CardioDx's Corus CAD Gene Expression Test Performs Equally Well in Both Women and Men for the Assessment of Obstructive Coronary Artery Disease, Study Shows

Corus CAD Offers an Accurate, Non-Invasive Approach Beyond Traditional Methods

PALO ALTO, Calif. – July 31, 2012 – CardioDx, Inc., a pioneer in the field of cardiovascular genomic diagnostics, today announced online publication of a study in the *American Heart Journal.* The paper, titled "A Gender Specific Blood-Based Gene Expression Score for Assessing Obstructive Coronary Artery Disease in Non-Diabetic Patients: Results of the PREDICT Trial," reported the performance of the company's Corus® CAD gene expression test for the assessment of obstructive coronary artery disease (CAD) in men and women presenting with typical and atypical symptoms suggestive of obstructive CAD. The article is in press (available online now) and will appear in the September issue of the journal.

"Corus CAD is unique as it is the only gender-specific diagnostic test currently available that accurately risk stratifies patients with obstructive coronary artery disease, accounting for key biological differences between men and women," said Alexandra Lansky, M.D., Associate Professor of Medicine and Director of the Cardiovascular Research Center at Yale University School of Medicine, who is the lead author of the study. "This study found that commonly used diagnostic approaches, including symptom evaluation and myocardial perfusion imaging, performed less well in women than in men for identifying obstructive coronary artery disease. In contrast, the Corus CAD test performed well in both women and men. Corus CAD offers a reliable diagnostic approach for the assessment of non-diabetic patients, particularly women, with suspected obstructive coronary artery disease."

The study analyzed clinical data from 1,160 patients (58% men and 42% women) enrolled in the PREDICT trial, a prospective, multicenter study designed to develop and validate the Corus CAD test. All patients enrolled in PREDICT had been referred for elective invasive coronary angiography. The patients were classified as cases or controls based on an assessment of obstructive CAD by quantitative coronary angiography (QCA). Data from the QCA analysis was then compared to the blood-based Corus CAD test results to determine test performance. Eric Topol, M.D., Director of the Scripps Translational Science Institute in La Jolla, Calif., was the principal investigator for the trial.

The results of the analysis showed that Corus CAD test scores were significantly correlated with obstructive coronary artery disease in both male and female cohorts in PREDICT. The Corus CAD score was significantly and independently associated with obstructive CAD in both men and women, while symptoms of typical angina were significantly associated with obstructive CAD only for men ($p<0.001$). Each 10-point increase in the Corus CAD score was associated with a twofold increase in the likelihood of obstructive disease in men and women, as well as with an increase in maximum percent stenosis, number of lesions, and total coronary plaque volume. Higher Corus CAD scores were significantly associated with increased likelihood of disease in the overall population and in the male

and female subgroups separately (all p=0.001), whereas commonly used myocardial perfusion imaging was not.

Women often have non-specific, atypical symptoms of CAD that make the assessment of CAD disease more difficult. Traditional diagnostic methods such as cardiac imaging do not account for gender-specific factors, and the real-world performance of these diagnostic tools is often compromised in women.[1] In addition, many traditional tests involve radiation exposure, and cumulative effective doses of radiation from imaging procedures have been shown to be higher in women than in men.[2]

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 percent were found to have no obstructive coronary artery blockage,[3] despite the fact that the majority of patients (84 percent) had received noninvasive diagnostic tests prior to referral to catheterization. The authors concluded that current modalities for identifying which patients should undergo elective invasive coronary angiography to diagnose obstructive CAD have limitations, and that better methods are needed for patient risk stratification. Typical and atypical presentations of stable chest pain account for up to two percent of all doctor's office visits each year, or as many as 10,000 patients every day in the U.S. [4,5]

"Traditional tests for obstructive coronary artery disease result in many cardiac catheterizations where no disease is found, especially in women," said Mark Monane, M.D., Chief Medical Officer of CardioDx. "This analysis from the PREDICT trial adds to the clinical evidence demonstrating that the Corus CAD test can accurately and non-invasively help clinicians identify whether or not patients need further diagnostic cardiac evaluation, enabling many patients to avoid unnecessary testing and exposure to radiation risks or imaging agent intolerance."

About Corus CAD

With a simple blood draw, Corus CAD can help primary care clinicians and cardiologists exclude obstructive coronary artery disease as the cause of a stable non-diabetic patient's symptoms. It is the first gender-specific test for obstructive coronary artery disease, accounting for critical biological differences between men and women. The test is safe and does not expose patients to radiation risks or imaging agent intolerance.

The Corus CAD test measures the RNA levels of 23 genes. Because peripheral blood cell RNA levels are altered when obstructive coronary artery disease is present, the Corus CAD score aids clinicians in assessing whether an individual patient's symptoms may be due to obstructive coronary artery disease.

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 promptly to the clinician's office. Corus CAD is currently available in the United States.

Corus CAD has 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.

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. For more information, please visit www.cardiodx.com.

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Media Contact: Nicole Osmer
650.454.0504
nicole@nicoleosmer.com

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