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PROSTOX™

Lab Report and Results

PATIENT INFORMATION

Name: Doe, John
DOB: 01-01-1966
Sex: Male
Patient ID: 9999999

PHYSICIAN INFORMATION

Ordering: Doex, James
Phone: 999-999-9999
NPI: 99999999

SAMPLE INFORMATION

Collected: 01-01-2022
Received: 01-05-2022 04:23pm
Reported: 01-08-2022 08:08am

TEST ORDERED

PROSTOX™

TEST RESULT & INTERPRETATION

Based on genetic biomarkers assayed, the patient falls into the **Low Risk** category for developing Grade 2 or higher long-term urinary toxicity after prostate directed SBRT

PATIENT RISK OF TOXICITY

Low risk High risk

NOTES

DNA was isolated from the specimen submitted and analyzed using PCR-based TaqMan assays to detect the wild-type and variant alleles for the genes of interest. Reference specimens, previously determined to carry both normal and variant alleles, served as controls in parallel testing with the patient specimen. The testing panel is based on a miRNA-based signature derived from a prostate patient cohort treated with SBRT and has an NPV of 96%, sensitivity of 79%, PPV of 80%, and specificity of 95% for predicting Grade 2 or higher long-term GU toxicity after prostate directed SBRT. Results do not predict a patient's likelihood of clinical response to SBRT, short-term side effects, or other long-term side effects.

The performance characteristics of the **PROS**TOX Screen were determined by MiraDx, Inc. This test has not been approved by the United States Food and Drug Administration and should not be used as the sole indicator of risk in determining treatment.

REFERENCES

Kishan AU, et al. Germline variants disrupting microRNAs predict long-term genitourinary toxicity after prostate cancer radiation. Journal for Radiotherapy and Oncology 2022;167:226-232. doi: 10.1016/j.radonc.2021.12.040.

Yuan Y, Weidhaas JB. Functional microRNA binding site variants. Mol Oncol. 2019;13(1):4-8. doi:10.1002/1878-0261.12421.

Kishan AU, et al. Long-term outcomes of stereotactic body radiotherapy for low-risk and intermediate-risk prostate cancer. JAMA Network Open 2019;2:e188006. doi:10.1001/jamanetworkopen.2018.8006.

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