DR. METZGER'S SATURDAY EVENING NEWSLETTER

FOR FEBRUARY 18, 2023

PROSTATE FORUM OF ORANGE COUNTY

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Non - Invasive Means of Determining Presence Of High Risk Prostate Cancer Will Become Easier To Get Via Iso-PSA Blood Test And May Eliminate The Need For Some Biopsies.

"Diagnostics companies enter agreement to expand access to blood-based IsoPSA test"

Urology Times **Feb 14, 2023** **Jason M. Broderick**

https://www.urologytimes.com/view/diagnostics-companies-enter-agreement-to-expand-access-to-blood-based-isopsa-test?utm_source=sfmc&utm_medium=email&utm_campaign=02152023_UT_PHO-23-URD0421_Photocure_Cysview_Monthly eNL&eKey=Y2ttZXR6Z2VyQG1hYy5jb20=

IsoPSA is included in the National Comprehensive Cancer Network Prostate Cancer guidelines for early detection of the disease.

Cleveland Diagnostics is expanding access to IsoPSA, its novel test for prostate cancer, by entering into *A real-world clinical validation study of IsoPSA was published in the Journal of Urology Practice in 2022.*

The blood-based, non-invasive IsoPSA test is used prior to an initial biopsy to assess the likelihood that a patient has high-grade prostate cancer.

By the middle of this year, patients nationwide will be able to access IsoPSA. Specifically, once the test is ordered by their doctor, patients will be able to "provide a blood specimen for testing at one of over 2100 Quest Diagnostics patient service center locations" across the country.

"We are very pleased to collaborate with Quest Diagnostics to expand patient access to IsoPSA. We believe Quest's broad reach and extensive laboratory services expertise will provide patients and their physicians with unparalleled access to transformative clinical insights," Arnon Chait, CEO of Cleveland Diagnostics, stated in a news release. "As the leader in oncology

testing, Quest is aligned with Cleveland Diagnostics' vision of providing physicians and their patients exceptional and more definitive understanding of their prostate conditions."

IsoPSA currently has an FDA Breakthrough Therapy designation and has been added to the National Comprehensive Cancer Network Prostate Cancer guidelines for early detection of the disease.

A real-world clinical validation study of IsoPSA was published in the *Journal of Urology Practice* in 2022.[2] The study included a diverse group of 38 community-based and academic sites within the Cleveland Clinic health system. There were 900 patients under evaluation for prostate cancer who were enrolled at these locations. Of these, 734 met the study inclusion criteria, which comprised age ≥50 years, total serum PSA ≥4 ng/ml and <100 ng/ml, and no history of prostate cancer. The study investigators assessed biopsy recommendations of participating clinicians before and after receipt of IsoPSA results.

The results showed that in men with total PSA ≥4 ng/ml, IsoPSA led to a 55% (284 vs 638) net reduction in prostate biopsy recommendations. Further, there was also a 9% reduction in MRI imaging recommendations.

"Prostate cancer is a leading cause of cancer – and cancer deaths – among men, and physicians are eager for improved tools to diagnose, stage and monitor this disease," Kristie Dolan, vice president and general manager of Oncology at Quest Diagnostics, stated in the news release. "We believe IsoPSA holds great promise to better inform physicians' diagnostic and treatment decisions for their patients being evaluated for prostate cancer, and we are pleased to work with Cleveland Diagnostics to expand access to this important new test, ultimately bettering patient outcomes by improving the diagnostic process."

References

1. Cleveland Diagnostics Announces Agreement with Quest Diagnostics to Expand Patient Access to IsoPSA® Prostate Cancer Testing. Accessed February 14, 2023. https://bwnews.pr/3lCNTfE

2. Scovell JM, Hettel D, Abouassaly R, et al. IsoPSA® Reduces Provider Recommendations for Biopsy and Magnetic Resonance Imaging in Men with Total Prostate Specific Antigen ≥4 ng/ml: A Real-World Observational Clinical Utility Study. Journal of Urology Practice. 2022;9(2):173-180. doi: 10.1097/UPJ.0000000000000291