Optimising our 2+ / FISH rate in HER2 testing in breast cancer: A prospective audit.

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Assessment of human epidermal growth factor 2 (HER2) status is mandatory in all cases of invasive breast cancer as overexpression of HER2 is associated with a poor prognosis, but also with response to targeted anti-HER2 therapy. Immunohistochemistry (IHC), the first line test, can be challenging to interpret. In our department we use fluorescent in-situ hybridisation (FISH) in the ~22% cases equivocal (2+) on IHC.

One pathologist prospectively allocated his HER2 2+ cases into likely negative (2neg), equivocal (2equiv), and likely positive (2pos) groups, between mid-July 2014 and mid-January 2016, following which these groups were audited, their IHC characteristics critically reviewed and their results compared to the outcomes on FISH testing.

Over this 18 month period 233 HER2 2+ cases were allocated, 115 (49.4%) into the 2neg group, 70 (30%) to the 2equiv group and 48 (20.6%) to the 2pos categories. 109 cases (94.8%) in the 2neg group were negative on FISH. Of the cases in this group which were amplified on FISH all were in the borderline positive range (ratio <2.2). 41/48 cases (85.4%) of cases in the 2pos group were positive on FISH testing. Of the 70 cases in the 2equiv group 53 (75.7%) were negative by FISH, while 17 (24.3%) were positive.

We detail the IHC expression characteristics associated with each of the three groups and predict that at FISH rate of between 12 and 15% of cases is achievable based on the results of this prospective audit.