



**The Corus<sup>®</sup> CAD Gene Expression Test Addresses the Clinical Challenges Associated with the Evaluation of Women Presenting with Symptoms Suggestive of Obstructive Coronary Artery Disease**

*- Two Studies to be Presented at "What a Difference an X Makes: The State of Women's Health Research" Validate the Accuracy and Clinical Utility of Corus<sup>®</sup> CAD, the Only Sex-Specific Test for the Assessment of Obstructive Coronary Artery Disease -*

**PALO ALTO, Calif. – [July 18, 2013]** – CardioDx, Inc., a leader in the field of [cardiovascular genomic diagnostics](#), today announced that the company will present two studies demonstrating the accuracy and clinical utility of [Corus<sup>®</sup> CAD](#) in evaluating women with symptoms suggestive of [obstructive coronary artery disease](#) (CAD) at the Society for Women's Health Research "What a Difference an X Makes: The State of Women's Health Research" Conference, taking place July 18-19, 2013 at the Pew Charitable Trusts Conference Center in Washington, D.C. Mark Monane, M.D., Chief Medical Officer, will highlight the latest clinical evidence supporting the value of personalized genomic medicine to assess CAD in women by accounting for key biological differences between women and men with obstructive CAD. The poster presentations will take place on Thursday, July 18<sup>th</sup> at 5:00 PM ET.

"CAD is an important women's health issue not only because it affects so many women, but because it affects women differently than men," said Phyllis Greenberger, President and CEO of the Society for Women's Health Research. "More than half of women with CAD will present with atypical or nonspecific, ambiguous symptoms such as shortness of breath, fatigue, and abdominal pain, thus making the diagnosis more difficult. There is a tremendous unmet medical need in evaluating CAD as many of the current noninvasive tests are not as specific or sensitive in women, yielding high rates of false positive and false negative results. This can lead to unnecessary additional cardiac procedures. More clinicians need to understand and recognize these significant sex differences in disease presentation so that women can receive the most effective medical care."

The first poster presented at the meeting, "A Gender-Specific Blood-Based Gene Expression Score for Assessing Obstructive Coronary Artery Disease in Nondiabetic Patients: Results of the Personalized Risk Evaluation and Diagnosis in the Coronary Tree (PREDICT) Trial," led by Alexandra Lansky, M.D., Associate Professor of Medicine and Director of the Cardiovascular Research Center, Yale University School of Medicine, demonstrated that Corus CAD has higher diagnostic accuracy in women than commonly used risk assessment modalities such as presentation of patients' symptoms and myocardial perfusion imaging (MPI). The study found that a positive MPI test result was not a statistically significant predictor of obstructive CAD in either women or men. In contrast, the Corus CAD gene expression score was found to be an effective independent predictor of obstructive CAD in both the female and male subgroups. The authors concluded that the Corus CAD test offers a more reliable diagnostic approach for the assessment of nondiabetic patients and, in particular, women with suspected obstructive CAD for whom symptoms and functional testing (like MPI) have proven unreliable.

A second poster presented at the conference, "The Use of a Personalized Gene Expression Test to Improve Decision Making in the Evaluation of Women with Symptoms of Suspected Coronary Artery Disease," confirmed the clinical utility of Corus CAD in the primary care setting. Corus CAD allowed

primary care physicians to confidently exclude the diagnosis of obstructive CAD in stable, symptomatic female patients. The study, led by Michael Conlin, M.D., Johns Creek Primary Care, is a sex-specific analysis showing that Corus CAD scores separated female patients into low risk (score  $\leq 15$ ) and elevated risk (score  $> 15$ ) groups, allowing primary care physicians to more appropriately triage patients. Use of Corus CAD led to a 77 percent reduction in referrals to cardiologists in the low-scoring female patient group ( $p < 0.001$ ). When used as the first-line diagnostic for CAD assessment, Corus CAD can more appropriately exclude obstructive CAD as the cause of patients' symptoms, so that clinicians can quickly look to other reasons for their patients' medical conditions.

"CardioDx is proud to be participating in this conference because we believe that personalized genomic medicine can help address the gender disparities in healthcare that affect many women with symptoms of obstructive CAD," said Dr. Monane. "Inconclusive test results due to sex differences overburden the healthcare system with diagnostic overutilization. Corus CAD addresses this problem with a sex-specific test that accounts for the key biological differences between women and men in CAD diagnosis. The Corus CAD test can provide a powerful sense of peace of mind for women when they know their symptoms are not due to a blockage in their heart arteries. The test has the potential to improve patient management decisions and increase efficiency within the healthcare system."

### **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.<sup>1</sup> 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 nondiabetic 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 invasive coronary angiography. The test involves a routine blood draw that is conveniently administered in the clinician's office. The test is simple, convenient, and most importantly, is the only sex-specific test for the diagnosis of obstructive coronary artery disease and 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.<sup>2,3</sup> 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 nearly 50 million Medicare enrollees 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 leader in the field of cardiovascular genomic diagnostics, 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](http://www.cardiodx.com).

## Forward-Looking Statements

This press release may contain forward-looking statements, including statements regarding the business strategy of CardioDx, the safety and efficacy, adoption rate and 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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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.