

# Does the Diagnostic Accuracy of Micro-Ultrasound Vary with Prostate Location?

## INTRODUCTION

**PRI-MUS™** (Prostate Risk Identification for Micro-Ultrasound) is an evidence-based risk assessment protocol<sup>1</sup> developed to identify suspicious areas in the prostate as visualized during routine clinical scanning by high-resolution **29 MHz micro-ultrasound** imaging. Multiple clinical studies have demonstrated the utility of the **PRI-MUS** protocol for characterizing tissue and helping to **direct targeted prostate biopsies** using **micro-ultrasound**. In this study we provide a prospective validation of PRI-MUS during its real-world clinical application.

## OBJECTIVE

This study tracks the performance of the **PRI-MUS** protocol after introducing the **micro-ultrasound** platform (**ExactVu™**, Exact Imaging, Markham, Canada) for **targeted prostate biopsy** into the Department of Urology at the Ordensklinikum Linz (Linz, Austria).

## METHODS:

- **399** consecutive subjects were examined by 5 urologists from January 2018 - May, 2019:
  - Median age: 66 years (IQR: 59-73)
  - Median PSA: 6.7 ng/mL (IQR: 4.5-11.2)
- Suspicious areas of the prostate were characterized in real-time using the **PRI-MUS** protocol. A targeted TRUS biopsy was then performed in the same session using the **ExactVu™** micro-ultrasound system (Exact Imaging, Markham, Canada)
- Areas marked with a **PRI-MUS ≥ 3** were considered targets.

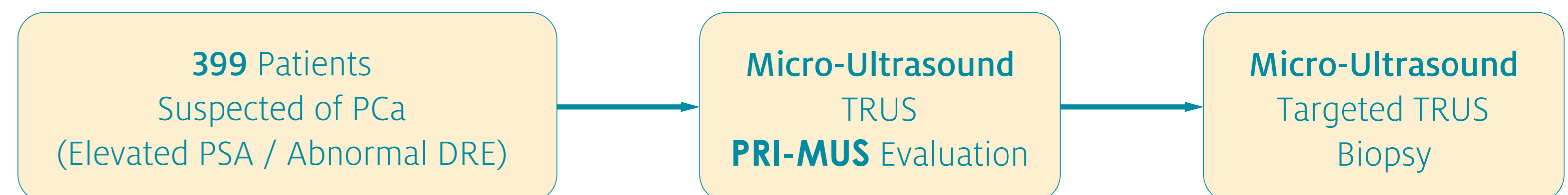


Figure 2: PRI-MUS Assessment Procedure using the ExactVu™ micro-ultrasound System (Exact Imaging, Markham, Canada)

