



## **New Patient Registry Study Reinforces the Value of the Corus<sup>®</sup> CAD Gene Expression Test in Helping Clinicians Reduce Unnecessary Cardiac Testing in Patients with Suspected Obstructive Coronary Artery Disease**

- Presented at Medical Quality 2014, the Annual Meeting of the American College of Medical Quality -

**PALO ALTO, Calif. – [April 3, 2014]** – CardioDx, Inc., a molecular diagnostics company specializing in [cardiovascular genomics](#), today announced interim results of a registry study examining the use of the [Corus<sup>®</sup> CAD](#) gene expression test in a real-world primary care setting for the assessment of patients with symptoms suggestive of obstructive coronary artery disease (CAD). The study was presented at Medical Quality 2014, the Annual Meeting of the American College of Medical Quality, taking place from March 27 – 30, 2014, in Alexandria, Va. Mark Monane, MD, Chief Medical Officer of CardioDx, also participated as a panelist on the conference’s genomics tract panel, “The View for ACMQ: Stakeholders Discussion on Genomics and Quality.”

Corus CAD is the first and only commercially available blood-based gene expression test that provides a current-state assessment of obstructive CAD in non-diabetic patients presenting with typical or atypical systems. With a 96% negative predictive value and 89% sensitivity, Corus CAD can help clinicians accurately rule out obstructive CAD as the source of their patients’ symptoms, so they may look to other causes.

The registry study, “Use of Personalized Medicine, Gene Expression Score Influenced Cardiology Referrals Among Patients Presenting with Symptoms Suggestive of Obstructive Coronary Artery Disease: Interim Results from the PRESET (A Registry to Evaluate Patterns of Care Associated with the Use of Corus CAD in Real World Clinical Care Settings) Registry,” demonstrated that the Corus CAD gene expression score influenced the rate of cardiology referrals among patients presenting with non-acute symptoms suggestive of obstructive CAD.

A total of 392 adults from 22 outpatient primary care sites in the U.S. were included in this interim analysis. Among the 177 patients (45%) with low ( $\leq 15$ ) Corus CAD scores, only 11% were referred for further cardiac testing. The authors concluded that Corus CAD can appropriately stratify patients presenting with symptoms suggestive of obstructive CAD and improve the quality of care without impacting patient safety.

“Annually, approximately three million non-diabetic patients present to primary care offices with symptoms suggestive of obstructive CAD,<sup>1,2,3</sup> and they often undergo additional and unnecessary non-invasive and invasive cardiac testing,” said Joseph Ladapo, M.D., Ph.D., Assistant Professor of Medicine, Department of Population Health and Medicine, NYU School of Medicine. “The results of this real-world analysis demonstrate that the gene expression score, when used in primary care for patients with symptoms suggestive of obstructive CAD,



can help physicians better identify low-risk patients and avoid further cardiac testing.”

The PRESET registry study (NCT01677156, [clinicaltrials.gov](https://clinicaltrials.gov)), which is planning to enroll 1,000 adult patients, is ongoing with further endpoint analysis planned upon the completion of enrollment.

“These real-world interim results gathered from 22 community-based primary care practices add to the growing body of evidence confirming the clinical utility of the Corus CAD test,” said Mark Monane, MD, Chief Medical Officer of CardioDx. “These interim findings are consistent with previous studies in the primary care and cardiology settings and show that clinicians are incorporating the results of the Corus CAD score into their decision-making process. There was a strong association demonstrated between low Corus CAD score and lack of referral for further cardiac evaluation, as clinicians are ruling out these patients for a cardiac etiology of their symptoms and turning their attention towards other potential causes underlying their patients’ symptoms.”

### **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>4</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 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.<sup>5,6</sup> In the COMPASS study, Corus CAD outperformed myocardial perfusion imaging (MPI) as a diagnostic test to exclude obstructive CAD by demonstrating a significantly higher sensitivity (89% vs. 27%,  $p < 0.001$ ) and a significantly higher negative predictive value (96% vs. 88%,  $p < 0.001$ ) than MPI for assessing the presence of obstructive CAD. Over 55,000 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, Calif.

### **About Gene Expression**

Corus CAD is a gene expression test, not a genetic test. Whereas genetic testing may inform on lifetime disease risk, the Corus CAD gene expression test provides a current-state assessment of obstructive CAD by looking at the gene expression changes associated with atherosclerosis. Gene expression levels change depending on a person’s disease status resulting from genetic and environmental factors.

## 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](http://www.cardiodx.com).

## Forward-Looking Statements

This press release may contain forward-looking statements, including statements regarding the safety and efficacy 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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<sup>1</sup> National Ambulatory Medical Care Survey: 2010 Summary Tables. CDC/NCHS, 2013. (Accessed July 8, 2013, at [http://www.cdc.gov/nchs/data/ahcd/namcs\\_summary/2010\\_namcs\\_web\\_tables.pdf](http://www.cdc.gov/nchs/data/ahcd/namcs_summary/2010_namcs_web_tables.pdf).)

<sup>2</sup> Cayley WE, Jr. Diagnosing the Cause of Chest Pain. *Am Fam Physician*. 2005;72:2012-21.

<sup>3</sup> Woodwell DA, Cherry DK. National Ambulatory Medical Care Survey: 2002 Summary. *Adv Data*. 2004:1-44.

<sup>4</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>5</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>6</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.