

# Men with PIRADS Score $\leq 3$ and SelectMDx Score $\leq 30\%$ can be Spared from Prostate Biopsy

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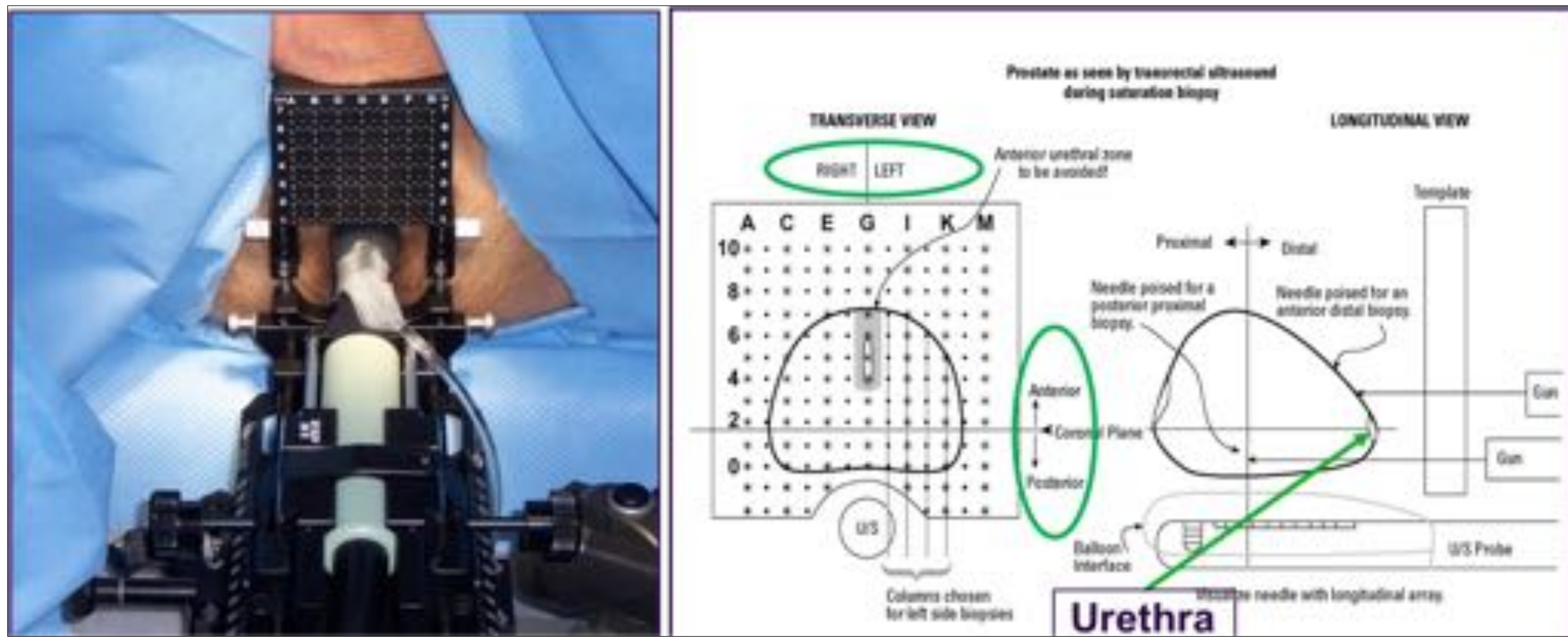
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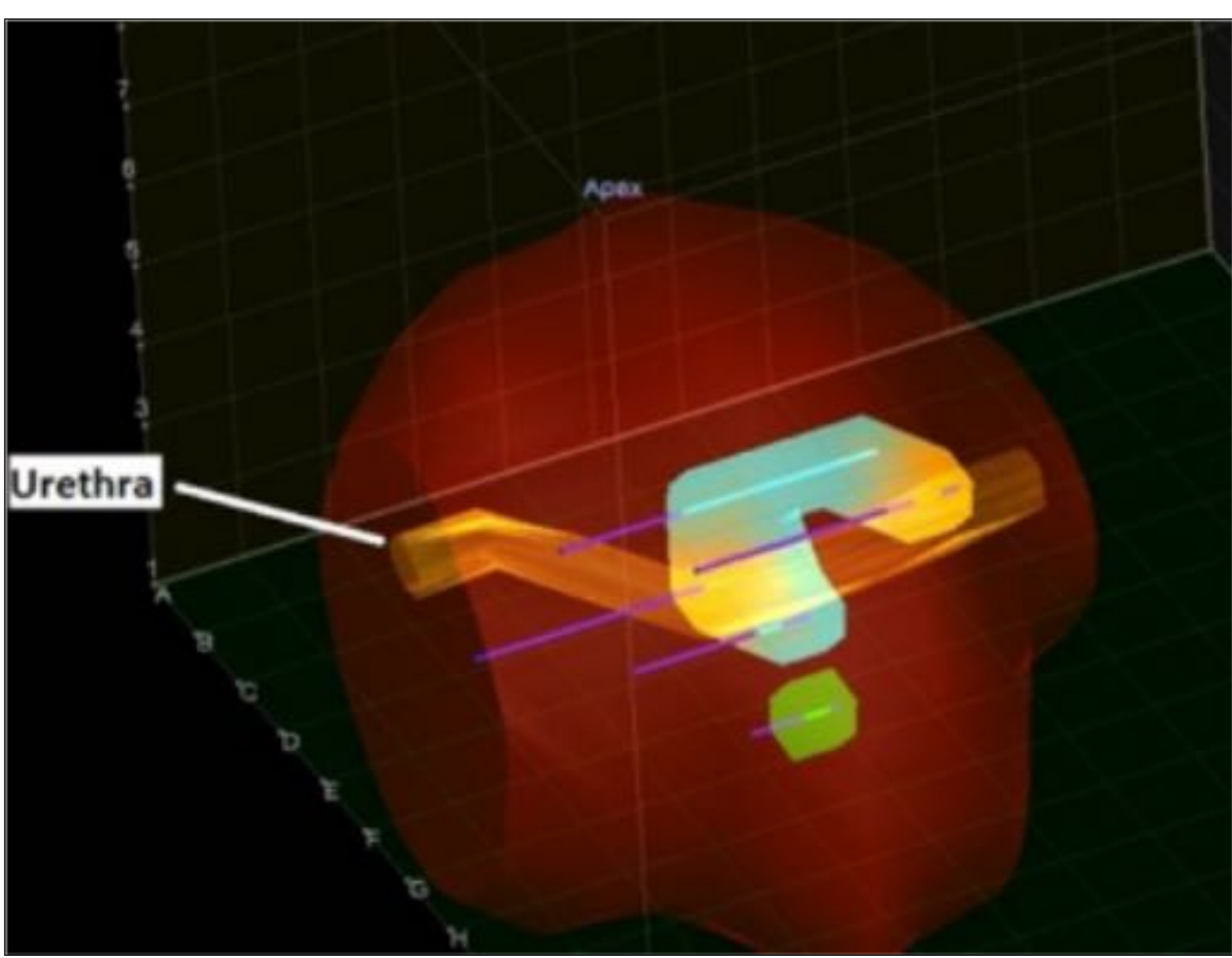
