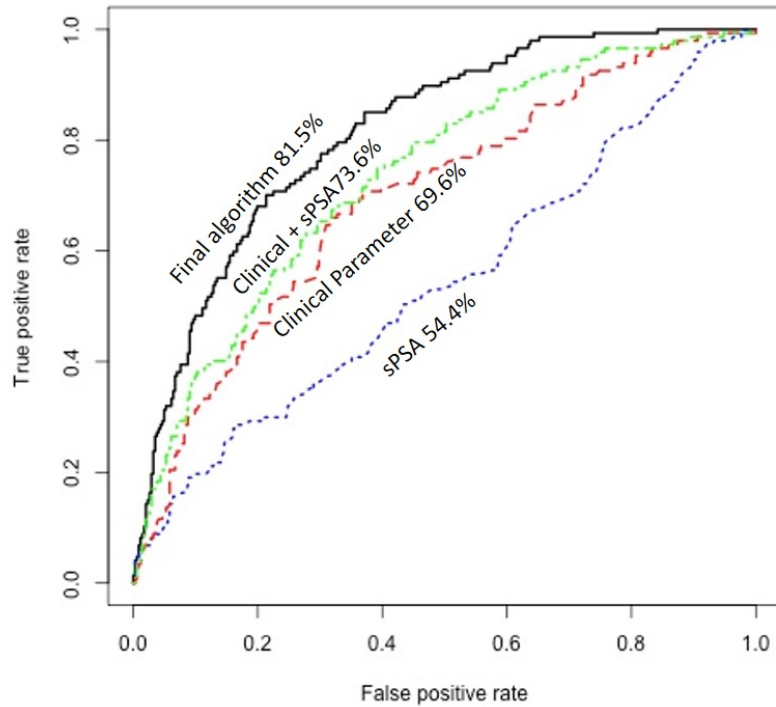


# Combined Urine and Plasma Biomarkers are Highly Accurate for Predicting High Grade Prostate Cancer

Urine/Plasma Assay (**NeoLAB Liquid Biopsy**) for predicting Gleason  $\geq 3+4$  using cell-free RNA (cfRNA) levels of UAP1, PDLIM5, IMPDH2, HSPD1, PCA3, PSA, TMPRSS2, ERG, AR, PTEN, and ERG



Multi-Center Prospective Study of **489 Patients**

	Cut-off	Sensitivity		Specificity		NPV		PPV	
		$\geq 3+4$	$\geq 4+3$	$\geq 3+4$	$\geq 4+3$	$\geq 3+4$	$\geq 4+3$	$\geq 3+4$	$\geq 4+3$
<b>Actual</b>									
<b>Predicted Positive</b>	Low	86%	96%	57%	59%	90%	98%	46%	46%
	Standard	91%	97%	51%	44%	93%	98%	44%	52%
	High	97%	99%	36%	37%	97%	99%	40%	40%

## Objective of the current study:

Clinical validation of the Urine/Plasma test using Prostatectomy data

## Characteristics of the **306 recruited patients**

Age (Median, Min-Max)	61 (36-77)
Prostate size (gm) (Median, Min-Max)	34 (9.22-160)
<b>Gleason</b>	
3+3	90 (29.4%)
3+4	122 (39.8%)
4+3	50 (16.3%)
3+5, 4+4, 4+5, 5+4	44 (14.4%)
<b>sPSA (ng/ml) (Median, Min-Max)</b>	
$\leq 4$	62 (20%)
4 to 10	198 (65%)
$>10$	46 (15%)

Testing and resulting were reported blindly

# NeoLAB Liquid Biopsy Test is More Accurate Than Biopsy in Predicting Prostatectomy Results

## Urine/Plasma Test in Predicting **Biopsy** Findings

	High sensitivity			Standard sensitivity			Low sensitivity		
	Value	Lower Limit	Upper Limit	Value	Lower Limit	Upper Limit	Value	Lower Limit	Upper Limit
Sensitivity	95%	91%	98%	92%	87%	95%	88%	83%	92%
PPV	71%	65%	76%	70%	65%	76%	70%	64%	75%
NPV	29%	10%	58%	28%	13%	50%	22%	10%	40%

## Urine/Plasma Test in Predicting **Prostatectomy** Findings

	High sensitivity			Standard sensitivity			Low sensitivity		
	Value	Lower Limit	Upper Limit	Value	Lower Limit	Upper Limit	Value	Lower Limit	Upper Limit
Sensitivity	97%	94%	99%	94%	90%	96%	92%	87%	95%
PPV	87%	82%	90%	87%	83%	91%	87%	83%	91%
NPV	43%	19%	70%	36%	19%	57%	31%	17%	50%

## Discrepancy Between Biopsy and Prostatectomy

Upgraded		Downgraded	
Gleason Score	No (%)	Gleason Score	No (%)
<b>3+3 to 3+4</b>	<b>49 (16%)</b>	<b>3+4 to 3+3</b>	<b>11 (4%)</b>
<b>3+3 to 4+3</b>	<b>9 (3%)</b>	<b>4+3 to 3+3</b>	<b>1 (0.3%)</b>
3+4 to 4+3	14 (5%)	<b>4+4 to 3+3</b>	<b>1(0.3%)</b>
3+4 to 4+4	2 (1%)	4+4 to 3+4	2 (0.7%)
3+4 to 4+5	2 (1%)	4+4 to 4+3	11 (4%)
4+3 to 4+4	3 (1%)	4+5 to 4+3	8 (3%)
4+3 to 5+4	1 (0.3%)	5+4 to 4+5	1 (0.3%)
4+4 to 4+5	1 (0.3%)	5+5 to 4+5	1 (0.3%)
4+5 to 5+4	1 (0.3%)		
Total	<b>82 (27%)</b>	Total	<b>36 (12%)</b>

## Sensitivity and Specificity of Prostate **Biopsy** in Predicting **Prostatectomy** Findings

	Estimated	95% Confidence Interval	
	Value	Lower Limit	Upper Limit
Sensitivity	78%	72%	83%
Specificity	71%	55%	83%
PPV	94%	90%	97%
NPV	36%	26%	46%

