnostics technology and make it available at the point-of-care and in at-home settings, it also required the new technology to be able to be commercialized at a price point that is relevant worldwide. Diagnostics, along with vaccines and therapeutics, are a vital tool in helping to combat illnesses like TB, which remains a significant problem in India and many other countries despite being a highly treatable disease. We are pleased to announce this submission to the FDA for this new platform."

**The Co-Dx PCR at-home and point-of-care platform (including the PCR Home™, PCR Pro, mobile app, and all associated test kits) is subject to review by the FDA and/or other regulatory bodies and is not yet available for sale.*

About Co-Diagnostics, Inc.:
Co-Diagnostics, Inc., a Utah corporation, is a molecular diagnostics company that develops, manufactures and markets state-of-the-art diagnostics technologies. The Company's technologies are 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 for its Co-Dx PCR at-home and point-of-care platform and to locate genetic markers for use in applications other than infectious disease.

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. No assurance can be given that the FDA will grant emergency use authorization for the Co-Dx PCR platform or that the Company will be successful in developing additional diagnostic tests for use with the platform. 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. There can be no assurance that any of the anticipated results will occur on a timely basis or at all due to certain risks and uncertainties, a discussion of which can be found in our Risk Factors disclosure in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 16, 2023, and in our other filings with the SEC. 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
Head of Investor Relations
+1.801.438.1036
investors@codiagnostics.com

Media Contact:
Jennifer Webb
ColtrinMethod PR
jcoltrin@coltrinmethodpr.com