Reviewer’s report

Title: Revisiting the technical validation of tumour biomarker assays (or how to open a Pandora’s box)

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Reviewer: Eleftherios P. Diamandis

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Minor Essential Revisions

In this mini-review Marchiò et Al draw attention to potential pitfalls in using biomarkers in medicine, with emphasis on assay validation by using immunohistochemical techniques. The paper is well-written, raises valid points and could undoubtedly contribute to improving the use of biomarkers in clinical practice by better validation of the analytical procedures used.

I have a few suggestions to improve the manuscript by referencing relevant work previously published on this and related fields:

1. A commentary that could complement reference 5 regarding mass spectrometry-based serum proteomic analysis can be found in JNCI 2003;95:489-90

2. Another JNCI Editorial has drawn attention to various pitfalls in using biomarkers, and provides suggestions for future improvements. This work should be referenced : JNCI 2010;102:1462-7.

3. An important paper providing practice guidelines for use of tumour markers in the clinic, with special emphasis on quality requirements (pre-analytical, analytical and post-analytical) has recently been published (Clin Chem.2008;54:E1-E10 by Dr. Sturgeon and colleagues). This is a very relevant paper dealing with similar issues raised in this manuscript and should be referenced.

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests