

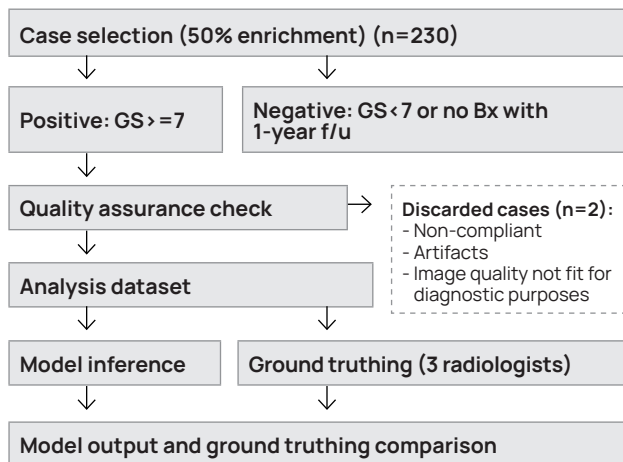
## → Pivotal study validation results

### CASE COHORT

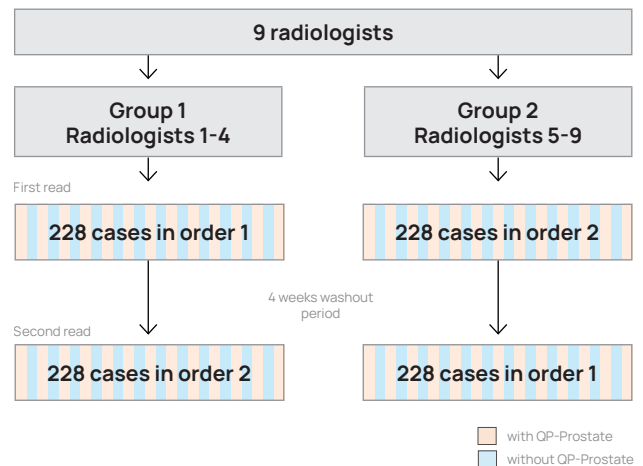
228 cases retrospectively chosen. Positives cases were biopsy-confirmed. Negative cases were either biopsy-confirmed or followed up clinically over a year with an MRI or stable/decreasing PSA.

### STUDY DESIGN

#### STANDALONE STUDY



#### CLINICAL READER STUDY



### CASE CHARACTERISTICS

#### BASELINE SUMMARY BY MRI SCANNER MANUFACTURER AT CASE-LEVEL

Sub-group	Ground truth positive for csPCa (N=114)	Ground truth negative for csPCa (N=114)	Total (N=228)
GE Medical Systems	26 (22.8%)	20 (17.5%)	46 (20.2%)
Philips Medical Systems	19 (16.7%)	21 (18.4%)	40 (17.5%)
Siemens	69 (60.5%)	73 (64.0%)	142 (62.3%)

#### BASELINE SUMMARY BY MRI FIELD AT CASE-LEVEL

Sub-group	Ground truth positive for csPCa (N=114)	Ground truth negative for csPCa (N=114)	Total (N=228)
1.5	17 (14.9%)	15 (13.2%)	32 (14.0%)
3	97 (85.1%)	99 (86.6%)	196 (86.0%)

#### BASELINE SUMMARY BY AGE AT CASE-LEVEL

Sub-group	Ground truth positive for csPCa (N=114)	Ground truth negative for csPCa (N=114)	Total (N=228)
≤65 years	61 (53.5%)	64 (56.1%)	125 (54.8%)
≥65 years	53 (46.5%)	50 (43.9%)	103 (45.2%)
Age, Mean ±SD	65.0 ± 7.0	64.4 ± 8.1	64.7 ± 7.6

## STANDALONE PERFORMANCE RESULTS

### LESION LEVEL - 95% CI



	AUC	Sensitivity	Specificity
<b>High marker</b>	73.8% (67.6% - 79.6%)	68.5% (60.2% - 76.7%)	74.2% (66.4% - 81.4%)
<b>Moderate marker</b>		79.5% (72.2% - 86.2%)	59.2% (50.0% - 67.9%)

### LESION ZONE SUBGROUPS - 95% CI



High-marker lesion	AUC	Sensitivity	Specificity
Peripheral zone	79.6% (71.4% - 86.0%)	67.6% (58.6% - 76.2%)	78.7% (66.0% - 90.2%)
Transition zone	66.2% (48.0% - 83.5%)	72.7% (52.4% - 90.9%)	66.7% (41.7% - 90.5%)

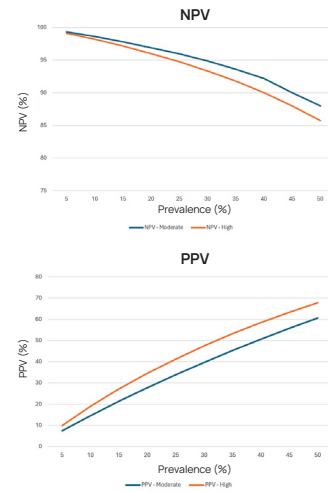
Moderate or high-marker lesion	AUC	Sensitivity	Specificity
Peripheral zone	79.6% (71.4% - 86.0%)	81.0% (73.1% - 88.3%)	74.5% (61.4% - 87.0%)
Transition zone	66.2% (48.0% - 83.5%)	72.7% (52.4% - 90.9%)	60.0% (33.3% - 85.0%)

### CASE LEVEL - 95% CI



	AUC	Sensitivity	Specificity
<b>High marker</b>	74.4% (67.8% - 80.1%)	81.6% (74.1% - 88.2%)	65.8% (57.4% - 74.2%)
<b>Moderate marker</b>		92.1% (87.0% - 96.5%)	40.4% (31.3% - 49.6%)

### PPV AND NPV FOR CSPCA IDENTIFICATION



Note: PPV and NPV depend on csPCa prevalence

## READER PERFORMANCE RESULTS

### CASE LEVEL - 95% CI



	Aided	Unaided	Difference
<b>AUC</b>	86.8% (83.4% - 90.2%)	84.9% (81.4% - 88.4%)	1.9% (0.1% - 3.8%)
<b>Sensitivity</b>	84.3% (76.5% - 92.1%)	80.4% (72.6% - 88.3%)	3.9% (1.8% - 5.9%)
<b>Specificity</b>	75.5% (64.5% - 86.6%)	75.0% (62.0% - 88.1%)	0.5% (-3.8% - 4.7%)

### LESION LEVEL - 95% CI



	Aided	Unaided	Difference
<b>AUC</b>	77.8% (73.1% - 82.4%)	73.8% (68.8% - 78.7%)	4.0% (2.2% - 5.9%)
<b>Sensitivity</b>	76.7% (69.1% - 84.4%)	71.9% (64.5% - 79.3%)	4.8% (2.1% - 7.5%)
<b>Specificity</b>	79.5% (71.0% - 88.1%)	77.1% (66.9% - 87.3%)	2.4% (-1.4% - 6.2%)

### RATE OF CONCORDANCE ACROSS RADIOLOGISTS



QP-Prostate CAD	Kappa (95% CI)
Aided	0.848 (0.823 - 0.872)
Unaided	0.807 (0.776 - 0.837)

### UNNECESSARY TARGETED BIOPSIES RATIO



QP-Prostate CAD	Odds ratio (95% CI)
Unaided:Aided	1.16 (0.85 - 1.58)