Title: IsoPSA is a Sensitive Assay for Cribriform and Intraductal Carcinoma

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Intro: IsoPSA, a serum assay that detects PSA isoforms associated with prostate cancer, improves upon the sensitivity and specificity of standard PSA. Here we report on the sensitivity of IsoPSA for detecting high risk cribriform and intraductal carcinoma (CC and IDC).

Methods: We re-reviewed biopsies of men that underwent biopsy as part of a prospective IsoPSA validation cohort. Men were designated for biopsy by typical screening indications. All patients also underwent IsoPSA testing. The previously established cutoff of IsoPSA K ≥ 8 was used to determine whether men would have been biopsied if IsoPSA alone was used. Men with CC or IDC (grouped CC/IDC) were compared to men without CC/IDC. The primary outcome was the proportion of men that would not have been biopsied by IsoPSA indications alone.

Results: Of 100 men with prostate cancer, CC or IDC was present in 31 men. In the CC/IDC negative group, 14 (20.2%) would have been spared biopsy by IsoPSA criteria. In the CC/IDC positive group, all 31 men would have been biopsied; IsoPSA was 100% sensitive (figure 1; p = 0.004).

Conclusion: In this cohort of men undergoing screening-indicated biopsy, IsoPSA would not have missed a single CC or IDC diagnosis. IsoPSA appears to be sensitive for high risk pattern 4 tumors.

![IsoPSA K ≥ 8 (cutoff for biopsy)](image)

Figure 1. Proportion of men with IsoPSA < 8 or ≥ 8. Men with isoPSA < 8 would not have been biopsied by IsoPSA criteria alone.
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