



Study Finds the Corus[®] CAD Gene Expression Blood Test Influenced Primary Care Decision-Making in the Assessment of Patients with Suspected Obstructive Coronary Artery Disease

- IMPACT-PCP Study Results Reinforce the Clinical Utility of Corus CAD in the Primary Care Setting, Where Almost 8,000 Patients Present With Non-Acute Chest Pain and Related Symptoms Every Day -
- Clinicians Modified Their Diagnostic Strategy in 58% of Patients Following a Corus CAD Test Score -

PALO ALTO, Calif. – March 10, 2014 – CardioDx, Inc., a molecular diagnostics company specializing in [cardiovascular genomics](#), today announced the publication of the IMPACT-PCP (Investigation of a Molecular Personalized Coronary Gene Expression Test on Primary Care Practice Pattern) trial reinforcing the value of [Corus[®] CAD](#) as an initial diagnostic test for the evaluation of patients presenting with non-acute symptoms suggestive of obstructive coronary artery disease (CAD) in the primary care setting. The study appears in the March 2014 issue of the *Journal of the American Board of Family Medicine*.

“Because the symptoms of obstructive CAD often can be ambiguous and overlap with many other highly prevalent conditions, primary care physicians constantly face the dilemma of determining if the cause of their patients’ symptoms is obstructive CAD or another underlying issue,” said Lee Herman, MD, Johns Creek Primary Care, Suwanee, GA. “New approaches are urgently needed to address the costs and safety considerations associated with the current usual care. These results indicate that the blood-based gene expression test, Corus CAD, can fulfill the need for a safe, accurate, convenient and cost-effective tool to drive clinical decision-making in the assessment of obstructive CAD in symptomatic patients.”

Corus CAD is the first and only commercially available blood-based gene expression test that provides a current-state assessment of obstructive CAD in non-diabetic patients presenting with typical or atypical symptoms. It is the only sex-specific test for the diagnosis of obstructive CAD that accounts for critical biological differences between men and women. With a 96% negative predictive value and 89% sensitivity, Corus CAD can help clinicians accurately rule out obstructive CAD as the source of their patients’ symptoms, so they may look to other causes.

The IMPACT-PCP study demonstrated that primary care clinicians’ decision-making was significantly influenced when integrating Corus CAD early in the diagnostic work-up for obstructive CAD. Patients with typical and atypical presentations of chest pain (n=251) were enrolled in the study and evaluated by nine primary care clinicians in four practices for assessment of symptoms. The clinician’s diagnostic strategy was evaluated before and after the Corus CAD results were known.

Following Corus CAD testing, clinicians modified their diagnostic strategy in 58% (145/251) of patients ($p < 0.001$). The greatest change in testing was seen in patients who had low Corus CAD scores (≤ 15), with 60% (76/127) of those patients experiencing a reduction in further cardiac testing. Of the 145 patients that had a change in their diagnostic plan, 57% (83/145) were female.

“The IMPACT-PCP trial adds to previous studies of clinical utility in cardiology, and highlights the ease with which the test can be integrated into everyday primary care practice for internists and family medicine physicians,” said Mark Monane, M.D., Chief Medical Officer, CardioDx. “As a blood test that can be performed right in the doctor’s office, the Corus CAD test can be ordered the same day of the patient’s visit, with test results generated within two to three days. It’s exciting to see healthcare moving towards personalized medicine, enabling care to be customized to each individual patient. As a personalized, advanced genomic test, Corus CAD is helping primary care clinicians accurately and efficiently determine whether or not their patients need further cardiac evaluation.”

About Obstructive Coronary Artery Disease

Coronary artery disease is a very common heart condition in the United States. One in six deaths among Americans is caused by CAD.¹ 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 Corus CAD

Corus CAD is a blood test that can safely, accurately and conveniently help primary care clinicians and cardiologists assess whether or not a stable non-diabetic patient’s symptoms are due to obstructive CAD, enabling many patients to avoid unnecessary noninvasive and invasive cardiac procedures and exposure to imaging-related radiation risks, imaging agent intolerance or complications with cardiac catheterization. The test involves a routine blood draw that is conveniently administered in the clinician’s office. The test is simple, convenient, and as a sex-specific test for the diagnosis of obstructive CAD, accounts for critical biological differences between men and women.

The test has been clinically validated in independent patient cohorts, including two prospective, multicenter U.S. studies, PREDICT and COMPASS.^{2,3} In the COMPASS study, Corus CAD outperformed MPI in diagnostic accuracy as a test to exclude obstructive CAD, demonstrating a significantly higher sensitivity (89% vs. 27%, $p < 0.001$) and a significantly higher negative predictive value (96% vs. 88%, $p < 0.001$) than MPI for assessing the presence of obstructive CAD. Over 50,000 Corus CAD test results have been commercially delivered to clinicians. Corus CAD is a covered benefit for the estimated 48 million Medicare beneficiaries in the U.S. CardioDx processes all Corus CAD test samples at its CLIA-certified and CAP-accredited clinical laboratory in Palo Alto, Calif.

About Gene Expression

Corus CAD is a gene expression test, not a genetic test. Whereas genetic testing may inform on lifetime disease risk, the Corus CAD gene expression test provides a current-state assessment of obstructive CAD by looking at the gene expression changes associated with atherosclerosis. Gene expression levels change depending on a person's disease status resulting from genetic and environmental factors.

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, cardiac arrhythmia and heart failure, CardioDx is

committed to expanding patient access and improving healthcare quality and efficiency through the commercialization of genomic technologies. For more information, please visit www.cardiodx.com.

Forward-Looking Statements

This press release may contain forward-looking statements, including statements regarding the safety, efficacy and the adoption rate of and the size of the market for Corus CAD and beliefs regarding the need for and value of gene expression diagnostics. These statements relate to future events and involve known and unknown risks, uncertainties and other factors that could cause actual levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These statements reflect the views of CardioDx as of the date of this press release with respect to future events and, except as required by law, it undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this press release.

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¹ Go AS, Mozaffarian D, Roger VL, et al. Heart Disease and Stroke Statistics--2013 Update: A Report From the American Heart Association. *Circulation*. 2013;127:e6-e245.

² 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.

³ 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;6:154-162.