# Co-Diagnostics, Inc. Receives CE Mark for Zika 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™ Zika Test technical file 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 Zika virus in European Union states and other markets that accept a CE-IVD mark as valid regulatory approval.

Dwight Egan, Chief Executive Officer of Co-Diagnostics, remarked, "The CE marking of the most recent iteration of our Zika test is a significant step towards meeting demand for disease detection products in one of our key target markets. Given the ability of Zika infections to be passed along through mosquito vectors as well as sexual transmission, the key component to preventing the occurrence of these tragic developmental disorders is an early, accurate, and affordable diagnosis for both men and women. Like many mosquito-borne illnesses, Zika infections tend to occur in cycles, but the World Health Organization ("WHO") has recently emphasized that the threat of Zika has not abated. We are confident that this test meets our high standards of quality and performance and will allow us to better meet the demand for affordable Zika diagnostic options, the absence of which can have awful consequences for families and create additional burdens on social health programs."

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), allowing sales of the product to commence as an IVD with the CE marking included. The Logix Smart Zika Test uses polymerase chain reaction ("PCR") technology to detect the presence or absence of the Zika virus in serum, plasma, collected alongside with urine, from patients suspected to be infected. While not lethal itself, studies have directly linked Zika with cases of microcephaly, a neurological disease that affects the brain development of fetuses. The WHO has raised the priority for R&D investments for Zika in their 2018 annual review of diseases.

Mr. Egan continued, "Co-Diagnostics' patented CoPrimer™ design platform, on which this test is built, has been shown to drastically reduce the occurrence of 'primer-dimers,' the often-occurring phenomenon that leads to false positives in PCR diagnostics. The groundbreaking multiplexing capabilities of CoPrimers is also being used to facilitate the development of another diagnostic test to identify and distinguish between Zika, dengue fever, and chikungunyua, three diseases with a high degree of comorbidity in regions where they are prevalent. We have already seen very promising verification results for this multiplexed screening test and look forward to being able to announce news related to its regulatory clearance in the near future, further augmenting our Company's molecular diagnostics product offerings in underserved markets of the world."

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

**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.Forward-looking statements in this release include statements regarding the (i) use of funding proceeds, (ii) expansion of product distribution, (iii) acceleration of initiatives in liquid biopsy and SNP detection, (iv) use of the Company's liquid biopsy tests by laboratories, (v) capital resources and runway needed to advance the Company's products and markets, (vi) increased sales in the near-term, (vii) flexibility in managing the Company's balance sheet, (viii) anticipation of business expansion, and (ix) 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.**

---

https://news.codiagnostics.com/2018-10-18-Co-Diagnostics-Inc-Receives-CE-Mark-for-Zika-Screening-Test