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:** 5 December 2013

**Reviewer:** DAVID J DABBS

**Reviewer's report:**

The authors beautifully illustrate how they executed detailed the analytical validity of the Prosigna test across multiple users and sites. The statistics at each level of potential assay variation are impeccable. Undoubtedly, this was information supplied for FDA clearance.

I authors do comment that the rigors of their reproducibility assessment is on par with oncoype Dx (reference cited), but it does appear to this reviewer that the authors rigorous study supercedes that of the published information from Genomic Health.

**Level of interest:** An exceptional article

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

'I declare that I have no competing interests'