Reviewer's report

Title: Analytical Validation of the PAM50-based Prosigna Breast Cancer Prognostic Gene Signature Assay and nCounter Analysis System Using Formalin-Fixed Paraffin-Embedded Breast Tumor Specimens

Version: 4 Date: 20 January 2014

Reviewer: Isabella Castellano

Reviewer's report:

Minor Essential Revisions

The topic of the present work has importance in its field. The study is well conducted. Results and discussion are well presented. However, in the opinion of the reviewer, the method section is difficult to read. For example I suggest the authors to shorten and simplify this section with schematic tables in which operator, test, run, ect are summarized.

In addition authors may provide additional information regarding the histopathological features of breast cancer samples used in this study.

The method of “macrodissection” is not well illustrated.

The abbreviations must be implemented with H&E, ER, PR.

Row 223: ER+ or PR+, must be rewrite as ER+, because ER-/PR+ breast cancer is a matter of discussion.

Row 198: “ROR Score” could be change in “ROR score variability” to avoid misunderstanding .

In the abstract too, method section should be revised to make it more understandable.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests' below. If your reply is yes to any, please give details below.