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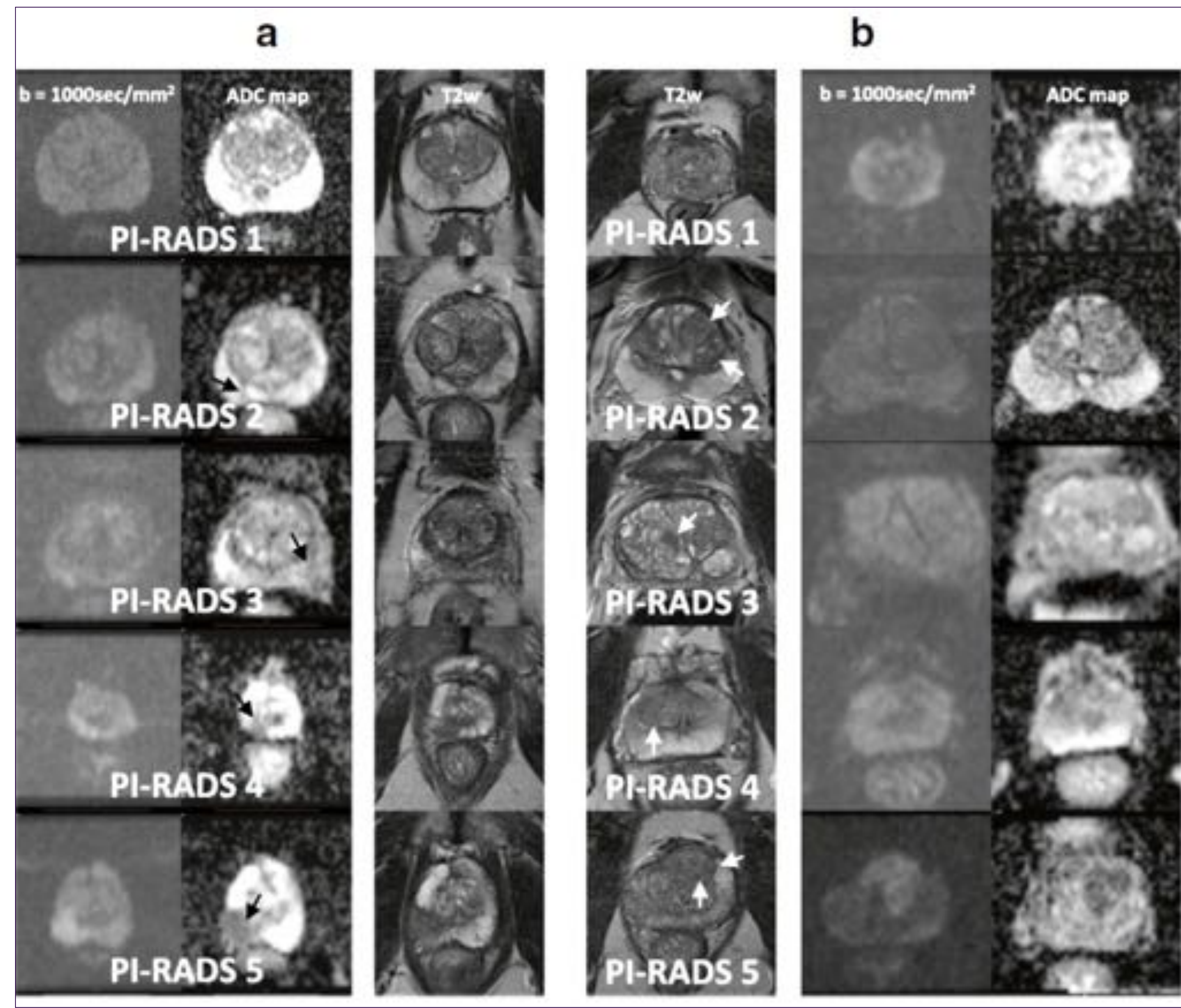
- Evaluated combined utility of PIRADS score and biomarkers to identify high grade (HG) and clinically significant (CS) prostate PCa
- Used histopathology of 5 mm grid interval transperineal mapping biopsy (TMB) as reference (**Fig. A**)
- TMB identified 34/39 (87%) patients with prostate cancer, 15/34 (44%) had high grade prostate cancer, and 18/34 (53%) had CS PCa. (**Fig B**)



