Reviewer's report

Title: Real-time PCR complements immunohistochemistry in the determination of HER-2/neu status in breast cancer

Version: 1 Date: 4 October 2005

Reviewer: Douglas Demetrick

Reviewer's report:

General

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

This is a relatively simple manuscript which details the comparison between a commercially available quantitative PCR test for HER2 amplification versus the conventional FISH test, when used to determine HER2 copy number in cases of breast cancer that were intermediately stained by anti-HER2 antibody. The manuscript is concise, well written and edited, and the focus on indeterminate IHC cases is rational.

Minor essential revisions would include:
1. The authors should mention that they are evaluating a commercial LightCycler assay in the abstract, in case the reader thinks that a novel assay has been developed.

2. The authors should review at least some of the abundant quantitative PCR data on assaying HER2, including several descriptions of Lightcycler assays, to place the relevance of their paper in an appropriate context.

3. The authors should also describe the sensitivity and specificity, as well as false positive and/or negative rates of their assay in comparison to the gold standard of FISH, and its performance in comparison to other published Lightcycler assays of HER2 copy number.

4. The authors should comment on the potential impact of their data to be altered by prevalence of cancer cells in the specimens chosen for DNA extraction versus FISH, and how dissection methods could influence the usefulness of their assay.

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Discretionary Revisions (which the author can choose to ignore)

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What next?: Accept after minor essential revisions
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:
I declare that I have no competing interests.