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# High concordance between hercep test IHC & HER2 FISH before & after implementation of ASCO/CAP 2007 guidelines

**Sophia K. Apple**
UCLA School of Medicine, USA

Human epidermal growth factor receptor 2 (HER2) is an important critical predictive marker in patients with invasive breast cancer who can benefit from treatment with trastuzumab. It is thus imperative to ensure accuracy and precision in HER2 testing. In 2007, The American Society of Clinical Oncology/College of American Pathologists ASCO/CAP guidelines proposed new recommendations for HER2 testing for IHC and FISH scoring in an effort to improve accuracy and utility of these companion diagnostic tests as a predictive marker for patients with invasive breast cancer. The goal of the new guidelines was to improve the concordance rate between the diagnostic tests for HER2 and decrease the number of inconclusive cases. This study examines the impact in concordance rates and number of inconclusive cases based on the recent change in HER2 testing guidelines as published by the American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) in a large study cohort.

Both IHC and HER2 FISH were performed on all specimens from our facility from years 2003 through 2011 (n=1437). Cases from 2003 to 2007 (1,016) were scored by FDA guideline prior to publication of ASCO/CAP guidelines, with IHC 3+ cases staining >10% of tumor cells and FISH amplification cutoff value of 2.0. The new ASCO/CAP guidelines were implemented and scored accordingly for cases from 2008 to 2011 (n=421), with IHC 3+ cases staining >30% of tumor cells and FISH amplification cutoff value of 2.2. We compared the concordance rate before and after ASCO/CAP guidelines to see if ASCO/CAP guidelines yielded improvement in concordance rate between IHC and FISH. For the 2003-2007 study population, the concordance between the IHC and FISH HER2 assays was 97.6% with a corresponding kappa coefficient of 0.90. For the 2008-2011 study population, the concordance between the two assays was 97.6% with a corresponding kappa coefficient of 0.89%. There was no significant difference in number of inconclusive rates before and after ASCO/CAP guidelines.

In our study, implementation of the new ASCO/CAP HER2 scoring guidelines did not show a significant difference in concordance rates and did not decrease the number of inconclusive cases in specimens.

## Biography

Sophia K. Apple M.D. is a Chief of Breast Pathology who has served on the UCLA School of Medicine faculty since she joined the Department of Pathology in 2002. She has published 47 original articles, numerous abstracts in USCAP, and book chapters. She is an author of the leading textbook titled "The Breast Imaging" through Elsevier Publisher. She is a national and international speaker in breast pathology. She currently serves on the editorial board of 5 medical journals. Dr. Apple received her M.D. at Wright State University Medical Center in 1992. She received her Masters degree in Biochemistry at New York University and earned her B.S. in Biochemistry at New York University. She was trained in her anatomical and clinical pathology residency and Cytopathology fellowship at UCLA. She worked as a partner physician at Southern Kaiser Permanente group at Woodland Hills for more than four years and received an award for the most outstanding physician of the year at 2001, just after 3 years of practice. She is also a Cytopathology Fellowship Director at UCLA. Dr. Apple's research focuses on factors associated with the development of breast cancer and features associated with breast cancer biomarkers. Her consultations are praised nationwide for their clinical insights and diagnostic acumen.

sapple@mednet.ucla.edu