



CardioDx Expands Patient Access to the Corus® CAD Test through National Agreement with Quest Diagnostics

CardioDx Also Separately Raises \$20 Million in New Financing to Support the Company's Commercial Growth and Operations

REDWOOD CITY, Calif. – September 16, 2015 – CardioDx, Inc., a molecular diagnostics company specializing in cardiovascular genomics, today announced a national specimen-draw agreement with Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, that will expand patient and clinician access to the Corus CAD lab-developed blood test for aiding the assessment of obstructive coronary artery disease (CAD)*.

Under a multi-year agreement, clinicians will be able to order blood draws on patients for testing through Quest's approximately 2,200 patient service centers and 4,000 phlebotomists in physician offices in the United States. Samples will be forwarded to CardioDx's CLIA-certified laboratory (in Redwood City, Calif.) for testing.

"This agreement will expand patient access to the Corus CAD test, a test that complements Quest's suite of advanced diagnostic information services for assessing risk of cardiovascular disease and personalizing treatment," said Patrick Plewman, General Manager of Quest Diagnostics Cardiovascular, Metabolic and Endocrinology Clinical Franchise. "The addition of this test to our offering provides a new avenue to generate value from Quest's uniquely large network of patient service centers and in-office phlebotomists in the United States."

"Following coverage of the Corus CAD test from Aetna and Coventry Health, this agreement with Quest represents another major milestone that will expand patient access to the test and allow CardioDx to strengthen relationships with clinicians," said David Levison, President and Chief Executive Officer of CardioDx. "Quest is the world leader in diagnostic testing, and we are thrilled that it will now be easier for patients to access the Corus CAD test."

CAD is the most common form of heart disease and is responsible for one in seven deaths in the United States.¹ Diagnosis typically involves medical imaging or invasive procedures in which a catheter is inserted in an artery or vein in your groin, neck or arm and threaded through a person's blood vessel to visualize the heart arteries.

The [Corus CAD test](#) is the first and only commercially available blood-based test that provides a current-state assessment of obstructive CAD. With a 96% negative predictive value,² the test incorporates age, sex, and gene expression measurements into a single score that indicates the likelihood of obstructive CAD. Combined with other clinical information, the test can help clinicians quickly, accurately, and safely determine if a patient's [symptoms](#) are caused by obstructive CAD.

Used early in the evaluation of symptomatic patients, the test can help clinicians determine whether or not further cardiac testing is necessary, thus helping patients avoid unnecessary noninvasive imaging



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and invasive cardiac procedures that are often more complex, expensive and expose patients to significant amounts of radiation and other adverse risks. Patients with low Corus CAD test scores had a statistically significant 82% decreased odds of referral for further cardiac evaluation or testing in a recently published study of 718 nonacute patients receiving the Corus CAD test in the primary care setting.³

“As concerns about radiation exposure and test overutilization continue to grow within the medical community, the Corus CAD test is well positioned to address the need for solutions that minimize risk and help streamline clinical decision-making,” added Mark Monane, M.D., Chief Medical Officer. “Quest has been at the forefront of adopting innovative diagnostic solutions that can help improve human health. We are proud to collaborate with them to help make the Corus CAD test available to more clinicians and patients across the country.”

Separately, CardioDx’s commercial operation continues to expand with a new \$20 million round of financing from Solar Capital Ltd. and Silicon Valley Bank as well as current investors. The financing was facilitated by Armentum Partners.

About Obstructive Coronary Artery Disease

Coronary artery disease (CAD) is a very common heart condition in the United States. 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.^{2,4} 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.



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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 coronary artery disease (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 core-lab computerized tomography angiography (CTA) (≥ 2.0 mm lumen diameter).

References

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2. 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.
3. 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.
4. 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.
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.