



## **New American Heart Association Scientific Statement Highlights the Use of the Corus® CAD Blood Test in Helping Clinicians Assess Obstructive CAD**

*- Scientific Statement Spotlights New Technologies in Expressed Genome Research That Further Precision Medicine in Cardiac Care –*

**REDWOOD CITY, CA** – October 12, 2017 – CardioDx, Inc., a molecular diagnostics company specializing in cardiovascular genomics, announced today that a Scientific Statement by the American Heart Association highlighted the use of the [Corus® CAD](#) blood test in the workup of patients with suspected coronary artery disease (CAD).<sup>1</sup> CAD is one of the leading causes of death in the U.S. resulting in one in seven deaths.<sup>2</sup>

Published in the peer-reviewed journal, *Circulation: Cardiovascular Genetics*, the AHA Scientific Statement, [The Expressed Genome in Cardiovascular Disease and Stroke: Refinement, Diagnosis, and Prediction: A Scientific Statement From the American Heart Association](#),<sup>1</sup> discussed how the expressed genome can now, and in the future, be used to diagnose and predict cardiovascular disease and manage patient treatment. The statement then highlighted two commercially available technologies stemming from this research.

“Since the human genome was sequenced 14 years ago, significant advancements have been made in the field of expressed genome research,” said Kiran Musunuru, M.D., Ph.D., the statement’s lead author and Associate Professor of Cardiovascular Medicine and Genetics at the University of Pennsylvania. “The AHA convened a panel of experts to review, evaluate and publish the state of the science in the diagnosis and prediction of cardiovascular disease with these technologies. We are optimistic that their use and application will continue to grow, enabling their widespread adoption and progress in this field. Our work identified two available tests that had generated sufficient data to be included in our review, including Corus CAD.”

[Corus CAD](#) is the only clinically validated blood test that uses age, sex and gene expression to measure the current likelihood of obstructive coronary artery disease\* (CAD) in symptomatic patients. The test was validated in both the [PREDICT](#)<sup>3</sup> and [COMPASS](#)<sup>4</sup> clinical studies. And the results were then independently confirmed in a third study -- the [NHLBI-sponsored PROMISE Corus CAD substudy](#).<sup>5</sup> With a 96% negative predictive value, the Corus CAD test is a simple blood test that incorporates age, sex, and gene expression measurements into a single score (1-40 scale) corresponding to the current likelihood of obstructive CAD.<sup>4,6</sup>

“We are delighted that the American Heart Association highlighted the clinical value of the [Corus CAD](#) test in the recent Scientific Statement,” says Khush F. Mehta, President and Chief Executive Officer of CardioDx. “With [Corus CAD](#), CardioDx is delivering on the promise of the human genome by empowering clinicians with enhanced solutions for better patient care.”

### **About Obstructive Coronary Artery Disease**

Coronary artery disease (CAD) is a very common heart condition in the United States. One in seven



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deaths among Americans is caused by CAD.<sup>2</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 procedures. 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>3,4</sup> 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.<sup>6</sup> In the NHLBI-sponsored PROMISE Corus CAD substudy, Corus CAD demonstrated similar clinical outcomes to MPI and coronary CT-angiography at 25 months follow-up (3.2% vs. 2.6%,  $p = 0.29$ ).<sup>5</sup> To date, over 240,000 Corus CAD test results have been provided to clinicians commercially. 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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\* 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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## References

- <sup>1</sup> Musunuru K, Ingelsson E, Fornage M, et al. The Expressed Genome in Cardiovascular Diseases and Stroke: Refinement, Diagnosis, and Prediction: A Scientific Statement From the American Heart Association. *Circ Cardiovasc Genet.* 2017;10(4):e1-e25.
- <sup>2</sup> Benjamin EJ, Blaha MJ, Chiuve SE, et al. On Behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics – 2017 Update: A Report from the American Heart Association. *Circulation.* 2017;135(10):e146-e603.
- <sup>3</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>4</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>5</sup> Voora D, Coles A, Lee KL, et al. An Age- and Sex-Specific Gene Expression Score is Associated With Revascularization and Coronary Artery Disease: Insights From the Prospective Multicenter Imaging Study for Evaluation of Chest Pain (PROMISE) Trial. *Am Heart J.* 2017;184:133-140.
- <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.