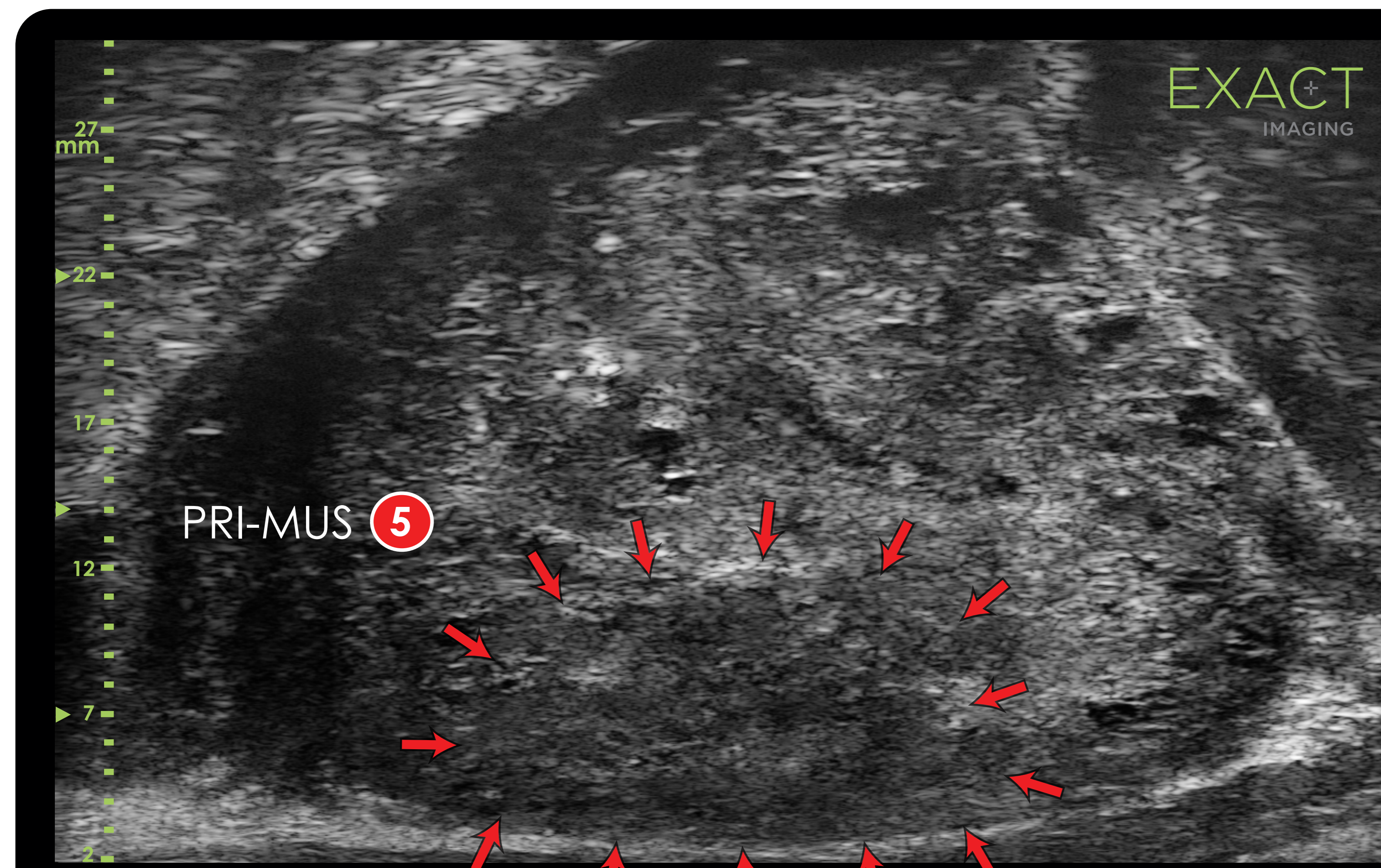


Figure 1A: PRI-MUS 5 target seen laterally on the Right Side towards the Base, characterized as a Mixed-echo Lesion and confirmed by pathology as a **Gleason 7 (4+3)** cancer.

