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### The 2013 ASCO/CAP recommendations on HER2 testing in breast cancer have increased equivocal HER2 FISH results and the use of anti-HER2 therapies

The status of HER2 must be evaluated for breast cancer patients to receive anti-HER2 therapy, by either IHC or ISH or a combination of both. Based on the recommendations of American Society of Clinical Oncologists (ASCO) and College of American Pathologists (CAP) in 2007, a positive result is IHC 3+, or dual probe FISH showing a ratio (HER2/chromosome 17 centromere signals)  $>2.2$ ; a negative result is IHC 0 or 1+, or dual probe FISH showing a ratio  $<1.8$ . An equivocal IHC (2+) is referred for FISH. A patient having an equivocal FISH result with a ratio  $\geq 2$  is qualified for anti-HER2 treatment. In 2013, ASCO and CAP updated the guideline for HER2 testing in breast cancer. With the new recommendations and when HER2 is evaluated by dual probe FISH, a positive result is a ratio  $\geq 2.0$ , or  $\geq 6.0$  copies of the HER2 gene; a negative result is a ratio  $<2.0$  or  $<4.0$  copies; an equivocal result is a ratio  $<2.0$  and  $4.0\sim 5.9$  copies. Our lab has performed dual probe FISH and reported HER2 status using the updated ASCO/CAP recommendations in the past 2 years. To evaluate the significance of the new recommendations on HER2 amplification detection and the use of anti-HER2 therapies, we have compared the results determined by the 2007 and 2013 recommendations on the same cases we reported since 2013. Our comparison has shown that the new recommendations have significantly increased the frequency of equivocal results and the use of anti-HER2 therapies for breast cancer.

### Biography

Yao-Shan Fan, MD, PhD, Professor of Pathology, Director of Cytogenetics & Molecular Laboratory, University of Miami Miller School of Medicine, USA. He worked as a lab director, assistant/associate professor at the University of Western Ontario, and the Chair of the Genetics Committee, Laboratory Proficiency Testing Program in Canada as well as a CCMG Cytogenetics Committee member. He has published 100 articles in peer reviewed journals, authored a book, "Molecular Cytogenetics: Protocols and Applications", and contributed to "Encyclopedia of Medical Genomics and Proteomics" as Editorial Advisory. His current research and services focuses on developmental disorders and molecular diagnosis of human cancers.

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