Co-Diagnostics Receives CE Mark for Tuberculosis Test Kit

SALT LAKE CITY–(BUSINESS WIRE)–**Co-Diagnostics, Inc. (Nasdaq: CODX)**, a molecular diagnostics company with a unique, proprietary platform for the development of molecular diagnostic tests, announced today that its Logix Smart™ MTB Test has obtained CE mark approval, the principle regulatory clearance allowing the test to be sold as an *in vitro* diagnostic ("IVD") for the diagnosis of tuberculosis in European Union states and other markets that accept a CE-IVD mark as valid regulatory approval.

The World Health Organization (WHO) confirms that as of 2016, the latest year for which data is available, tuberculosis (TB) is one of the top 10 causes of death globally, proving fatal to 1.7 million people, and is the leading killer of individuals infected with HIV. Prompt and accurate TB treatment is also believed to have saved 53 million lives between 2000 and 2016, with a success rate as high as 83% in 2015. However, symptoms of tuberculosis may be mild or non-existent early on, and many affected people seek a diagnosis too late after the disease has advanced, which is then more difficult to treat and more likely to be fatal. In some regions, cost prohibits residents from seeking a tuberculosis diagnosis.

Dwight Egan, Chief Executive Officer of Co-Diagnostics, remarked, "This granting of this CE mark represents a milestone not only for Co-Diagnostics, but for all individuals in need of an affordable, high-quality TB diagnostic in areas not blessed with wealth or access to philanthropic subsidies. Our proprietary design platform and CoPrimer™ technology, on which this test was built, are now also being used to design tests for HIV and multi-drug resistant tuberculosis ("MDR-TB"). These diagnostics are in high demand where TB is prevalent and will further augment the tools available to people in those areas, in addition to expanding the Company's footprint there as well."

Co-Diagnostics will manufacture its Logix Smart MTB test in the Company's ISO 13485:2016 facility for the development and manufacture of IVD Medical Devices located in Utah, USA, and at this time is not seeking approval by the FDA for sale in the United States due to the low domestic rate of tuberculosis incidents.

The CE mark confirms that the test meets the Essential Requirements of the European Community's In-Vitro Diagnostic Medical Device Directive (IVDD 98/79/EC). The Logix Smart MTB Test detects DNA of mycobacteria tuberculosis (MTB) complex members and functions via real-time polymerase chain reaction (PCR) to detect and amplify the *IS6110* and *MPB64* regions of the MTB genome.

About Co-Diagnostics, Inc.:

Co-Diagnostics, Inc., a Utah corporation, is a molecular diagnostics company with a proprietary diagnostic testing technology and development platform that intends to manufacture and sell reagents used for diagnostic tests that function via the detection and/or analysis of nucleic acid molecules (DNA or RNA), and license the use of its platform to other non-competing developers.

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. 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.
