Wren Laboratories
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PROSTest

PATIENT NAME	Example Report, PROSTest Normal	**ACCESSION**	25031100002
PATIENT DOB	February 3, 2025	**ORDER CODE**	WR25-0000177
PATIENT GENDER	M	**ORDER ALT ID**	
PATIENT PHONE		**SAMPLE TYPE &**	Whole Blood
ACCOUNT	Testing	**SOURCE**	
PROVIDER	Tracy Auster	**COLLECTED**	03/11/2025, 09:23 AM EDT
REPORT STATUS	AMENDED	**RECEIVED**	03/11/2025, 09:23 AM EDT
		REPORTED	06/03/2025, 01:29 PM EDT

TEST INFORMATION	PROSTest	**DIAGNOSIS CODES**	C61

PROSTest Results

PROSTest Score: Negative

03/11/2025
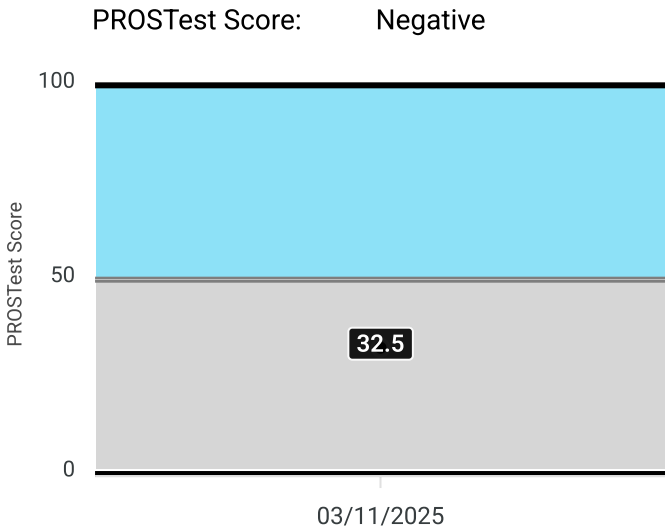
The PROSTest Score is 32.5, it is Negative.

The PROSTest™ is a proprietary PCR-based gene expression assessment assay of 27 prostate cancer (PCa)-relevant RNA genes in a peripheral blood sample [1-3]. Venous blood is collected in a tube containing RNA-stabilization buffer provided by Wren Laboratories. PCR data from the 27 genes is made into a machine-learning algorithm diagnostic score. The test score indicates the likelihood on a scale from 0 to 100 that a patient may have PCa [1, 2].

Scores of 0-49 are associated with low probability of PCa disease. Scores of 50-100 are associated with high probability of PCa. Increase of PROSTest scores in serial samples qualified as a biomarker of recurrence after surgery in the absence of image-detectable disease or what's called minimal residual disease (MRD) [1]. The test was also qualified to detect recurrence or progression upon monitoring of patients' post-treatment [1, 2].

Scores ≥50 correlate with Gleason Grade. The higher the PROSTest score the greater the chance of clinically significant disease (GG2-5).

Laboratory Developed Test (LDT)
This test was developed, and its analytical performance characteristics (Table 1) determined under different conditions by Wren Laboratories LLC, which is a CLIA-certified, CAP-accredited and NYS-licensed clinical laboratory, qualified to perform high-complexity clinical laboratory testing. The assay has been validated pursuant to CLIA regulations and is used for clinical management. The test has not been cleared or approved by the FDA. Men with pancreatic cancer may have falsely elevated scores.

Population	Overall PROSTest Accuracy (%)	PROSTest sensitivity in PCa (%)	PROSTest specificity in all non-PCa (BPH & controls) (%)
All comers regardless of PSA result	92.3%	93.1%	92.4%
Subjects with age ≥45 years and PSA ≥3.0ng/mL	93.0%	94.9%	89.3%

References

[1] Prostate. 2024 Jun;84:850-865.   [2] Prostate. 2025; Jan 21:e24858.   [3] Cancer Epidemiol. 2024 Oct;92:102642.