Highlights of the Validation of the Corus® CAD Blood Test

Multicenter Validation of the Diagnostic Accuracy of a Blood-Based Gene Expression Test for Assessing Obstructive Coronary Artery Disease in Nondiabetic Patients


ClinicalTrials.gov Identifier: NCT00500617
Patients who have symptoms suggestive of CAD or Are asymptomatic high risk

Clinical referral for angiography

Enrollment in PREDICT

ICA‡

Noninvasive imaging/testing

Corus CAD blood test

FIGURE 1: PREDICT study design

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


‡Data analyzed by quantitative coronary angiography core lab.
KEY FINDINGS

Majority of Patients Sent for Invasive Coronary Angiography Did Not Have Obstructive CAD

- Only 37% of all patients in PREDICT were found to have obstructive CAD by quantitative coronary angiography (QCA) [SEE FIGURE 2]
  - In women, the rate of obstructive CAD was particularly low (26%)
  - These findings from the PREDICT study are consistent with those reported by Patel, et al. in a study of 398,978 patients published in the New England Journal of Medicine in 2010.

Corus® CAD Test Has High Sensitivity and Negative Predictive Value (NPV)

- Test sensitivity and NPV are 85% and 83%, respectively.

Corus CAD Test Score is Proportional to the Presence and Extent of Obstructive CAD

- The higher the test score, the higher the likelihood of obstructive CAD [SEE FIGURE 3]
  - The Corus CAD score is significantly correlated with coronary atherosclerotic plaque burden as measured by maximum percent stenosis [SEE FIGURE 4]

Corus CAD Test Improves Classification of Patient Disease Status

- The combination of test score and clinical factor assessment is significantly better than clinical factor assessment alone
- Independent of myocardial perfusion imaging result or clinical risk, increasing test score is associated with increasing likelihood of obstructive CAD

FIGURE 2: Percent of patients in PREDICT found to have obstructive CAD by QCA

FIGURE 3: Relationship between test score and likelihood of obstructive CAD

FIGURE 4: Correlation between test score and plaque burden

$\text{This performance correlates to patients in PREDICT who had a likelihood of obstructive CAD of approximately 20% at a score threshold of 14.75. At this likelihood, test specificity and positive predictive value are 43% and 46%, respectively.}$
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.

Corus® CAD Intended Use
The Corus CAD test is a quantitative in vitro diagnostic test performed in a single laboratory, using age, sex, and the gene expression profile of cells found in peripheral blood specimens to help a clinician identify the likelihood that a patient has coronary artery stenosis of at least 50%. The test should be performed on patients with a history of chest pain, with suspected anginal equivalent to chest pain, or with a high risk of coronary artery disease (CAD), but with no known prior myocardial infarction or revascularization procedures. The test is not intended for patients with acute myocardial infarction, high-risk unstable angina, systemic infectious or systemic inflammatory conditions, diabetes, or who are currently taking steroids, immunosuppressive agents, or chemotherapeutic agents.

The test is performed on a blood specimen obtained from the patient. The test incorporates age, sex, and the expression levels of multiple genes using an algorithm with weighted gene expression levels to generate a quantitative score. The results of the test should be used by clinicians in conjunction with other tests and clinical information when assessing a patient’s CAD.

The Corus CAD test is for prescription use only. The test is not intended to be used to screen for stenosis among patients who are asymptomatic and not considered at high-risk for CAD, to predict or detect response to therapy, or to help select the optimal therapy for patients.

REFERENCES: