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CardioDx Launches Gene Test For Obstructive Coronary Disease

CardioDx is gradually rolling out its ***Corus CAD*** gene expression test, which quantifies the likelihood of obstructive coronary artery disease in patients with stable chest pain and no previous history of cardiac disease.

The roll-out began soon after completion of the Personalized Risk Evaluation and Diagnosis in the Coronary Tree (PREDICT) trial of Corus CAD. The study collected over 2,800 patient samples from 40 sites in the U.S. The company expects to release results of the study by the end of this year and to publish the data in 2010.

"It identifies individuals and provides the physician with the likelihood that they have obstructive disease and really focuses on clinically meaningful information," CardioDx CEO David Levison told "The Gray Sheet."

Despite all of the advances in cardiac imaging and functional testing, the clinical need for an assay that tests stable chest-pain patients for coronary disease is "enormous," Levison says. "The noninvasive assessment of coronary disease continues to be challenging, and there is great diversity in how physicians are treating these patients," he said.

In the PREDICT study, all of the patients had already been referred by a physician to an interventionalist for a coronary procedure such as stenting, but the subsequent angiograms showed that only 36% of the patients had obstructive coronary disease.

A major advantage of Corus CAD is that it yields a single objective score corresponding to the percentage chance that the patient has coronary artery disease. The score is derived from expression levels of 23 genes and other characteristics related to inflammation of the coronary arteries.

The test is sold as a kit to physicians' offices. The kit includes all of the equipment needed to draw and store the blood sample, as well as a special cold shipping package to send the sample to CardioDx's processing lab in Palo Alto, Calif. The total turnaround time from the time the blood sample is taken until the results are given to the doctor is two days.

So far, the test is available in Kentucky, Maryland, Illinois, Washington, Wisconsin, Minnesota, North Carolina, Texas and Arizona, and the firm expects to add more states in 2010.

"The reason to not roll out in all 50 states initially is that we really wanted to make sure we understood how this test was going to be integrated into clinical practice," Levison said.

"We're still just learning about what information physicians want, how to integrate this into their practice. It will take a little bit longer before we feel comfortable that we really understand how physicians want to use this product, and at that point we will look at expanding into more geography."

CardioDx Credo: Help Doctors Make Decisions

"One of the tenets of our organization is that we only want to be working on diagnostics where the physician can make a specific decision after getting the results of our test," Levison said. "We spent a lot of time upfront early in the process, as physicians, to write the product specifications before we spent a lot of money on R&D."

The test is primarily intended for outpatient cardiologist clinics and primary care physician offices that need to be able to identify which patients do not have coronary artery disease. "We interviewed 1,100 physicians in the course of the last three and a half years, talking to them specifically about what their needs were in the clinical evaluation of coronary artery disease, and it was very clear from the physicians that they want a 'rule out' test."

"They want a test with high sensitivity and high negative-predictive value so that they can rest assured that those patients have a low likelihood of disease and they can focus on the patients with a higher risk, because they can't aggressively treat all the patients they see with stable chest pain."

Many Corus CAD buyers are small cardiology practices that do not have access to some of the imaging technology and this test helps determine if the patient should be referred for further evaluation, he said. Also, large cardiology practices are using the test for patients who are poor candidates for contrast imaging because of renal impairment or other contraindications.

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