

Co-Diagnostics, Inc. to Undergo ISO 13485:2016 Audit

Audit to prepare for eventual sales into the US market

SANDY, Utah--([BUSINESS WIRE](#))--**Co-Diagnostics, Inc. (NASDAQ: CODX)**, a molecular diagnostics company with a unique, proprietary platform for the development of molecular diagnostics, will be undergoing a Stage II Upgrade Assessment Audit to ISO 13485:2016.

The International Organization of Standards (ISO) is a non-government entity comprised of academic and industry professionals which certifies that companies are compliant with industry-standard best practices in their production and operations. ISO 13485:2016, the international standard for medical device quality management systems, differs from the 2003 version of the standard in its increased emphasis on risk management. It also harmonizes more closely the quality system regulations found in FDA 21 CFR Part 820, the law for medical device companies manufacturing or selling products for the US. The audit will be performed this week by DQS Inc., one of the leading global certification bodies for management systems.

Dwight Egan, Co-Diagnostics CEO, remarked, "The risk management activities required by the new 13485:2016 standard parallel our commitment to producing high-quality products that meet and exceed customer expectations. Although we are not required to upgrade to the new standard until March 2019, this standard helps us realize our company policy and helps us prepare for our eventual entry into the US market. We look forward to the credibility that this upgraded certification will bring to our company."

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.

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