



## **CardioDx Multi-Center Trial Validates Blood-Based Gene Expression Test to Assess the Presence of Obstructive Coronary Artery Disease**

*Results Published in Annals of Internal Medicine*

**PALO ALTO, Calif. – October 4, 2010** – CardioDx, a pioneer in the field of cardiovascular genomic diagnostics, today announced publication of results from the **Personalized Risk Evaluation and Diagnosis In the Coronary Tree (PREDICT)** trial in the *Annals of Internal Medicine*, the journal of the American College of Physicians.

Findings from the PREDICT trial validate the ability of Corus™ CAD, the company's blood-based gene expression test, to help clinicians confidently identify which of their stable symptomatic patients are likely to need further assessment for obstructive coronary artery disease (CAD). Eric Topol, M.D., Director of the Scripps Translational Science Institute in La Jolla, Calif., is the principal investigator for the trial.

“The critical question that we addressed – can the gene expression from white blood cells provide information about blockages of the coronary arteries? – was answered and validated in a select cohort who also underwent angiography,” said Dr. Topol. “The findings may help our future ability to direct coronary angiography to the patients with real clinical need.”

“With Corus CAD, clinicians now have an entirely new, safe and convenient way to assess the presence of obstructive coronary artery disease,” said John McPherson, M.D., assistant professor of Medicine, Division of Cardiovascular Medicine at Vanderbilt Heart and Vascular Institute in Nashville, Tennessee, who served as an investigator for the trial. “Corus CAD has become an invaluable tool in my daily practice, providing complementary information to clinical factors and helping me better non-invasively evaluate whether a patient's symptoms are due to obstructive coronary artery disease. The test can be easily administered in any practice setting – I use it both in our urban academic practice and in outlying rural clinics.”

“The publication of the clinical validation study and the successful launch of Corus CAD are important milestones for CardioDx and go a long way toward fulfilling our vision of developing genomic tools that help clinicians answer difficult clinical questions,” said David Levison, chief executive officer of CardioDx. “We are delivering unique information to cardiologists deciding which patients require advanced imaging or potential catheterization, and to primary care clinicians deciding which patients need a specialist referral. Given widespread interest among clinical and regulatory communities in reducing radiation exposure from medical imaging, we believe there may be increasing demand for a ‘no-radiation alternative’ like Corus CAD to help clinicians safely assess patients with symptoms suggestive of coronary artery disease.”

A study published in the March 11, 2010 issue of the *New England Journal of Medicine* found that in nearly 400,000 patients who underwent elective invasive angiographic procedures, 62% were found to have no obstructive coronary artery blockage. As in the PREDICT trial, this study enrolled patients with

suspected coronary artery disease. The study authors concluded that current modalities for identifying which patients should undergo elective invasive coronary angiography to diagnose coronary artery disease have limitations, and that better methods are needed for patient risk stratification. Similarly, the PREDICT study found that 63% of patients enrolled had no obstructive coronary artery disease.

“I see broad potential for a test like Corus CAD to transform the way obstructive coronary artery disease is diagnosed, to the benefit of both clinician and patient,” said Alexandra Lansky, M.D., a cardiologist at New York-Presbyterian Hospital-Columbia University Medical Center and director of Clinical Services at its Center for Interventional Vascular Therapy. Dr. Lansky was also an investigator for the PREDICT study. “Patients for whom current testing methods yield less accurate results, including obese patients and women, may especially benefit.”

Although experts have long agreed that cardiovascular disease develops and presents differently in women versus men, Corus CAD is the first sex-specific test for obstructive coronary artery disease to directly account for critical biological differences between men and women.

The prospective, blinded, multi-center PREDICT trial was designed to develop and validate gene expression tests that accurately determine the likelihood of obstructive coronary artery disease in stable patients with symptoms suggestive of coronary artery disease. Obstructive coronary artery disease was defined in the study as at least one atherosclerotic plaque causing 50 percent or greater luminal diameter stenosis in a major coronary artery ( $\geq 1.5$ mm lumen diameter) as determined by invasive quantitative coronary angiography (QCA).

1,343 non-diabetic patients from 39 U.S. clinical sites, enrolled between July 2007 and April 2009, were included in the development and prospective validation of Corus CAD. All patients had been referred for elective invasive coronary angiography. The patients were classified as cases or controls based on whether they had obstructive coronary artery disease or not, as determined by quantitative coronary angiography (QCA). Blood samples were also collected from the patients, and data from the QCA analysis was then compared to Corus CAD test results to determine test performance. Both QCA technicians and CardioDx analysts were blinded to patient disease status. In the validation study, Corus CAD demonstrated a sensitivity of 85 percent (the probability that someone with a positive test result does indeed have obstructive coronary artery disease) and a negative predictive value of 83 percent (the probability that someone with a negative test result does not have obstructive coronary artery disease).

### **About Gene Expression Testing**

Gene expression testing provides valuable tissue and cell-specific information about the molecular mechanisms involved in disease processes, enabling evaluation of an individual patient's disease state, activity, and/or progression at a given point in time. Unlike genetic tests, which measure genetic variations, mutations, traits and predispositions – factors that are constant over a person's lifetime – gene expression testing assesses a dynamic process, integrating both genetic predisposition and additional behavioral and environmental influences on current disease state.

### **About Corus CAD**

Corus CAD is the first and only clinically validated blood-based test for 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. Corus CAD is a decision-making tool that can help primary care clinicians and cardiologists evaluate whether a non-diabetic patient's symptoms are due to obstructive coronary artery disease. It is the first sex-specific test for obstructive coronary artery disease, accounting for critical biological differences between men and

women. The Corus CAD test procedure uses the RNA levels of 23 genes. Because the RNA levels are increased or decreased when obstructive coronary artery disease is present, Corus CAD is able to measure the likelihood that an individual patient has obstructive coronary artery disease from a simple blood sample. Corus CAD is commercially available through an innovative patient sample kit that includes everything needed for blood collection and express delivery to the company's CLIA-certified Palo Alto, Calif. laboratory. Test results are delivered to the clinician's office in less than 72 hours. Corus CAD is currently available in the United States.

For more information please visit <http://www.cardiodx.com/media-kit/>.

### **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. The company was honored as a winner of the Wall Street Journal's prestigious Technology Innovation Awards for 2010. Privately held, CardioDx is funded by Kleiner, Perkins, Caufield & Byers, TPG Biotech, Mohr Davidow Ventures, Intel Capital, Pappas Ventures, DAG Ventures, Asset Management Company and GE Capital.

For more information, please visit [www.cardiodx.com](http://www.cardiodx.com).

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