



## **CardioDx Announces New Data Supporting the Clinical Utility and Validity of Corus CAD at the American Heart Association Scientific Sessions 2012**

*Data Demonstrates that the Corus CAD Test Provides Insight Into the Amount and Type of Plaque; Use of the Test Increases Patient Compliance with Lipid-lowering Drugs*

**PALO ALTO, Calif. – November 8, 2012** – CardioDx, Inc., a pioneer in the field of cardiovascular genomic diagnostics, today announced new data from three studies supporting the clinical validity and utility of Corus<sup>®</sup> CAD, the company's blood-based gene expression test to safely, accurately and conveniently help clinicians determine whether or not patient symptoms are due to obstructive coronary artery disease (CAD). Data was presented this week at the American Heart Association Scientific Sessions 2012 conference in Los Angeles, Calif.

Corus CAD is a decision-making tool that can help primary care clinicians and cardiologists exclude obstructive coronary artery disease as the cause of a stable nondiabetic patient's symptoms. The test involves a routine blood draw conveniently administered in the clinician's office, and does not expose patients to risk of radiation or imaging agent intolerance. It is the only sex-specific test for obstructive CAD, accounting for critical biological differences between men and women. Corus CAD has now been used to assess more than 31,000 U.S. patients.

### ***Clinical Validity***

Two studies supporting the clinical validity of Corus CAD by Dr. Szilard Voros, M.D., FACC, FSCCT, FAHA; Associate Professor of Medicine/Cardiology and Radiology at Stony Brook University, in collaboration with other investigators, analyzed results from more than 600 patients in the PREDICT and COMPASS validation studies of Corus CAD. The first study examined expression of individual genes in the Corus CAD algorithm in relationship to maximum percent stenosis, coronary artery calcification, and coronary plaque composition, as measured by coronary CT angiography. This analysis showed that coronary calcium is associated with only a subset of the Corus CAD genes that reflect overall maximum percent stenosis.

The second study showed that coronary artery plaque burden and maximum percent stenosis significantly correlate with Corus CAD scores, as measured by cardiovascular CT angiography. In particular, these data showed that the Corus CAD score correlated with both calcified and non-calcified plaque, but was more significantly associated with non-calcified plaque.

"These two studies help illuminate our understanding of the Corus CAD gene expression test, and show that the Corus CAD scores are not only associated with the presence of obstructive coronary artery disease, but may also provide insight into the amount of plaque, the kind of plaque, and the degree of narrowing of the coronary vessel," said Dr. Voros.

### ***Clinical Utility***

The clinical utility study, by lead author Kelly Parsons, Ph.D., Senior Research Manager at Express Scripts, showed that physicians' use of Corus CAD was associated with increased medication adherence among patients prescribed lipid-lowering therapy. Results of the study showed that patients with elevated Corus CAD scores (>15), indicating greater plaque burden and increased likelihood of

obstructive CAD, were more adherent to prescribed lipid-lowering agents (75 percent vs. 64 percent,  $p < 0.05$ ).

“Lipid-lowering medications, such as statins and fibrates, are critical for the management of cardiovascular disease,” said Mark Monane, M.D., Chief Medical Officer of CardioDx. “Although \$20 billion is spent annually on lipid-lowering agents, long-term studies on this class show adherence rates to be only 40 to 60 percent. This study suggests that Corus CAD may be a useful tool for improving medication adherence among patients who have been prescribed lipid-lowering agents.”

The Corus CAD gene expression test has been validated in three independent patient cohorts enrolled as part of two prospective, multicenter studies, PREDICT and COMPASS. The PREDICT study first validated the ability of Corus CAD to assess whether or not a stable, nondiabetic patient’s symptoms are due to obstructive CAD. In the COMPASS validation study, Corus CAD demonstrated very high negative predictive value (96 percent) in a patient population reflecting the test’s intended-use population, outperforming myocardial perfusion imaging (MPI) in diagnostic accuracy and negative predictive value. In these studies, Corus CAD was validated using CT angiography and the gold standard for diagnosis of coronary artery disease, invasive coronary angiography.

### **About Corus CAD**

With a simple blood draw, Corus CAD 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 coronary artery disease (CAD), enabling many patients to avoid unnecessary invasive procedures and exposure to imaging-related radiation risks or imaging agent intolerance. The test has been clinically validated in multiple independent patient cohorts, including two prospective, multicenter U.S. studies, PREDICT and COMPASS. Additionally, a retrospective, multicenter chart review study and the prospective IMPACT trial at Vanderbilt University 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 been used commercially by clinicians in more than 31,000 patients and is a covered benefit for more than 40 million Medicare enrollees in the U.S.

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 nondiabetic stable patients who present with typical or atypical symptoms suggestive of CAD, with no known history of CAD, have no prior myocardial infarction (MI) or revascularization procedure, and are not currently taking steroids, immunosuppressive agents or chemotherapeutic agents.

### **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).

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