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Plaxgen Pilots Test for Predicting Statin Response With Regional Hospital Group

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NEW YORK (GenomeWeb) – Diagnostics firm Plaxgen has launched its StatRes test for predicting patient response to statins to a limited number of customers.

The Freemont, California-based company has signed an agreement with a regional hospital group in Northern California and will be offering the test at the group's seven facilities, Shanmugavel Madasamy, Plaxgen's founder and CEO, told GenomeWeb this week. He declined to disclose the hospital group's name at this time.

The company is also planning a large-scale clinical validation study of the test, Madasamy said.

Launched by Madasamy in 2007, Plaxgen uses a technology that combines the capture of target biomarkers on plaque arrays with the isolation and analysis of those markers by techniques including flow cytometry and MALDI mass spec.

The company recently published two studies that used its platform, one last year in Clinica Chimica Acta, in which researchers identified serum proteins involved in the plaque particle formation in Alzheimer's disease, and one in July in the American Journal of Cardiology, in which company scientists predicted how patients would respond to different statins.

The company's plaque array system works essentially as an enrichment step, allowing researchers to investigate only plaque-related serum proteins, as opposed to the full serum proteome. The arrays are composed of soluble plaque-forming constituents that are then incubated with serum from test subjects. These plaque-forming constituents work as substrates for the plaque-related serum analytes, allowing for their pull-down and subsequent analysis.

In the AJOC study , the researchers looked at thirty serum samples from patients with high cholesterol who had gone on to receive statin treatment. Using the plaque array platform, they measured the formation of high-density lipoprotein (HDL) in these samples in the presence of four different statins as well as in their absence.

They gauged the effectiveness of a given statin by measuring the change in the level of HDL formation in their presence and then compared this to standard low-density lipoprotein measurements in the patients to see if the StatRes test was predictive of patient response.

In the case of 15 samples from patients on simvastatin treatment, the results from the StatRes test correlated with conventional LDL measurements in 13 patients, or 87 percent. In the case of 15 patients on atorvastatin, the StatRes test correlated with LDL measurements in 12 patients, or 80 percent.

Though the size of the study was small, the results indicate the potential usefulness of the approach, Madasamy said, noting that while statins are frequently prescribed to patients

with high cholesterol levels, doctors have few good ways of deciding what statin to give to a particular patient.

"They select one, they monitor the patient for six months or more, and then [if it is not working], they change to a different statin or lipid-lowering drug," he said. "That is the current practice. It is like shooting in the dark."

The hope, he said, is that the StatRes test can help predict statin efficacy from the outset, helping patients see results sooner and reducing costs by cutting down on ineffective treatments.

Plaxgen is currently planning a large clinical validation study looking at thousands of patients on statin treatments and sampling them at the starting point and then one, two, and four years later, Madasamy said. With the results from that study, the company plans to take the test through the US Food and Drug Administration regulatory process.

In the meantime, the company has begun offering the test to its regional hospital customer out of its CLIA laboratory.

Plaxgen is also working on expanding the StatRes test to include imaging of plaque particles, which Madasamy said could give physicians additional information for assessing patient risk.

"Right now, doctors look mainly at HDL, LDL numbers, but somebody who has good HDL and LDL still can have a heart attack or stroke," he noted. "So what we are doing is not only looking at the numbers but also looking at the particle images, and what we see is that when we look at the images, there are different subpopulations."

Madasamy said that a publication on this imaging research will be forthcoming in the next several months.

In addition to establishing the StatRes test's potential for predicting patient response to statins, the AJOC study also shed light on how statins increase HDL levels.

Statins are known to decrease LDL levels by inhibiting the HMG-CoA reductase enzyme, which is involved in the body's production of LDL. Statins are also known to increase HDL levels, but the mechanism underlying this effect is less well understood, Madasamy said.

Using the plaque array platform, the researchers were able to demonstrate that statins increased the formation of HDL in buffer solutions both with and without the addition of serum, indicating that the drugs may alter lipid levels not only through the established enzymatic pathway but via non-enzymatic mechanisms, as well.

In addition to StatRes, Plaxgen is working on a test for characterizing plaques associated with Alzheimer's disease, named Amyload, and a test for aiding preclinical diagnosis of atherosclerosis and related disease, named Atheroload.

Amyload is based on the early detection and quantitation of Aβ42 and tau particles in the blood that signal the formation in the brain of the amyloid plaques seen in Alzheimer's disease. Atheroload is intended for the detection of abnormal low- and high-density lipoprotein cholesterol particle formation.

Privately funded, Plaxgen has raised around $4 million since its launch. The company currently has fewer than 10 employees but plans to expand its staff in the coming year, Madasamy said.