Reviewer’s report

Title: Clinical evaluation of prostate cancer gene 3 score in diagnosis among Chinese men with prostate cancer and benign prostatic hyperplasia

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Reviewer: Joseph Zabell

Reviewer's report:

This is a relatively well-written manuscript evaluating the role of utility of PCA3 assay to predict biopsy-detected prostate cancer in Chinese men. While the authors limit the generalizability of their findings by exclusively studying Chinese men, they were upfront about this in their study objectives. Overall, they found their assay of PCA3 to be a valuable predictor for prostate cancer on biopsy, and found both PCA3 and PSA to be independent predictors of finding cancer on biopsy.

While the statistical analyses are relatively robust and well described, the most significant weakness of the manuscript comes in the description of their methods of handling and obtaining tissue. The most significant issues are as follows:

- Methods: Section 2.2 This section of the paper included an over-abundance of detail beyond what is relevant for most clinicians.

- What is lost in this methods section and subsequent discussion is that this analysis appears to be evaluating PCA3 and psa mRNA from prostate tissue that has already been collected. While this may have been relevant to early studies examining this as a biomarker, the current clinical relevance is more closely tied to serum PSA measurements, and urine PCA 3 tests to help determine the need for biopsy. In this manuscript, the authors declare utility of PCA3 as a biomarker, but are basing this on tissue samples (which presumably would only be available after a biopsy), without relating this directly to appropriate urinary biomarker results. Furthermore, they do not clearly cite or describe any evidence or literature that has previously clarified the relationship between urinary PCA3 and tissue mRNA levels. Thus, this study appears to be using information that would only be obtained after a biopsy, in attempt to inform biopsy decision making, when both PSA and PCA3 can be determined prior to biopsy through other methods.

While this study, limited to Chinese men, does suggest utility for PCA3 as a biomarker, using urine samples (which is most clinically useful) and examination of men who subsequently underwent biopsy would be a much more powerful, and clinically useful analysis.

Are the methods appropriate and well described? If not, please specify what is required in your comments to the authors.
No

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

No

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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Acceptable

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