CIHRT Exhibit P-2236

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From:

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Friday, September 16, 2005 11:55 AM Pathology Discussion Group

Subject:

RE: [PATHO-L] Ventana ER/PR cutoff?

In One of their papers (a SWOG) study, any brown nuclear staining above 1% was considered positive. In that study, (Int. J. Cancer (Pred. Oncol.): 89, 111?117 (2000)) there seemed to be a linear relationship between ER/PR expression and Tamoxifen response. (their categories: 0 - no staining; 1 any nuclear staining in <1/100; 5 > 2/3 (of all nuclei)). they combined 2 with 3, and 4 with 5.

Also, see there results of Fisher et al., which presents the data of the National Surgical 2005;103:164?73) advocating "any-or-none" scoring. To quote:

"A National Institutes of Health consensus statement relating to adjuvant therapy for breast carcinoma in 2000 concluded that patients with tumors that exhibited "any extent" of receptors should be treated, implying the use of an any-or-none measurement. The literature also revealed that the splits between positive and negative IHC receptor status have been almost exclusively arbitrary and variable. We favor the use of the word "split(s)"26 rather than "cut-off" for this purpose, because the plural of the latter

(In fact this paper mentions that the SWOG group used proportion and intensity in most of its papers, but only proportion in one paper).

bottom line, is that there isn't good evidence that there is a "cut-off" level of ression, below which patients will not benefit from Tamoxifen or related drugs, and given the dismal outcome of recurrent/metastatic breast cancer, oncologists tend to follow Mahesh.

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