

**SAMPLE**

Patient Report

**PATIENT**

**Patient Name:** David Sample  
**Date of Birth:** 12/27/1952  
**MRN/Patient#:** 8979821  
**Prostate Volume:** 30cc  
**Family History:** None  
**PSA:** 9 ng/ml **DRE:** Normal

**SPECIMEN**

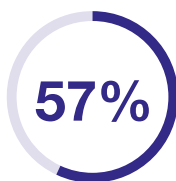
**Specimen#:** 72389  
**Collection Date:** 11/05/2015  
**Received Date:** 11/07/2015  
**Report Date:** 11/09/2015  
**Specimen Type:** Urine  
**MDxH Accession#:** SL-91322

**ACCOUNT**

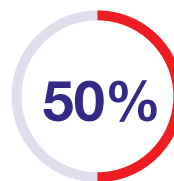
**Physician:** Randolph Smith, MD  
**Account:** Urology Associates  
**Address:** 15279 Alton Parkway  
Suite 100  
**City/State/Zip:** Irvine CA 92618

**Patient Result:**

The SelectMDx test result for this patient indicates a 57% likelihood of detecting prostate cancer, with a 50% probability for Gleason score  $\geq 7$ , when performing a standard 12-core TRUS guided biopsy.



Likelihood of prostate cancer upon biopsy



Likelihood of detecting Gleason score  $\geq 7$  cancer

**Test Description:**

SelectMDx 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 mRNA biomarkers to aid in the patient selection for prostate biopsy. Higher levels of DLX1 and HOXC6 mRNA are associated with an increased probability for Gleason score 7 (GS $\geq 7$ ) prostate cancer. The SelectMDx test result indicating the likelihood of detecting GS $\geq 7$  prostate cancer upon biopsy is calculated by combining DLX1 and HOXC6 mRNA levels with established clinical risk factors, including PSA, prostate volume, DRE, family history and age, is based on a logistic regression model that yields an area under the curve (AUC) of 0.88 (95% CI: 0.85 - 0.91). Performance is based on the presence of all relevant data elements; if all data are not available, or 5 $\alpha$ -reductase inhibitors (5-ARIs) have been administered to decrease serum PSA levels, results should be interpreted with caution and AUC of the test may vary.

**Comments:**

**References:**

- 1) Van Neste et al; Detection of High-grade Prostate Cancer Using a Urinary Molecular Biomarker-Based Risk Score. European Urology 2016. <http://dx.doi.org/10.1016/j.eururo.2016.04.012>.
- 2) Leyten et al; Identification of a Candidate Gene Panel for the Early Diagnosis of Prostate Cancer. Clin Cancer Res 2015. Jul 1;21 (13):3061-70.
- 3) Hamid et al; The role of HOXC6 in prostate cancer development. The Prostate 2015. Dec;75 (16):1868-76.

**Disclaimer:**

MDxHealth is regulated under the Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists as an accredited laboratory to perform high complexity clinical testing. The SelectMDx for Prostate Cancer test was developed and its performance characteristics determined by MDxHealth. The test is intended for use as an aid to clinicians for patient management decisions about the need for a prostate biopsy on men with clinical factors suggesting an increased risk for prostate cancer. Use outside of this indication has not been validated by MDxHealth. Test results should be interpreted in conjunction with other laboratory and clinical data available to the clinician and relevant guidelines on the decision for biopsy.

MDxHealth is certified by DEKRA for ISO 9001:2008 Quality Management System. This test was performed by MDxHealth Inc., 15279 Alton Parkway, Suite 100, Irvine, California 92618. CLIA# 05D2033858; CAP# 8015399.

General information about SelectMDx for Prostate Cancer can be found at [www.mdxhealth.com](http://www.mdxhealth.com). If you have any questions regarding this report, please contact MDxHealth Client Services at 866.259.5644 or [clientservices@mdxhealth.com](mailto:clientservices@mdxhealth.com).

Jess Savala, Jr., MD, Laboratory Director

