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Proteomics: 'Studies Back Promarkerd For Kidney Disease'

Proteomics says two studies and an industry application note show "the robust technical performance of the Promarkerd predictive test for diabetic kidney disease".

Proteomics said the studies and note, all co-authored by Proteomics chief executive officer Dr Richard Lipscombe, showed a high correlation between the original Promarkerd mass spectrometry (MS) and the more recently developed Promarkerd immune-assay (IA) platforms and "proves the reliability of the Promarkerd test system".

The first research article, titled 'A robust multiplex immunoaffinity mass spectrometry assay (Promarkerd) for clinical prediction of diabetic kidney disease', was published in the journal Clinical Proteomics and available at: <u>https://bit.ly/3mQOxSg</u>.

The article concluded that "an immunoaffinity capture targeted mass spectrometry assay was developed and optimized ... [showing] statistically comparable results to those obtained from the original immune-depletion method and was also able to provide comparable results when deployed to an independent laboratory".

"Taking a research grade assay and optimizing to a clinical grade workflow provides insights into the future of multiplex biomarker measurement with an immunoaffinity mass spectrometry foundation," the article concluded.

"In the current format the Promarkerd immune-affinity assay has the potential to make a significant impact on prediction of diabetic kidney disease with consequent benefit to patients," the journal article concluded.

An industry application note, titled 'From Nanoflow to Standard Flow LC/MS for Routine Quantitative Plasma Proteomics in Diabetic Kidney Disease Research' published by Agilent Technologies said that "successful and reproducible analysis of the eight peptides in whole plasma comparable to depleted plasma analysis highlights the analytical sensitivity and robustness offered by the 6495 LC/TQ for routine protein measurement in biomarker research".

The abstract is available at: <u>https://bit.ly/34VuQmbt</u>.

The second research article, titled 'The New and the Old: Platform Cross-Validation of Immunoaffinity Mass Spectrometry versus ELISA for PromarkerD, a Predictive Test for Diabetic Kidney Disease' was published in the journal Proteomes and an abstract is available at: <u>https://pubmed.ncbi.nlm.nih.gov/33126588/</u>.

"The performance characteristics of the two technology platforms were compared using a cohort of 100 samples, with Promarkerd test scores demonstrating a high correlation (R = 0.97)," the abstract said.

"These technologies illustrate the potential for large scale, high throughput clinical applications of proteomics now and into the future."

Proteomics said that there was high correlation between the advanced mass spectrometry platform and the traditional immunoassay enzyme-linked immune-sorbant assay (Elisa) platform, "with more than 90 percent of the samples achieving Promarkerd risk scores within five percent of the other platform's score".

"Both technology platforms were successfully validated for assay reproducibility, robustness and stability for the Promarkerd test system," the company said.

Proteomics said the results "form an essential basis for regulatory approvals related to the Promarkerd test system and its adoption by pathology laboratories worldwide" and showed the potential for adoption of the Promarker platform in clinical practice. Dr Lipscombe said that "this type of robust performance data is essential in achieving regulatory approvals for the Promarkerd test system".

"Not only do the results prove the test can be used reliably in today's clinical laboratories, but they also offer an insight into the use of the Promarker platform in clinical practice in the decades to come," Dr Lipscombe said.

Proteomics was unchanged at 50 cents.