Select mdx for Prostate Cancer

SAMPLE Patient Report

Patient

Patient Name: David Sample
Date of Birth: 12/27/1959
MRN/Patient #: 8979821
Prostate Volume: 30cc
PSA: 6.7 ng/mL
DRE: Normal

Specimen

Specimen #: 72389
Collection Date: 1/28/2023
Received Date: 02/01/2023
Report Date: 02/04/2023
Specimen Type: Post DRE Urine
Mdx Accession #: SL-91322

Account

Physician: Dr. Smith
Account: Urology Associates
Address: 15279 Alton Parkway, Suite 100
City/State/Zip: Irvine, CA 92618

PATIENT RESULT: LOW RISK

Low Risk: This patient's test result indicates a low risk for the detection of Gleason Score (GS)≥7 prostate cancer on biopsy.

In the Select mdx pivotal study, for **Low Risk** patients, Select mdx yielded:

- Negative Predictive Value of 95% for detection of GS≥7 prostate cancer, and
- Negative Predictive Value of > 99% for for detection of GS≥8 prostate cancer.[1]

Test results should be interpreted in conjunction with other available laboratory and clinical data and relevant guidelines to augment the patient-physician shared decision making process, including the decision for biopsy. Select mdx does not replace other clinical and genetic risk factors, which should be considered as independent risk factors for prostate cancer.

In the Select mdx pivotal study[1], a clinical model combining urinary biomarkers and clinical factors was applied to generate a risk score that increases with the probability of detecting GS≥7 cancer on biopsy. This raw score has been converted to a personalized positive predictive value that ranges from 0 - 100%. For patients with Low Risk test results, the personalized positive predictive value should be interpreted in conjunction with other available laboratory and clinical data (published performance characteristics reported in the pivotal study exclude all patients with Low Risk Select mdx test results from the calculation of positive predictive value):

- Personalized positive predictive value of 8% for detection of GS≥7 prostate cancer, and
- Personalized positive predictive value of 22% for detection of GS 6 prostate cancer.

Questions about these results? Contact Client Services at 866.259.5644 or go to www.mdxhealth.com/selectreport

Test Description:

Select mdx for Prostate Cancer is a reverse-transcription PCR (RT-PCR) assay performed on urine specimens collected immediately following DRE from patients who are being considered for prostate biopsy. The test measures the urinary mRNA levels of DLX1 and HOXC6 biomarkers to aid in patient selection for prostate biopsy. Higher levels of DLX1 and HOXC6 mRNA are associated with an increased probability for GS≥7 prostate cancer.[1] A clinical model combining DLX1 and HOXC6 mRNA levels with established clinical risk factors, including PSA, prostate volume, DRE findings and age, is used to estimate the likelihood of detecting GS≥7 prostate cancer upon biopsy, with an area under the curve (AUC) of 0.85 (95% CI: 0.83-0.88), in addition to the likelihood of no cancer or GS≤6 disease.[2] Performance is based on the presence of all relevant data elements; if all data are not available, results should be interpreted with caution and AUC of the test will vary. Performance characteristics were established in a clinical validation study of 1,955 men from Germany, France, and The Netherlands undergoing initial prostate biopsy due to suspected prostate cancer.[2] Due to EU privacy regulations, patient racial and ethnic data were unavailable and may not reflect the diversity of a US population. Select mdx is not indicated for use in patients receiving treatment known to directly affect PSA levels (including 5a-reductase inhibitors such as finasteride or dutasteride). These medications are known to affect components of the Select mdx clinical model, and patients on such medications were excluded from Select mdx clinical validation studies.

Comments:

References:
[1] Haese A, et al. J Urol 2019; Hendriks RJ, et al. Prostate 2017; Hessels D, et al. Trans Med Communications 2017; Dijkstra S, et al. BJU Int 2017; Van Neste L, et al. Eur Urol 2017; Alinezhad S, et al. PLoS ONE 2016; Leyten GH, et al. C/in Cancer Res 2015; Vinarskaja A, et al. Cancers 2011.
[2] Haese A, et al. J Urol 2019.

Disclaimer:
Mdxhealth is regulated under the Clinical Laboratory Improvement Amendments (CUA) and College of American Pathologists (CAP) as an accredited laboratory to perform high complexity clinical testing. The Select mdx for Prostate Cancer test was developed, and its performance characteristics determined by mdxhealth. It has not been reviewed by the U.S. Food and Drug Administration. The FDA has determined such clearance or approval is not necessary.

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Ruben Gamez, MD, Laboratory Director

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Mdxhealth • 15279 Alton Parkway, Suite 100, Irvine, CA 92618 • P: 866.259.5644 • F: 949.788.0014 • E: cs@mdxhealth.com • www.mdxhealth.com