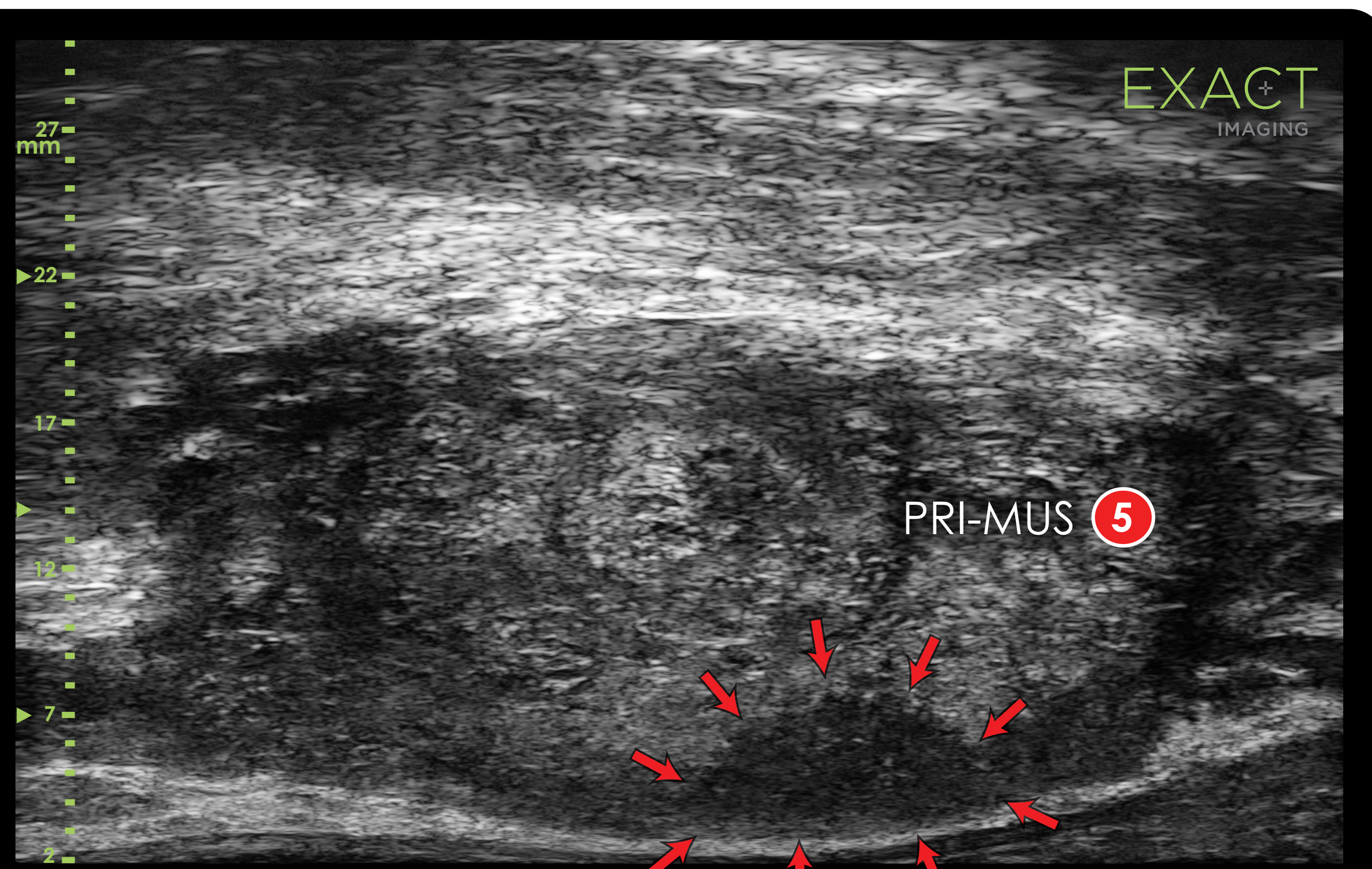


Figure 1B: PRI-MUS 5 target seen medially on the Left Side, characterized as a hypochoic-smudgy lesion and confirmed by pathology as a **Gleason 9** cancer.

## RESULTS:

- **PRI-MUS accuracy** ranged from **0.68-0.83** depending on anatomical area
- Accuracy highest in apex, lowest in base
- Anterior targets not often graded, but surprisingly accurate with AUC 0.80

