



CardioDx Real-World Registry Study Shows Use of the Corus[®] CAD Gene Expression Test Helps Reduce Unnecessary Patient Referrals for Cardiac Testing

- Corus[®] CAD is Effective in Excluding the Diagnosis of Obstructive Coronary Artery Disease in the Primary Care Setting and Helps Reduce Unnecessary Healthcare Expense -

PALO ALTO, Calif. – [October 21, 2013] – CardioDx, Inc., a molecular diagnostics company specializing in [cardiovascular genomics](#), today announced results of a multi-center, real-world registry study demonstrating the clinical utility of [Corus[®] CAD](#), a blood-based gene expression test, in the evaluation of patients with symptoms suggestive of obstructive coronary artery disease (CAD) in the primary care setting. The study will be presented at the 35th Annual Meeting of the Society for Medical Decision Making, taking place October 19-23, 2013 in Baltimore, MD.

“Better methods are needed to assess whether or not obstructive CAD is the cause of patients’ symptoms in the primary care setting, so that clinicians may quickly explore non-cardiac sources if it is not,” said Joseph Ladapo, M.D., Ph.D., Assistant Professor of Medicine, Department of Population Health and Medicine, NYU School of Medicine. “Each day, approximately 8,000 patients with non-acute chest pain present to the outpatient clinic for evaluation, and 9 out of 10 of these patients do not have stable CAD as the cause of their symptoms. The Corus CAD test, with its high negative predictive value of 96% and high sensitivity of 89% as demonstrated in the COMPASS study, may help clinicians optimize patient care and reduce unnecessary cardiac testing by ruling out obstructive CAD early in the assessment pathway.”

The study, titled “**The Clinical Utility of a Novel Genomic-Based, Gene Expression Test in a Study Registry Evaluating Patients with Symptoms Suggestive of Obstructive Coronary Artery Disease in the Ambulatory Care Setting: Results from the REGISTRY I Study,**” found that Corus CAD changes clinical decision making by assessing the likelihood of obstructive CAD in primary care patients. This study, conducted in seven community-based primary care practices, evaluated 342 patients presenting to primary care with non-acute typical symptoms such as chest pain, pressure or heaviness that may radiate to the neck, shoulder, jaw, back or arm, or atypical symptoms such as sudden onset of weakness, nausea, vomiting or body aches. The study found that each 10-point decrease in the Corus CAD score was associated with a 13-fold decrease in the likelihood of referral for further cardiac testing ($p < 0.0001$). Low-scoring patients (≤ 15) had a 94 percent decrease in the likelihood of cardiac testing referral compared to patients with non-low (> 15) Corus CAD scores ($p < 0.0001$). Additionally, no major adverse cardiac events were noted at 30-days’ follow-up.

“Overutilization of diagnostic testing is a costly healthcare expense in the U.S.,” said Mark Monane, M.D., Chief Medical Officer, CardioDx. “There are few effective options for primary care clinicians in the office setting to accurately help exclude the presence of obstructive CAD, leading to referrals to cardiology that may not be necessary. Corus CAD offers these clinicians the convenience of performing a noninvasive, blood-based diagnostic test right in their offices and the confidence of knowing that the results are accurate. In this real-world registry study of primary care practices, Corus CAD use was associated with lower referral patterns among low score patients. Given the 96% negative predictive value, Corus CAD has the ability to help clinicians reliably exclude obstructive CAD as the cause of patients’ symptoms early in the diagnostic pathway.”

About Obstructive Coronary Artery Disease

Coronary artery disease is a very common heart condition in the United States. One in six deaths among Americans is caused by CAD.¹ CAD can cause a narrowing or blockage of the coronary arteries (vessels to the heart that supply the heart with blood, oxygen, and nutrients), reducing blood flow to the heart muscle. This narrowing or blockage in the coronary arteries is often referred to as obstructive CAD, characterized by the presence of atherosclerosis, or plaque.

About Corus CAD

Corus CAD is a blood test that can safely, accurately and conveniently help primary care clinicians and cardiologists assess whether or not a stable non-diabetic patient's symptoms are due to obstructive CAD, enabling many patients to avoid unnecessary noninvasive and invasive cardiac procedures and exposure to imaging-related radiation risks, imaging agent intolerance, or complications with cardiac catheterization. The test involves a routine blood draw that is conveniently administered in the clinician's office. The test is simple, convenient, and as a sex-specific test for the diagnosis of obstructive CAD, accounts for critical biological differences between men and women.

The test has been clinically validated in independent patient cohorts, including two prospective, multicenter U.S. studies, PREDICT and COMPASS.^{2,3} In the COMPASS study, Corus CAD outperformed MPI in diagnostic accuracy, demonstrating a significantly higher sensitivity (89 percent vs. 27 percent, $p < 0.001$) and a significantly higher negative predictive value (96 percent vs. 88 percent, $p < 0.001$) than MPI for assessing the presence of obstructive CAD. Over 40,000 Corus CAD test results have been commercially delivered to clinicians. Corus CAD is a covered benefit for the estimated 48 million Medicare beneficiaries in the U.S. CardioDx processes all Corus CAD test samples at its CLIA-certified and CAP-accredited clinical laboratory in Palo Alto, CA.

About CardioDx

CardioDx, Inc., a molecular diagnostics company specializing in cardiovascular genomics, is committed to developing clinically validated tests that empower clinicians to better tailor care to each individual patient. Strategically focused on coronary artery disease, cardiac arrhythmia and heart failure, CardioDx is committed to expanding patient access and improving healthcare quality and efficiency through the commercialization of genomic technologies. For more information, please visit www.cardiodx.com.

Forward-Looking Statements

This press release may contain forward-looking statements, including statements regarding the safety, efficacy and the adoption rate of and the size of the market for Corus CAD and beliefs regarding the need for and value of gene expression diagnostics. These statements relate to future events and involve known and unknown risks, uncertainties and other factors that could cause actual levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These statements reflect the views of CardioDx as of the date of this press release with respect to future events and, except as required by law, it undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this press release.

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¹ Go AS, Mozaffarian D, Roger VL, et al. Heart Disease and Stroke Statistics--2013 Update: A Report From the American Heart Association. *Circulation*. 2013;127:e6-e245.

² Rosenberg S, Elashoff MR, Beineke P, et al. Multicenter Validation of the Diagnostic Accuracy of a Blood-Based Gene Expression Test for Assessing Obstructive Coronary Artery Disease in Nondiabetic Patients. *Ann Intern Med*. 2010;153:425-434.

³ Thomas GS, Voros S, McPherson JA, et al. A Blood-Based Gene Expression Test for Obstructive Coronary Artery Disease Tested in Symptomatic Nondiabetic Patients Referred for Myocardial Perfusion Imaging: The COMPASS Study. *Circ Cardiovasc Genet*. 2013;6:154-162.