CardioDx Announces Positive Results from Clinical Utility Study Evaluating the Corus® CAD Blood Test's Influence on Clinical Decision-Making in the Assessment of Obstructive Coronary Artery Disease in Women

96% of Women with Low Corus CAD Test Scores Avoid Further Cardiac Testing

REDWOOD CITY, Calif. – April 1, 2015 – CardioDx, Inc., a molecular diagnostics company specializing in cardiovascular genomics, today announced the publication of a new study examining the effect of the use of an age, sex, and gene expression score on clinical decision-making and the rate of further cardiac evaluation in symptomatic female patients in the outpatient setting. The study examined the use of the Corus CAD test, a blood test which incorporates age, sex, and gene expression, in 320 women presenting with stable symptoms suggestive of obstructive coronary artery disease (CAD).* The study indicated that women with low Corus CAD test scores (≤15) were significantly less likely to be referred for further cardiac evaluation (OR 0.013, p<0.0001) by their primary care clinicians within 45 days of follow-up. Only 4% of women (10/248) with low Corus CAD test scores received further testing for obstructive CAD.

The study, an aggregated analysis of female cohorts from the IMPACT-PCP[1] and REGISTRY I[2] studies, was recently presented at the American College of Cardiology 64th Annual Scientific Meeting and is published on-line today ahead of the November 2015 print issue of *Menopause: The Journal of The North American Menopause Society*.[3]

"Current testing approaches for identifying obstructive CAD have been shown to be less accurate in women than men, and these diagnostic challenges lead to both over-testing of low-risk women and under-testing of high-risk women," said Joseph A. Ladapo, M.D., Ph.D., Assistant Professor of Medicine, Department of Population Health and Medicine, NYU School of Medicine and lead author of the study. "This study demonstrates that incorporating the age, sex, and gene expression score early in the diagnostic pathway, as a part of the patient's clinical assessment, can help clinicians rule-out obstructive CAD in menopausal women presenting with chest pain and other angina symptoms."

The Corus CAD test is the first and only commercially available blood-based test incorporating age, sex, and gene expression measurements that provides a current-state assessment of obstructive CAD in non-diabetic patients presenting with non-acute typical or atypical symptoms. With a 96% negative predictive value,[4,7] the Corus CAD test can help clinicians accurately rule out obstructive CAD as the source of their patients' symptoms.

The study included 320 women presenting to 16 primary care providers across 9 practice sites and 6 states. The mean Corus CAD test score was 10.3±8.2, with a range of 1 (corresponding to a 1% likelihood of obstructive CAD) to 38 (corresponding to a 62% likelihood of obstructive CAD). Overall, 77.5% of women (248/320) had low Corus CAD test scores. The referral rate for further cardiac evaluation was 4% (10/248) among women with low Corus CAD test scores versus 83.3% (60/72) among women with elevated scores (p<0.0001).

"The use of the Corus CAD test can help primary care clinicians more safely evaluate symptomatic women and help rule-out obstructive CAD in women who are unlikely to benefit from further cardiac testing," said Mark Monane, M.D., FACP, Chief Medical Officer of CardioDx. "The Corus CAD test can contribute to the effort by the American Heart Association and other professional organizations to ensure that radiation exposure from cardiovascular imaging is kept as low as reasonably achievable. Pursuing this goal is particularly important for women, who are already at greater risk of radiation exposure and side effects and complications from cardiovascular testing than men."

About Obstructive Coronary Artery Disease

Coronary artery disease (CAD) is a very common heart condition in the United States. One in six deaths among Americans is caused by CAD.[5] 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 the Corus CAD Test

Corus CAD is the first and only commercially available blood test that can safely and conveniently help primary care clinicians and cardiologists assess whether or not a stable non-diabetic patient's symptoms may be due to obstructive coronary artery disease. The test incorporates age, sex and gene expression measurements into a single score that indicates the likelihood of obstructive CAD. Clinicians use the Corus CAD score, along with other clinical information, to determine whether further cardiac testing is necessary, which can help patients avoid unnecessary exposure to radiation associated with medical imaging testing, as well as possible reactions to imaging dyes and/or potential complications from invasive cardiac tests requiring catheterization. The test involves a routine blood draw that is conveniently administered in the clinician's office. The Corus CAD test is the only sex-specific test for the evaluation of obstructive CAD because it accounts for key cardiovascular differences between men and women.

The test has been clinically validated in independent male and female patient cohorts, including two prospective, multicenter U.S. studies, PREDICT and COMPASS.[4,6] In the COMPASS study, the Corus CAD test outperformed myocardial perfusion imaging (MPI) as a diagnostic tool to exclude obstructive CAD by demonstrating a higher negative predictive value (96% vs. 88%, $p<0.001$) than MPI for assessing the presence of obstructive CAD.[7] To date, over 100,000 Corus CAD test results have been provided to clinicians. CardioDx processes all Corus CAD test samples at its CLIA-certified and CAP-accredited clinical laboratory in Redwood City, California.

The Corus CAD test 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 10 Medical Breakthroughs.

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, CardioDx is committed to expanding patient access and improving healthcare quality and efficiency through the commercialization of genomic technologies. Please visit www.cardiodx.com for additional information.

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* Obstructive CAD is defined as at least one atherosclerotic plaque causing ≥50% luminal diameter stenosis in a major coronary artery (≥1.5 mm lumen diameter) as determined by invasive quantitative coronary angiography (QCA) or core-lab computed tomography angiography (CTA) (≥2.0 mm).

[1] Herman L, Froelich J, Kanelos D, et al. Utility of a Genomic-Based, Personalized Medicine Test in Patients Presenting with Symptoms Suggesting Coronary Artery Disease. *J Am Board Fam Med*. 2014;27(2):258-67.
[2] Ladapo JA, Lyons H, Yau M, et al. Enhanced Assessment of Chest Pain and Related Symptoms in the Primary Care Setting Through the Use of a Novel Personalized Medicine Genomic Test: Results From a Prospective Registry Study. *Am J Med Qual.* 2014 May 5. [Epub ahead of print]
[3] Ladapo JA, Herman L, Weiner B, et al. Use of a Blood Test Incorporating Age, Sex, and Gene Expression Influences Medical Decision-Making in the Evaluation of Women Presenting with Symptoms Suggestive of Obstructive Coronary Artery Disease: Summary Results From Two Ambulatory Care Studies in Primary Care. *Menopause*. 2015 March 31. [Epub ahead of print]
[4] 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(2):154-162.
[5] Go SO, Mozaffarian D, Roger VL, et al. on Behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics—2013 Update: A Report from the American Heart Association. *Circulation*. 2013;127(1):e6-e245.
[6] 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.
[7] The COMPASS study demonstrated that the Corus CAD algorithm has an NPV of 96% at the pre-specified threshold of 15 in a population of men and women referred to MPI.