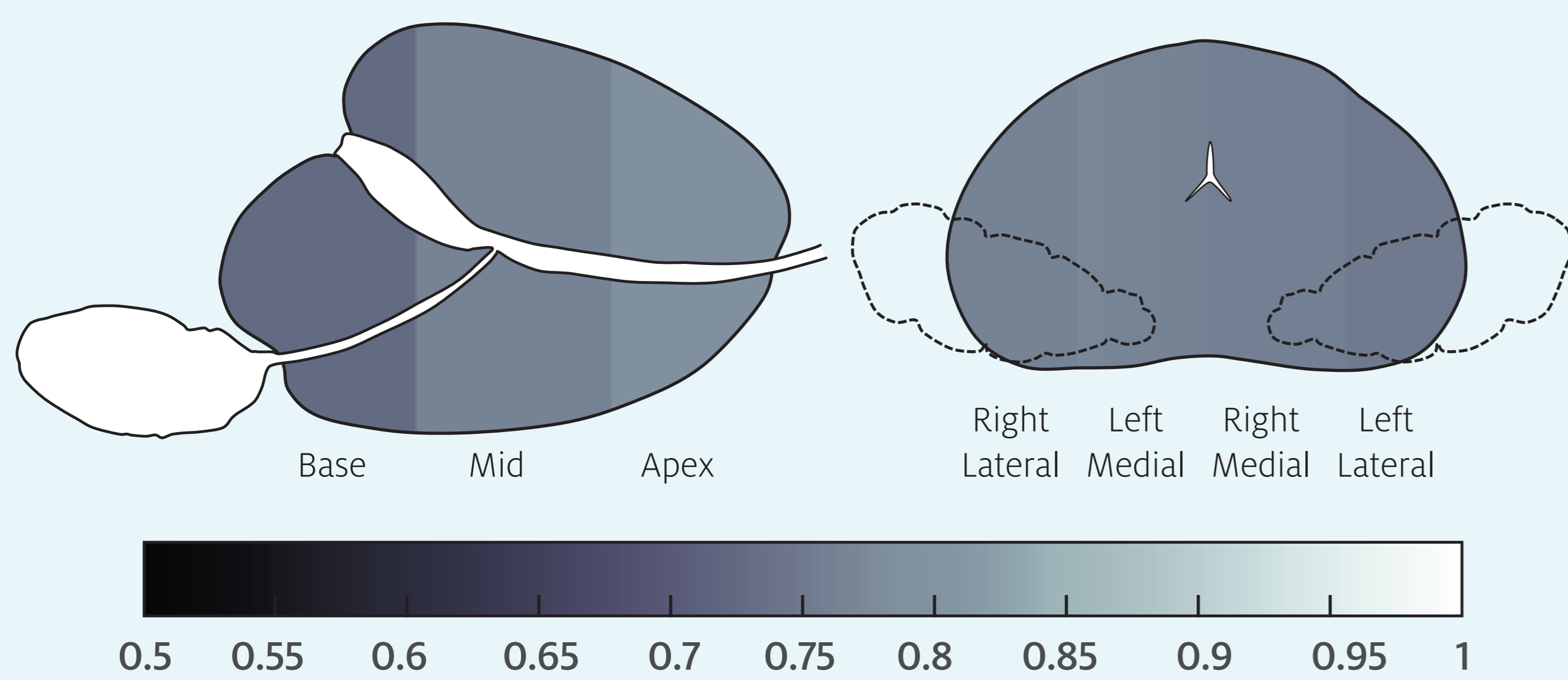


Figure 2: Accuracy (AUC) was relatively uniform throughout, though there was some improvement from Base to Apex, likely due to anatomical heterogeneity in the Base with the presence of Central Zone/Ejaculatory Duct and Bladder Neck muscular tissue. Small variability was also noted from Right Lateral to Left Lateral, possibly due to ergonomics of transrectal ultrasound scanning.

