



**CardioDx Announces Publication of the IMPACT-CARD Trial Demonstrating Use of Corus<sup>®</sup> CAD Test Influenced Cardiologists' Clinical Management of Patients with Symptoms Suggestive of Obstructive Coronary Artery Disease**

*- Use of Corus<sup>®</sup> CAD Led to a Statistically Significant Reduction in Additional Cardiac Testing -*

**PALO ALTO, Calif. – May 20, 2013** – CardioDx, Inc., a pioneer in the field of [cardiovascular genomic diagnostics](#), today announced the publication of the IMPACT-CARD (Investigation of a Molecular Personalized Coronary Gene Expression Test on Cardiology Practice Pattern) trial in *Critical Pathways in Cardiology*. This prospective study conducted at Vanderbilt University Medical Center evaluated the clinical utility of [Corus<sup>®</sup> CAD](#), a blood-based [gene expression test](#) for the assessment of obstructive [coronary artery disease](#) (CAD), in decision-making by cardiologists regarding their diagnostic testing strategy.

The primary objective of the trial was to measure the effect of Corus CAD on cardiologists' decision-making using a pre- and post-study design. In the prospective cohort of 83 evaluable patients presenting with typical or atypical symptoms suggestive of obstructive CAD, cardiologists' diagnostic strategies were evaluated before and after using the Corus CAD test. Cardiologists changed their diagnostic testing strategy in 58 percent of patients ( $p < 0.001$ ) and there was an overall reduction in testing after obtaining the Corus CAD result. Furthermore, among patients with decreased testing, 91 percent had a low Corus CAD score, defined as less than or equal to 15, while 100 percent of patients with increased testing had elevated scores ( $p < 0.001$ ).

"The evaluation of symptomatic patients for obstructive CAD is highly variable, with only 10 to 30 percent of typical or atypical presentations of chest pain cases definitively confirmed as obstructive CAD, despite extensive and costly cardiac imaging and invasive testing. Better methods are needed to more accurately assess the likelihood of obstructive CAD in patients in a cardiologist office-based setting, especially among patients with low pre-test probability of disease such as women and patients with atypical symptoms on presentation," said John A. McPherson, MD, Associate Professor of Medicine, Vanderbilt University Medical Center. "More efficient evaluation of obstructive CAD has important benefits for both patients and the health system overall. Improving risk stratification of patients has the potential to help reduce the number of unnecessary diagnostic tests and procedures, resulting in less patient exposure to ionizing radiation, imaging agent intolerance, and risks of complications."

"The IMPACT-CARD trial shows us that the current effort to reduce inefficiencies and contain costs in healthcare and the growing promise of a genomic-based diagnostic test to customize and provide the most optimal care for each patient are complementary forces," said Mark Monane, MD, Chief Medical Officer of CardioDx. "In both the cardiology and primary care setting, Corus CAD helps clinicians effectively determine whether or not their patients' symptoms are due to obstructive CAD and therefore need further cardiac evaluation, leading to better decisions for patients and cost-savings that can be realized by the healthcare system."

## **About Obstructive Coronary Artery Disease**

Coronary artery disease is a very common heart condition in the United States. One in five 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 CardioDx**

CardioDx, Inc., a pioneer 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 poised to expand patient access and improve healthcare quality and efficiency through the commercialization of genomic technologies. For more information, please visit [www.cardiodx.com](http://www.cardiodx.com).

## **About Corus CAD**

Corus CAD is the only clinically validated blood-based test for the assessment of obstructive coronary artery disease. The test involves a routine blood draw conveniently administered in the clinician's office and does not expose patients to risks of radiation or imaging agent intolerance. It is the only sex-specific test for obstructive coronary artery disease, accounting for critical biological differences between men and women.

The test has been clinically validated in multiple 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, sensitivity (89 percent vs. 27 percent,  $p < 0.001$ ) and negative predictive value (96 percent vs. 88 percent,  $p < 0.001$ ) and demonstrated excellent performance for excluding obstructive coronary artery disease relative to both invasive angiography and CTA.<sup>3</sup> Additionally, a retrospective, multicenter chart review study and the prospective IMPACT CARD trial at Vanderbilt University, the first of our two prospective clinical utility studies, demonstrated that Corus CAD use yields statistically significant and clinically relevant changes in patient management decisions in both primary care and cardiology settings.

Corus CAD has also been recognized by *The Wall Street Journal's* Technology Innovation Awards, honored as a Gold Edison Award recipient, and named one of *TIME's* Top Ten Medical Breakthroughs. CardioDx was recently honored as one of *FierceMedicalDevices'* "Fierce 15" most promising privately held medical device and diagnostic companies.

The Corus CAD test is intended for use in non-diabetic stable patients who present with typical or atypical symptoms suggestive of CAD, with no known history of CAD, no prior myocardial infarction (MI) or revascularization procedure, and who are not currently taking steroids, immunosuppressive agents or chemotherapeutic agents.

Corus CAD has been used commercially by clinicians in more than 38,000 patients and is a covered benefit for more than 40 million Medicare enrollees in the U.S.

## 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> Lloyd-Jones D, Adams R, Carnethon M, et al. Heart Disease and Stroke Statistics--2009 Update: A Report From The American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2009;119:480–486.

<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.