Reviewer's report

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

Version: 1 Date: 07 Oct 2015

Reviewer: Joseph Zabell

Reviewer's report:

The authors have made several substantive changes to this retrospective analysis correlating PCA3 scores to prostate biopsy results that address a number of the issues discussed in the previous review. However, there remain several issues to address:

- In Abstract conclusion, the wording of this sentence seems to overstate the findings of this study, as this is limited to a select population of Chinese men and given that results are based on tissue, the connection to how this will help predict biopsy outcomes is not terribly clear. The authors should be cautious not to overstate their conclusions.

- In abstract and methods, the wording has been simplified some which improves the readability. However, the authors declare that the formalin-fixed, paraffin-embedded tissue blocks were collected before biopsy. Where did these tissue blocks come from, if not from a biopsy? Further clarity in this methodological explanation is necessary to allow the reader to appropriately interpret the utility of these findings.

- While the discussion better places the results of this study into context with some updated language in the revision, the several of the conclusions drawn do not appear to be supported by the data. For example:

  - "The study evaluated the PCA3 assay as an additional tool in guiding biopsy decisions in Chinese men." and "This study showed that the PCA3 assay could provide important information for Chinese men who would consider prostate biopsy" How is this so when the marker for PCA3 used in this study was obtained after men had already received a biopsy?

  - Furthermore, the authors refer to PSA and PCA3 values throughout the paper as it pertains to the mRNA derived from their tissue blocks, rather than the more commonly used serum or urine values used in clinical literature. This creates relative confusion as to how the conclusions are applied.

- In short, several of the conclusions should be simplified and focused as hypothesis generating. From this data, it appears that one could conclude that increased PCA3 in biopsy tissue may correlate with cancer, but conclusions beyond this are difficult to draw, given that, as the authors state, "clinical relevance was limited" by the use of tissue blocks rather than
urine PCA 3 measures. Further discussion of this limitation and examining of the clinical context of this study is warranted.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**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

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