## BIOPSY PATHOLOGY OUTCOMES PER PATIENT

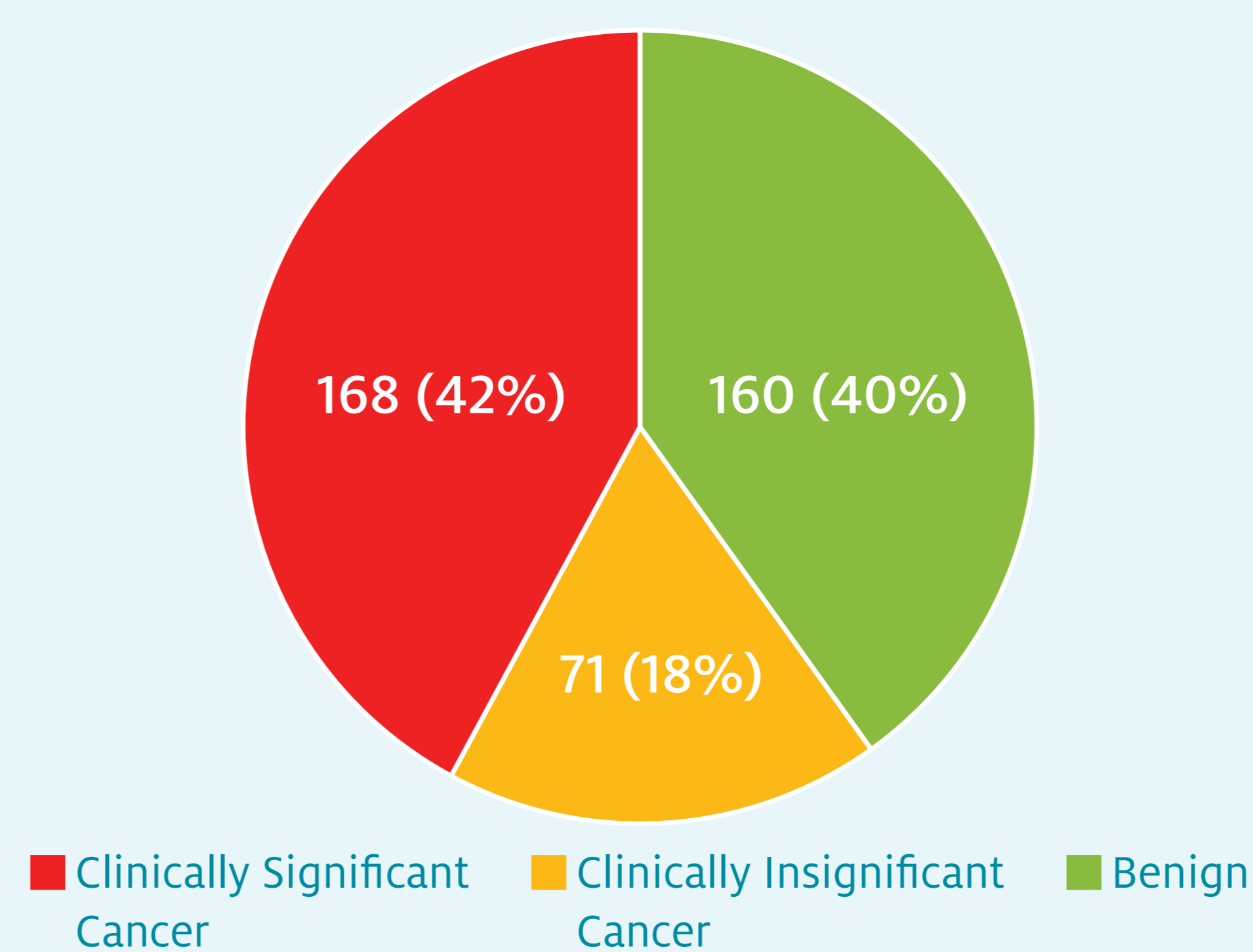


Figure 3: Summary of Targeted Biopsy Results using Micro-Ultrasound. 160/399 (40%) of all patients were diagnosed with benign conditions, 71/399 (18%) were diagnosed with low grade prostate cancer with (Gleason = 6) and the remaining 168/399 (42%) were diagnosed with clinically significant cancer (Gleason > 6)

- 239/399 (60%) of the patients were diagnosed with PCa
- 168/239 (70%) of cancers were clinically significant (Gleason > 6)

