Overdetection and overtreatment of indolent prostate cancer (PCa) remains a significant health issue requiring noninvasive assays to guide the prostate biopsy decision process. We demonstrated that the ExoDx™ Prostate (IntelliScore) derived from a urine exosome gene expression assay ([1]), discriminates GS 7 PCa from GS 6 and benign disease in the PSA grey zone, potentially reducing the number of unnecessary biopsies ([2]).

**Abstract**

**Methods:**

The urine test results and clinical data from the ExoDx™ Prostate (IntelliScore) validation cohort ([2]) were re-annotated using the ISUP grading system shown in Table 1. Here, we analyze the performance of EPI to discriminate:

- ISUP 1 (GS ≤ 6) from ISUP 2-5 (GS ≥ 7)
- ISUP 1+2 (GS ≤ 4+3) from ISUP 3-5 (GS ≥ 4+3)

**Results:**

We used two different cut-points ([1]) to assess the performance of EPI by fabricated biopsies. Accuracy, specificity, and negative predictive value (NPV) were significantly different in the two cut-points (Table 3). The demographic properties of the intended use population are shown in Table 2.

**Conclusions:**

The ExoDx™ Prostate (IntelliScore) is a noninvasive, first-catch non-DRE gene expression assay that accurately discriminates low-grade from high-grade PCa in both PCa definitions ([3]). The test has the potential to reduce the number of unnecessary biopsies and perform equally well in contemporary approaches to PCa stratification.

**References:**
