

Co-Diagnostics Completes Submission of CE Mark Registration for Tuberculosis Screening Test

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 technical file has been submitted for registration with the European Community, and that the CE marked *in vitro* diagnostic (“IVD”) is expected to be available for purchase early in August in markets that accept a CE mark as valid regulatory approval.

Dwight Egan, Chief Executive Officer of Co-Diagnostics, commented, “The CE marking of the Company’s tuberculosis test, our flagship product for infectious disease, represents a major milestone for Co-Diagnostics. This newest iteration of our MTB screening test has been tailored to target detection of the two genes present in a broad range of tuberculosis infections, to greatly mitigate the potential of false negatives and improve the diagnosis and prognosis of patients afflicted with this disease worldwide. Being built on Co-Diagnostics’ proprietary CoPrimer™ design platform also means that ‘primer-dimers,’ the often-occurring phenomenon that leads to false positives in these types of diagnostics, are virtually eliminated.”

The technical file dossier includes a description of the test to support conformance to the CE marking standards, which will confirm that the test meets the Essential Requirements of the European Community’s In-Vitro Diagnostic Medical Device Directive (IVDD 98/79/EC). The registration process is expected to be complete by the end of July, at which point sales of the product may commence as an IVD with the CE marking included. 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.

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.

Mr. Egan continued, “The key component to battling tuberculosis is an early, accurate, and affordable diagnosis. We are confident that the time we have taken to ensure this test meets our high standards of quality and performance will allow us to better meet the global demand for detection of a disease with 99.9% of infections occurring outside of the United States, and that causes over 1.5 million deaths per year. Roughly 95% of these deaths occur in low and middle-income countries, which includes those in Eastern Europe in addition to many across Central America and the Caribbean basin. In the case of the latter, the Departments or Ministries of Health recognize clearance by the European Community as valid regulatory approval to allow sale of CE marked products throughout their jurisdictions.”

Co-Diagnostics will manufacture its Logix Smart MTB test in the Company’s ISO 13485:2016 facility for 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.

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.

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