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

Company's Logix Smart™ MTB Test to be available for purchase with CE mark in August 2018

LONDON, UNITED KINGDOM, July 17, 2018 /EINPresswire.com/ -- 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.

The technical file dossier and CE marking confirms 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.

The newest iteration of their 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. It is built on Co-Diagnostics' proprietary CoPrimer™ design platform to virtually eliminate "primer-dimers," the often-occurring phenomenon that leads to false positives in these types of diagnostics.

The key component to battling tuberculosis is an early, accurate, and affordable diagnosis. The Company believes that this will help them 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.
Click here to read more about Co-Diagnostics.

This Press Release has been prepared by the Healthcare Trends Team of The Wall Street Club.

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 and The Wall Street Club undertake no 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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