**Fig A: TMB**



**Fig B: Histopathology**



**Fig C: PIRADS**

- Serum and post-DRE urine used for phi and Select MDx tests
- mpMRI classified using PIRADS scores (**Fig C**)
- Multivariate logistic regression analyses (MLRA) and receiver operating characteristic (ROC) curves were used to determine diagnostic accuracy. DeLong test was used to determine statistical significance of ROC curves.

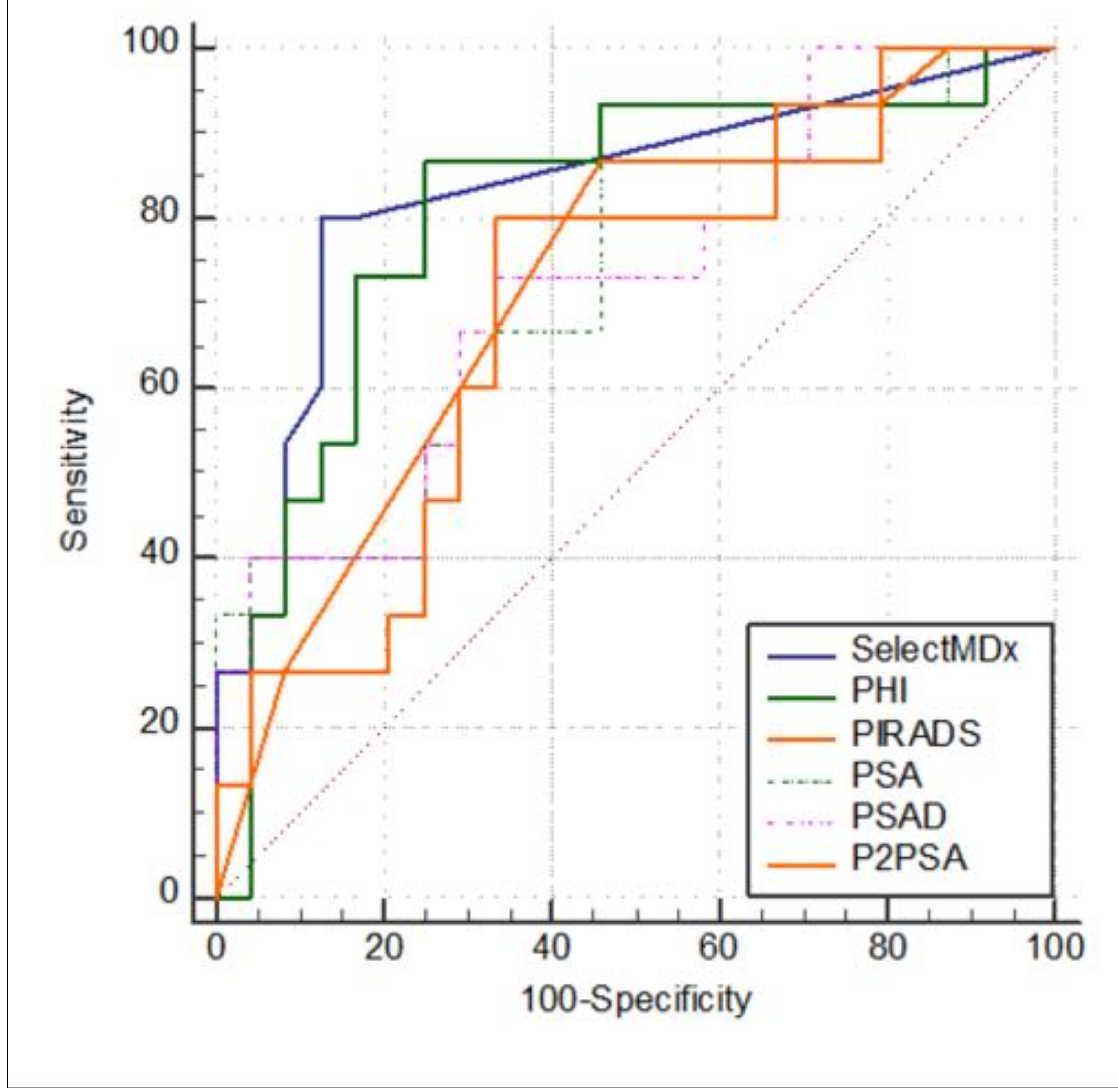


**Table: SelectMDx, phi, and PIRADS Results Compared to Histopathology of TMB**

Performance Measure	SelectMDx > 0%		phi ≥ 27		PIRADS ≥ 3	
	HG PCa	CS PCa	HG PCa	CS PCa	HG PCa	CS PCa
Sensitivity	80%	67%	93%	94%	93%	94%
Specificity	88%	81%	29%	33%	21%	24%
PPV*†	36%	28%	10%	14%	9%	12%
NPV*†	98%	96%	98%	98%	97%	97%
Accuracy	82%	74%	54%	62%	49%	56%
AUC of ROC Curves	0.83	0.75	0.81	0.75	0.72	0.66
AUC with PIRADS	0.89	0.8	0.84	0.8	-	-

\*PPV = positive predictive values; NPV = negative predictive value  
 †NPV and PPV calculated assuming HG cancer prevalence = 8% and CS cancer prevalence = 10%

- Both phi ≥ 27 and PIRADS score ≥ 3 show very high sensitivity for HG and CS cancer (shown in red), but very low specificity
- SelectMDx shows high sensitivity and NPV for HG and CS cancer (shown in green)
- mpMRI has very high sensitivity, but low specificity for HG and CS PCa. SelectMDx test has high specificity to identify men without the respective diseases.
- **Thus, men with PIRADS ≤ 3 and SelectMDx ≤ 30% can be spared from unnecessary prostate biopsy.**