## CANCER DETECTION BY PRI-MUS SCORE

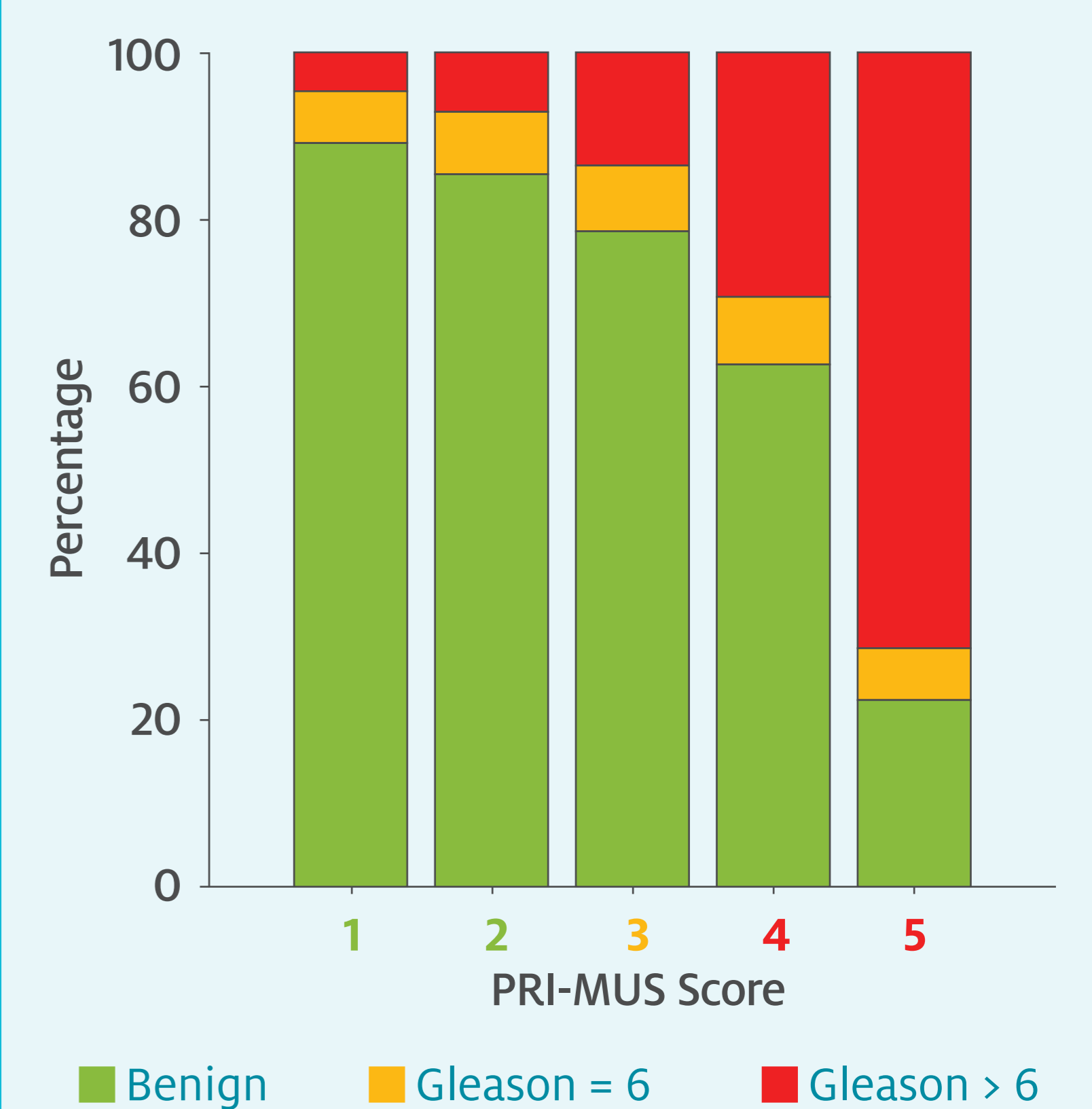


Figure 4: Cancer Detection by PRI-MUS Score. A clear improvement in detection rate with PRI-MUS score is shown as has been previously reported. Interestingly, the fraction of insignificant cancer is uniform across score.

## CONCLUSIONS:

- **Micro-ultrasound based PRI-MUS accuracy** is relatively uniform across prostate areas, more study required in anterior and transition zones
- **Micro-ultrasound provides a highly sensitive real-time targeting tool for prostate biopsies, thereby improving detection rates of csPCa at our clinic**
- Exciting potential to reduce false-negatives without relying on multi-modality, multi-specialty solutions like mpMRI.

## REFERENCES

1. Ghai S, Eure G, Fradet V, et al: *Assessing Cancer Risk on Novel 29 MHz Micro-Ultrasound Images of the Prostate: Creation of the Micro-Ultrasound Protocol for Prostate Risk Identification*. J. Urol. 2016; 196: 562-569.