



CardioDx Announces Positive Data from a Large Primary Care Registry on the Impact of the Corus CAD Test in the Assessment of Obstructive Coronary Artery Disease in Women

Subgroup Analysis from the PRESET Registry Presented at The North American Menopause Society 2015 Annual Meeting

REDWOOD CITY, Calif. – September 30, 2015 – CardioDx, Inc., a molecular diagnostics company specializing in [cardiovascular genomics](#), announced today results from a subgroup analysis of the primary efficacy endpoint of the community-based patient registry, the PRESET Registry.¹ This analysis evaluated how the [Corus® CAD test](#), a blood-based test that integrates age, sex, and gene expression levels into a single score indicating the likelihood of obstructive CAD*, impacted clinicians' diagnostic strategy for cardiac evaluation of women. Data from the subgroup analysis will be presented at The North American Menopause Society (NAMS) Annual Meeting on October 1, 2015 in Las Vegas, Nevada.

The results of the patient registry analysis demonstrated the Corus CAD test was adopted into clinical practice and helped clinicians determine the need for further cardiac evaluation or testing in female patients presenting with symptoms suggestive of obstructive CAD. The test also showed clinical utility in impacting clinicians' medical decision-making on whether or not to refer patients to cardiology or for additional cardiac testing.

“With most CAD diagnostic tests, female patients are at risk of diagnostic inaccuracies, due to high false positive and false negative rates, which can lead to additional and potentially harmful cardiac tests and their associated risks such as radiation exposure and procedural risks,” said Gregory Pokrywka, M.D., FACP, FNLA, NCMP, Director, Baltimore Lipid Center, Baltimore, MD., and lead author of the study. “Our subgroup analysis of the PRESET Registry demonstrates the adoption of the Corus CAD test into a primary care practice setting impacted clinicians' decision-making among mid-life women. Women with low Corus CAD (≤ 15) scores were referred less often for additional testing.”

The analysis, “The Clinical Utility of a Blood Test Incorporating Age, Sex and Gene Expression in the Evaluation of Women Presenting with Stable Symptoms Suggestive of Obstructive Coronary Artery Disease in a Large Primary Care Registry (The PRESET Registry): Subgroup Analysis of the Primary Efficacy Endpoint,” assessed 369 stable, non-acute adult female subjects presenting with symptoms suggestive of obstructive CAD.

The women in the PRESET Registry subgroup analysis had a median age of 59 years and a median Corus CAD test score of 9 (range: 1-40). Among the 272 patients (74%) with low Corus CAD test scores (≤ 15), only 21 (8%) were referred for further cardiac testing (OR 0.18; p-value < 0.0001 versus women with a non-low (> 15) Corus CAD test score). The analysis is expected to have one-year follow-up results.

“Primary care clinicians used the Corus CAD test to help rule out obstructive CAD early in the diagnostic work-up of these women,” said Mark Monane, M.D., FACP, Chief Medical Officer of



CardioDx. “We look forward to continuing to grow the clinical evidence base of our Corus CAD test as part of our commitment to help address this important diagnostic challenge in the care for women in mid-life and beyond.”

About Obstructive Coronary Artery Disease

Coronary artery disease (CAD) is a very common heart condition in the United States. One in seven deaths among Americans is caused by CAD.² 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 or clinical laboratory patient service center. The Corus CAD test is the only sex-specific test for the evaluation of obstructive CAD because it accounts for 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.^{3,4} 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.⁵ 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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For media inquiries, please contact Glenn Silver of Lazar Partners, +1-212-871-8485, gsilver@lazarpartners.com.

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

References

- ¹ Ladapo JA, Budoff M, Ross L, et al. Primary Endpoint Results from a Community-Based Registry Evaluating the Use of a Blood-Based Age/Sex/Gene Expression Test in Patients Presenting with Symptoms Suggestive of Obstructive Coronary Artery Disease: the PRESET Registry (A Registry to Evaluate Patterns of Care Associated with the Use of Corus[®] CAD in Real World Clinical Care Settings). *Circ Cardiovasc Qual Outcomes*. 2015;8:A142.
- ² Mozaffarian D, Benjamin EJ, Go AS, et al. On Behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics – 2015 Update: A Report from the American Heart Association. *Circulation*. 2015;131(4):e29-e322.
- ³ 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.
- 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 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.