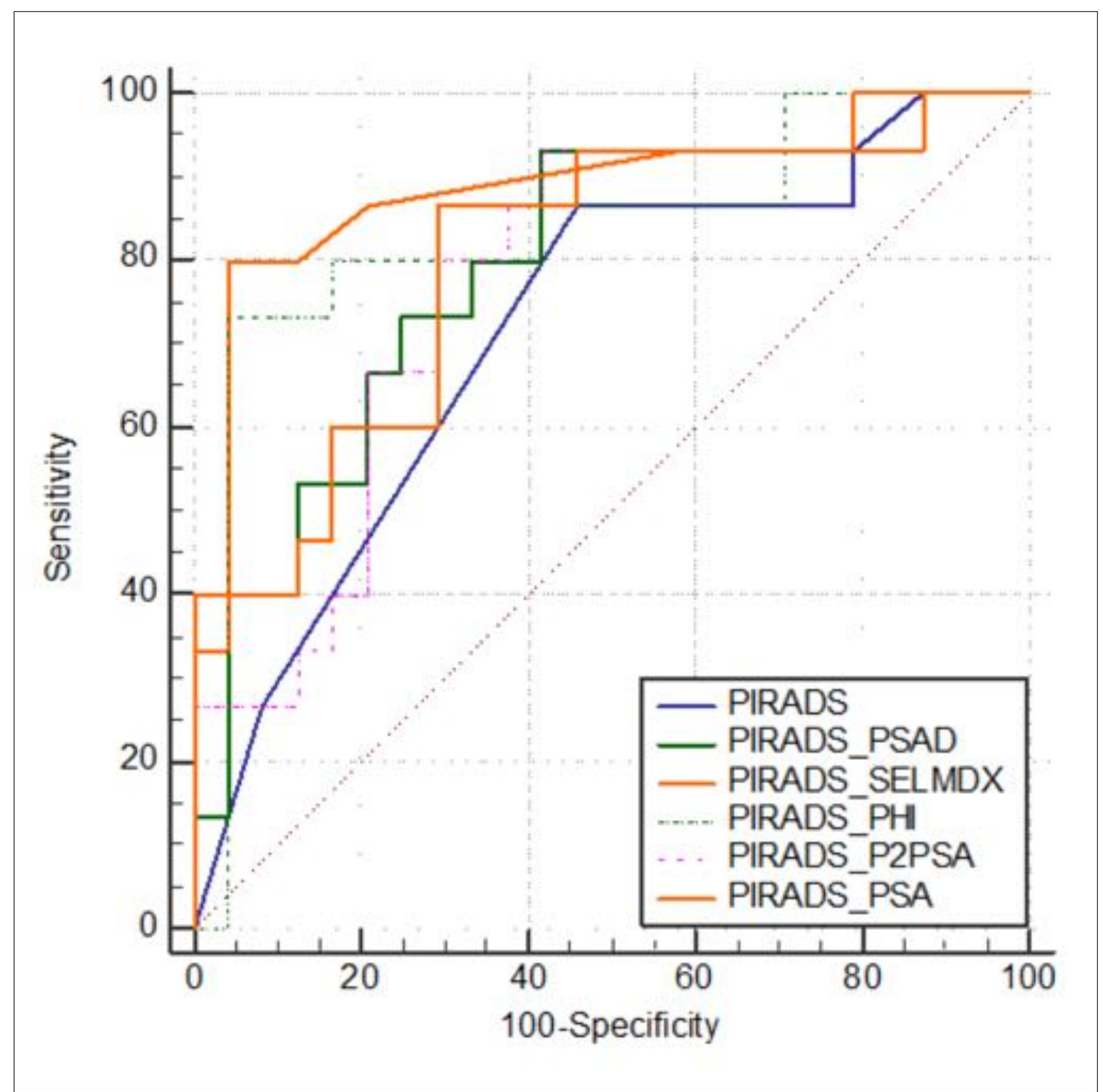


Variable	AUC	SE <sup>a</sup>	95% CI <sup>b</sup>
SelectMDx	0.832	0.0675	0.678 to 0.932
PHI	0.808	0.0774	0.651 to 0.916
PIRADS	0.718	0.0799	0.551 to 0.850
PSA	0.742	0.0834	0.577 to 0.868
PSAD	0.722	0.0859	0.556 to 0.853
P2PSA	0.700	0.0870	0.532 to 0.836

<sup>a</sup> DeLong et al., 1988  
<sup>b</sup> Binomial exact

Variable	AUC	SE <sup>a</sup>	95% CI <sup>b</sup>
PIRADS	0.718	0.0799	0.551 to 0.850
PIRADS_PSAD	0.792	0.0767	0.632 to 0.905
PIRADS_SELMDX	0.885	0.0658	0.742 to 0.964
PIRADS_PHI	0.844	0.0732	0.693 to 0.940
PIRADS_P2PSA	0.781	0.0763	0.619 to 0.897
PIRADS_PSA	0.808	0.0725	0.651 to 0.916

<sup>a</sup> DeLong et al., 1988  
<sup>b</sup> Binomial exact



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