3 New miR Scientific Urine Tests Diagnose, Classify Prostate Cancer, Data Shows

MARCH 6, 2020 BY VANESSA PATAIA IN NEWS.

Click here to subscribe to the Prostate Cancer News Today Newsletter!

The bioscience company miR Scientific has presented breakthrough data on three urine-based tests to detect and classify prostate cancer from RNA molecules, called small non-coding RNAs (sncRNAs).

The first test, the Sentinel PCa Test, identifies evidence that prostate cancer is present. The Sentinel CS Test, the second exam, shows whether patients have low-grade, or intermediate and high-grade prostate cancer. The last assessment, the Sentinel HG Test, identifies men with high-grade, high-risk prostate cancer.

Each of the tests works by measuring the levels of sncRNA found inside small vesicles — called exosomes — that cancer cells release for cell communication.

These vesicles contain cellular material, including proteins, DNA, RNA, and fat molecules, and can be found in a variety of bodily fluids, including urine.
In addition to their diagnostic abilities, the tests can be used to monitor prostate cancer progression.

"The results … demonstrate that the miR Scientific Sentinel Tests can transform clinical practice with broadly new and powerful capabilities to directly classify patients into actionable pathways: those with no evidence of prostate cancer, patients in need of definitive treatment, and patients eligible for active surveillance, which the Sentinel Tests can monitor," Sam Salman, chairman & CEO of miR Scientific, said in a press release.

Derya Tilki, MD, an urologist at the Martini-Klinik Prostate Cancer Center at the University Hospital Hamburg-Eppendorf, in Germany, presented the results of a validation study for the tests at the 2020 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium, held recently in San Francisco.

The oral presentation was titled "Analysis of small non-coding RNAs in urinary exosomes to classify prostate cancer into low-grade (GG1) and higher-grade (GG2-5)"

The case-control validation study included 1,436 patients and evaluated both the tests' sensitivity, or their ability to correctly identify those with a disease, and their specificity — their ability to correctly identify those without a disease.

First, the researchers used a group of 836 patients to identify sncRNAs that could help identify prostate cancer patients, distinguish those with low-grade disease from men with intermediate or high-grade disease, and identify men with high-grade, high-risk prostate cancer.

Then, in a second group of 600 patients, the team validated their findings.

In total, the algorithms for each test examined the presence and levels of 200–280 small non-coding RNAs.

The results showed that the Sentinel PCa Test had a sensitivity of 94% and a specificity of 92%, meaning that only 6% of patients with the condition had negative results on the test, and 8% of those without prostate cancer had a positive result.

The Sentinel CS Test had a sensitivity of 93% and a specificity of 90%; meaning it correctly identified 93% of patients with low-grade disease, and 90% of those with intermediate or high-grade disease.

Finally, the Sentinel HG Test had a sensitivity — the proportion of patients correctly identified as having high-grade, high risk prostate cancer — of 94%. It had a specificity – the proportion of patients correctly identified as not having high-grade, high-risk disease – of 96%.

“The accuracy demonstrated by the miR Scientific Sentinel tests is significantly better than that of other current technologies,” Salman said.

He said the tests “could prove to be even more accurate as we are currently ascertaining what proportion of this discordance [number of false positives or false negatives] represents misattribution of core needle biopsy histopathology [diagnosis based on tissue observations under a microscope] or genuine misclassification errors of the Sentinel Tests.”

The three tests are part of the miR Scientific Disease Management Platform, which aims to contribute more accurate and effective diagnoses and treatments for urological cancers like prostate cancer. The platform’s goal is to positively impact the cost of healthcare for everyone involved, and to improve the standard of care and outcomes for patients.

“miR Scientific believes that the results suggest that the non-invasive Sentinel tests can be used as part of the Sentinel Prostate Cancer Disease Management Platform to provide patients and health care providers with an unprecedented level of information, allowing for more accurate and effective treatment of these cancers,” Salman said. The tests can be used as standalones or in combination. Their validation means they can now be used worldwide to provide a diagnosis and help disease management of prostate cancer.

“The burden of over diagnosis and unnecessary treatments in prostate cancer worldwide is well known,” said James M. McKiernan, MD, a professor and chairman of the department of urology at Columbia University College of Physicians and Surgeons.

“What has been lacking is an effective, non-invasive tool to identify which patients may harbor aggressive cancers that are life threatening,” McKiernan said. “The miR Scientific platform of liquid biopsy represents a highly sensitive and accurate way to identify these patients with less need for invasive procedures.”

Go here to read the original story on *Prostate Cancer News Today*.