# UNDERSTANDING THE PATIENT REPORT

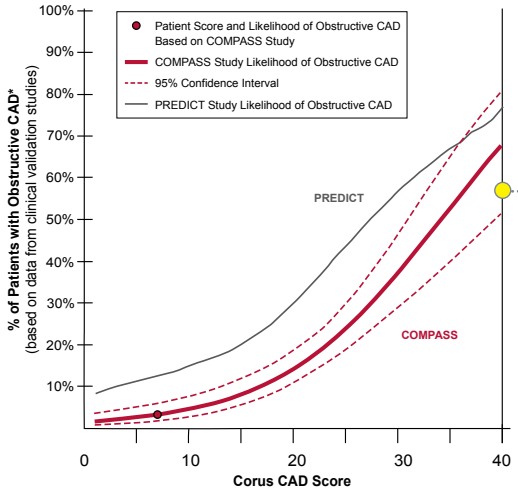
CORUS® CAD

## PATIENT REPORT

CORUS® CAD

| Patient Name | Medical Record # | Blood Collection Date | Sample ID # |
|---|---|---|---|
| Jane Doe | 00000 | 03-Mar-2013 | TRF105690 |

**Date of Birth:** 01-Jan-1952 **Clinic Name:** Cardiology Consultants **Date Received:** 04-Mar-2013
**Sex:** Female **Clinician:** Rex Morgan **Date Reported:** 06-Mar-2013




**7**
**PATIENT SCORE**

Likelihood of Obstructive CAD*†:
**3%**
**95% Confidence Interval: 2-6%**

### TEST DESCRIPTION

The Corus CAD test has been validated in two clinical studies: PREDICT[1] (symptomatic and asymptomatic patients referred for cardiac catheterization, NCT00500617) and COMPASS[2] (symptomatic patients referred for myocardial perfusion imaging, NCT01117506).

The Corus CAD algorithm integrates age, sex, and gene expression to calculate a score that indicates the likelihood of the presence of obstructive coronary artery disease (CAD) in a patient.[1-4] The score ranges from 1-40.

* 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 (QCA) or core-lab computed tomography angiography (CTA)(≥2.0mm lumen diameter).

† Likelihood function and corresponding 95% confidence interval derived by logistic regression on the COMPASS validation study data.

### TEST RESULT INFORMATION

The Corus CAD test likelihood is based on the COMPASS validation study (NCT01117506). The study analyzed 431 non-diabetic patients who had no previously diagnosed myocardial infarction or revascularization, and who presented with typical or atypical symptoms suggestive of obstructive CAD. The prevalence of CAD in this study was 15%.[2] Overall sensitivity, specificity, and NPV were 89%, 52%, and 96% respectively at a pre-specified threshold of ≤15.[2] The result of the test should be used by clinicians in conjunction with other tests and clinical information in their assessment of CAD in their patients, and in developing patient-specific clinical management plans.

Comments

This test was developed and its performance characteristics determined by Smart Heart. This test is used for clinical purposes. The Smart Heart Commercial Laboratory is both CAP-accredited and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high-complexity clinical testing.

**Lab Director: ALISON GALVAN M.D. CA License CDS00800933 CLIA #19D2087059**


[1] Rosenberg S, et al. *Ann Intern Med.* 2010;153:425-434.
[2] Thomas GS, et al. *Circ Cardiovasc Genet.* 2013;6(2):154-162.
[3] Wingrove JA, et al. *Circ Cardiovasc Genet.* 2008;1:31-38.
[4] Elashoff MR, et al. *BMC Med Genomics.* 2011;4:26.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### Patient Score

Ranges from 1 to 40, with lower values associated with lower likelihood of obstructive coronary artery disease (CAD)*. **The COMPASS study showed that 96% of patients with low Corus CAD scores (≤15) did not have obstructive CAD.**¥

### Likelihood of Obstructive CAD

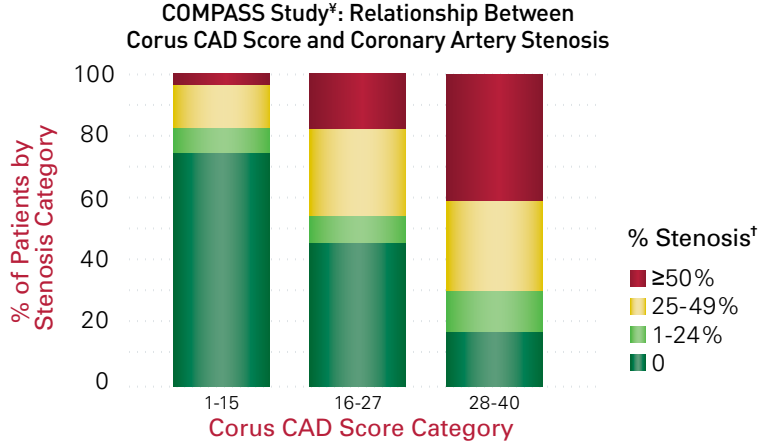
Derives from the patient score and is reported with a 95% confidence interval (CI). A 95% CI indicates there is a 95% chance that the actual likelihood is within this range.

### Graph

- The COMPASS study curve depicts the likelihood of obstructive CAD in patients with typical and/or atypical symptoms suggestive of obstructive CAD at or prior to referral for noninvasive imaging procedures. The COMPASS study population is reflective of the patients for whom the Corus CAD test is most commonly used, and the obstructive CAD prevalence in this study was 15%.
- The PREDICT study evaluated patients referred for invasive coronary angiography, and the obstructive CAD prevalence in this study was 37%.

### COMPASS Study Information and CAD Likelihood Interpretation

The Corus CAD test results are based on the COMPASS clinical validation study. The lower the Corus CAD score, the lower the likelihood of obstructive (≥50% stenosis) CAD and moderate (25-49% stenosis) CAD, and the higher the likelihood of no coronary artery disease.



## 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.

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

¥ The COMPASS study found that the Corus CAD algorithm has a sensitivity of 89% and an NPV of 96% at the pre-specified threshold of 15 in the overall population of men and women referred to MPI. 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.

† Stenosis is a narrowing of a major coronary artery as determined by invasive QCA or core-lab CTA.



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