

Co-Diagnostics, Inc. Granted ISO 13485:2016 Certification

SANDY, Utah--([BUSINESS WIRE](#))--**Co-Diagnostics, Inc. (NASDAQ: CODX)**, a molecular diagnostics company with a unique, proprietary platform for the development of molecular diagnostics, has been granted ISO 13485:2016 certification following successful completion of an audit of its quality management system. The audit was performed in August by DQS Inc., one of the leading global certification bodies, and included a review of the Company's quality management system to ensure compliance with the newest version of the ISO 13485 standard.

The International Organization of Standards (ISO) is a non-government entity comprised of academic and industry professionals that certifies that companies are compliant with industry-standard best practices in their production and operations. Medical device manufacturers are required to update their quality systems to the new standard by March 2019 in order to remain in compliance. The 2016 standard for quality management systems places an increased emphasis on risk management and harmonizes more closely with the quality system regulations found in FDA 21 CFR Part 820, the law for medical device companies manufacturing or selling products for the US, and the European Commission's new IVDR 2017/746 for in-vitro diagnostics. The Company's certificate is valid until September 2020 with a scope that encompasses the design and manufacture of medical device products for the handling, stabilization, separation, purification, amplification, and detection of nucleic acids.

Dwight Egan, Co-Diagnostics CEO, remarked "Harmonizing with the US and European Commission's emphasis on risk management is an important step in the direction of ensuring Co-Diagnostics' products meet the high standards of quality expected by international regulators, and customers. We look forward to the credibility that will accompany our willingness to comply with the same standards met by much larger companies with greater reach and resources."

About Co-Diagnostics, Inc.:

Co-Diagnostics, Inc., a Utah corporation, is a molecular diagnostics company that has developed and 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 to sell diagnostic equipment from other manufacturers as self-contained lab systems.

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.

Disclaimer:

This news release does not constitute an offer to sell or a solicitation of an offer to buy the securities described herein, nor shall there be any sale of these securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

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