



## **New Study Published in *The American Journal of Medicine* Expands the Clinical Evidence Underscoring the Value of the Corus® CAD Blood Test to Help Safely Direct Cardiovascular Care**

*– PRESET Registry Demonstrates the Corus CAD Blood Test Was Associated with Cardiac Referrals, and the Test Reduced Potentially Unnecessary Cardiac Workup of Patients –*

**REDWOOD CITY, Calif. – April 12, 2017** – [CardioDx, Inc.](#), a molecular diagnostics company specializing in [cardiovascular genomics](#), announced today the publication of results from the multi-center, community-based PRESET Registry in the peer-reviewed journal, *The American Journal of Medicine*.<sup>1</sup> The study results provided further confirmation of the clinical utility of the [Corus CAD test](#) to help clinicians in real-world practice determine if their patients' symptoms are due to a blockage in the heart arteries, and if referral to cardiology or to advanced cardiac testing was necessary. Previously validated with a 96% negative predictive value and 89% sensitivity, the Corus CAD test is a precision medicine blood test that integrates age, sex, and gene expression levels into a single score indicating the current likelihood of a significant narrowing or blockage in the coronary arteries, also known as obstructive\* coronary artery disease (CAD).

The PRESET Registry (NCT01677156, [clinicaltrials.gov](#)) demonstrated that patients with low Corus CAD scores (defined as  $\leq 15$ ) were less likely to undergo cardiac referral, were unlikely to have positive findings on further cardiac work-up, and had a low rate of adverse cardiovascular events at one year follow-up.

Every day, approximately 8,000 patients present to primary care clinics with signs and symptoms of obstructive CAD. Yet, a review of published patient data suggests that only 10% of patients presenting with chest pain to primary care clinicians for evaluation are actually found to have CAD. The majority of chest pain symptoms are caused by non-cardiac sources such as heartburn, muscle spasm, anxiety, or lung-related conditions.<sup>2</sup>

"The PRESET Registry provides doctors and patients with further evidence that, as a first-line assessment tool for patients with symptoms suggestive of CAD in outpatient clinics, the age, sex, and gene expression score (Corus CAD) can safely and reliably help clinicians direct cardiac care," said Joseph A. Ladapo, Assistant Professor, Division of General Internal Medicine and Health Services Research, David Geffen School of Medicine at University of California at Los Angeles. "Patients with low scores were less likely to undergo further cardiac evaluation and testing, and this saves some patients from being unnecessarily exposed to the risks of cardiac procedures and radiation from cardiac nuclear imaging, along with the costs associated with pursuing advanced cardiovascular testing."

The primary objective of the study was to evaluate the clinical utility or impact of the Corus CAD test on medical decision-making, specifically cardiac referrals. Results demonstrated that patients with low Corus CAD scores ( $\leq 15$ ) had an 85% decreased odds of referral for further cardiac evaluation or testing versus elevated Corus CAD scores ( $>15$ ). Only 10% of patients with low [Corus CAD test](#) scores versus 44% of elevated scoring patients were referred by clinicians to cardiology or for advanced cardiac testing (unadjusted Odds Ratio (OR) = 0.15,  $p < 0.0001$ ; adjusted OR after accounting for clinical covariates = 0.18,



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$p < 0.001$ ). Furthermore, when evaluating the Corus CAD score as a continuous variable from 1-40, the higher the Corus CAD score, the more likely the patient was to undergo cardiac referral. Major adverse events and revascularization were noted in 1.2% (3/252) of patients with low Corus CAD scores and 4.5% (14/314) of patients with elevated Corus CAD scores ( $p < 0.03$ ).

“The need for better cardiac care and safer tests has always been the goal of the Corus CAD test,” said Mark Monane, MD, FACP, Chief Medical Officer of CardioDx. “The final analysis of the PRESET Registry showed that clinicians are integrating the Corus CAD test into real-world clinical decision-making to help risk stratify patients to the appropriate care pathway. Incorporating the Corus CAD test into the primary care setting provides an opportunity for patients, healthcare providers, and managed care payers to benefit, as expensive and potentially risky cardiac tests or procedures may be avoided in patients with low Corus CAD scores.”

### **About the PRESET Registry**

The PRESET Registry (A Registry to Evaluate Patterns of Care Associated with the Use of Corus CAD in Real World Clinical Care Settings) assessed the effects of the Corus CAD score on clinical decision-making in stable non-diabetic patients without a history of obstructive CAD. The analysis included patients from 21 primary care practices from the time period of September 2012 through August 2014. This final endpoint analysis included 566 patients with typical or atypical symptoms suggestive of obstructive CAD and one-year follow-up post-Corus CAD testing.

### **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.<sup>3</sup> 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 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.<sup>4,5</sup> In the COMPASS study, the Corus CAD test outperformed myocardial perfusion imaging (MPI) as a diagnostic tool to exclude obstructive CAD by



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demonstrating a higher negative predictive value (96% vs. 88%,  $p < 0.001$ ) than MPI for assessing the presence of obstructive CAD.<sup>6</sup> To date, over 220,000 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](http://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](mailto:gsilver@lazarpartners.com).

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

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<sup>1</sup> Ladapo JA, Budoff M, Sharp D, et al. Clinical Utility of a Precision Medicine Test Evaluating Outpatients with Suspected Obstructive Coronary Artery Disease. *Am J Med.* 2017;130(4):482.e11-482.e17.

<sup>2</sup> Cayley WE Jr. Diagnosing the Cause of Chest Pain. *Am Fam Physician.* 2005;72(10):2012–2021.

<sup>3</sup> 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 – 2016 Update: A Report from the American Heart Association. *Circulation.* 2016;133(4):e38-e360.

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> 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.