



Proteomics International Presents Study Data Supporting PromarkerD Kidney Disease Test

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NEW YORK – Australian diagnostics firm Proteomics International has released results from a recent clinical trial demonstrating the usefulness of its PromarkerD test for identifying diabetes patients at risk of developing chronic kidney disease.

The company is hoping the results will help drive commercialization of the test as it works to drive uptake following receipt this spring of the CE mark for the assay.

The findings were part of the CANVAS study, a study from drugmaker Janssen looking at cardiovascular and renal outcomes for type 2 diabetes patients using the drug canagliflozin (Invokana). Proteomics International is collaborating with Janssen to evaluate the PromarkerD test within the CANVAS study to determine its effectiveness for predicting decline in kidney function and drug response for trial subjects.

Proteomics International presented results from the study this week in a poster at the Scientific Sessions of the American Diabetes Association. In an analysis of 3,000 subjects, the researchers found that patients identified as high-risk by the test were 13.5 times more likely than patients identified as low-risk to develop chronic kidney disease within the next four years. Patients identified as being at moderate risk were 5.3 times more likely to develop CKD than low-risk patients.

The work follows other studies of the PromarkerD test, including a [four-year, 576-patient study](#) Proteomics International completed in 2015 in which they identified 67 percent of patients who went on to develop diabetic kidney damage over a four-year period. A four-year, [792-patient study](#) published in 2017 found that the test identified patients who would go on to develop kidney damage in the next four years with sensitivity of 86 percent and specificity of 78 percent.

Richard Lipscombe, managing director of the company, said that the patient group in the CANVAS study was generally sicker and at higher risk for cardiovascular and renal disease and had had diabetes for a longer period of time than the cohorts the company has examined in previous studies.

Lipscombe said the company now planned, in collaboration with Janssen, to look at how the PromarkerD score changed with treatment to see if it could be useful for monitoring response to treatment.

He said that the findings from the CANVAS study correlated well with those from previous studies and noted that one of the more significant results from the company's perspective was the ability to effectively group patients as either high or low risk.

"We got some great data on being able to differentiate the high versus low risk, good odds ratios for that high-risk category," he said, noting that this form of result would prove more useful for clinicians than a standard sensitivity and specificity model.

"We think this approach that we've shown here is a more robust method to take into the future," he said.

Proteomics International received a CE mark for a mass spectrometry version of the test in November of 2019, a CE mark for its PromarkerD Hub software in January 2020, and a CE mark for an immunoassay version of the test in April.

The company launched the test in Spain in 2019 through a two-year licensing agreement with Patria Europe. Dublin-based clinical diagnostics firm Atturo runs the mass spec tests for Proteomics International's European customers. Proteomics International offers it in Europe on a self-pay basis, Lipscombe said.

While Proteomics International developed the PromarkerD test using mass spec and brought it to the clinic using that technology, it has since shifted to focus on an immunoassay version, Lipscombe said.

"We thought clinical proteomics was here and ready to go," he said. "But unfortunately, we discovered that clinical mass spec is still a struggle for many pathology labs."

"Our experience has been that the labs struggled to use the technology reproducibly and get the sensitivity that we would expect," he added. "And I think the bigger players [in the clinical lab space] have recognized that and so are reluctant to adopt a mass spec platform at the moment. I think there are concerns about the costs and the throughput still not matching the other platforms."

While, as Lipscombe noted, mass specs are commonly used in clinical labs for small molecule tests, they are still infrequently used for protein assays, and for multiplexed protein assays like the PromarkerD test, in particular.

While companies including Sera Prognostics and Integrated Diagnostics have launched multiplexed protein tests using mass specs, both of these companies put resources into building their own CLIA facilities for running these tests, as opposed to outsourcing testing to independent clinical labs.

Integrated Diagnostics has also since sold these assets to proteomics diagnostics company Biodesix.

The PromarkerD mass spec test is also somewhat more complex as it uses immunoaffinity enrichment of three of its protein targets to achieve the required sensitivity.

The company also launched a mass spec version of the test in the Dominican Republic in 2018 that it plans to move to an immunoassay format.

Lipscombe said Proteomics International will continue to offer the mass spec test run by Atturo in the EU while it seeks an EU-wide licensing partner for the immunoassay version of the test, which it hopes to sell as a kit for use in clinical labs. He noted that this effort has been delayed by the ongoing SARS-CoV-2 pandemic.

While not traditionally focused on infectious disease, the company has done some SARS-CoV-2 work. It received a \$200,000 grant from the Western Australia Health Department and Western Australia Translation Network to develop a saliva-based diagnostic for the virus as well as to do research into protein markers that could help predict the course of a patient's infection.

The company is also moving toward commercialization of the test in the US, where it will likely launch it as a laboratory-developed test. It is currently looking for partners in the country who could help bring the test to market, Lipscombe said.

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