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JAMES M. McKIERNAN, MD
John K. Lattimer Professor of Urology at CUMC
Chair, Urology

Herbert Irving Pavilion
161 Fort Washington Avenue
New York, NY 10032
212-305-5526 Tel
212-305-6813 Fax

Date of Request: 09/23/2020
NCCN Guidelines Panel: Prostate Cancer Early Detection

Dear NCCN Committee Members:

I would like to take this opportunity to respectfully submit my comments to the NCCN Prostate Cancer Early Detection Panel for consideration with respect to the miR Scientific Sentinel Prostate Cancer Test Platform. The miR Scientific Test Platform interrogates small noncoding RNAs (sncRNA) isolated from urinary exosomes and classifies patients as those with prostate cancer and those with no evidence of prostate cancer. Further, this novel test platform has the capability to risk stratify patients who are diagnosed with prostate cancer. The accuracy of the miR Scientific Test Platform in carrying out these functions was validated in the recent August 10, 2020 publication in the Journal of Urology (1). The publication demonstrated high levels of sensitivity (> 93%) and specificity (> 90%) across detection and risk classifications as shown in the Table below. These results were achieved in this multi-center study with greater than 1400 subjects, including a prospective validation cohort of 803 patients.

These results signify that the miR Scientific Sentinel Prostate Cancer Test Platform is a powerful tool that accurately discriminates and distinguishes cancer from no cancer and accurately classifies the risk associated with the cancers of diagnosed patients. With the demonstrated performance characteristics, the test platform may hold great promise to provide a superior alternative to PSA testing. It clearly should be considered as a secondary screening/diagnostic tool in the evaluation of patients with an elevated PSA. Further, in diagnosed patients with its multiple functions, this test platform provides a high throughput assessment of the sncRNA expression in urinary exosomes to define the risk of aggressive vs non-aggressive prostate cancer. The results as detailed in the Journal of Urology publication and the resultant table below represent a significant breakthrough in the field.

Given the above, the miR Scientific Test Platform now provides a validated, viable option with sensitivity and, especially specificity unmatched by other tests, including the other available molecular assays. As such, I suggest for the Panel's consideration that the Test Platform be recommended for:

Specific Changes:

1. On Page PROSD-3 footnote i, for use as a molecular biomarker in the further evaluation of the indication for biopsy to determine cancer vs no cancer. As such, inclusion of the miR Scientific Sentinel Prostate Cancer Platform would be entirely appropriate in footnote i to be listed among the other molecular assays. If further validation studies confirm these performance characteristics demonstrated in the recent publication, the miR Scientific Test Platform might be considered "preferred".

2. On Page PROSD-4, similar to my first considered suggestion, placement in footnotes i and p, along with the other identified molecular biomarker test assays to better define risk, including for monitoring individuals considered higher risk but with a negative first biopsy. Once again if the published sensitivity and specificity results are confirmed in future validation studies, it would suggest the miR Scientific Test Platform could be identified as the "preferred" biomarker in this area.

	Results of MIR SCIENTIFIC SENTINEL PROSTATE CANCER TEST PLATFORM		
Predicts	Cancer vs no cancer	Gleason Grade ≥2	Gleason Grade ≥3
Sensitivity	94%	93%	94%
PPV	92%	91%	91%
Specificity	92%	90%	96%
NPV	94%	92%	97%

In summary, the miR Scientific Sentinel Prostate Cancer Test Platform represents a significant advance in enhancing the ability to determine the risk of having prostate cancer or not. In addition, it also is capable of accurately determining the risk of harboring clinically intermediate and high risk prostate cancer versus low risk prostate cancer. The incorporation of these assays into routine practice has the capability of improving a clinician's decision making regarding initial as well as repeat prostate biopsy. It may also result in less unnecessary biopsies, increase the numbers of patients appropriately assigned to active surveillance, and better define patient subpopulations in need of appropriate therapeutic interventions.

I appreciate the opportunity to express my views and appreciate the work of the two Prostate Cancer Panels of the NCCN.

Best Regards,

James McKiernan, MD

Disclosure: Dr James McKiernan is a member of the scientific advisory board of miR Scientific.

References:

1. Wang WW, Sorokin I, Aleksic I, et al. Expression of Small Noncoding RNAs in Urinary Exosomes Classifies Prostate Cancer into Indolent and Aggressive Disease. *J Urol*. 2020;204(3):466-47