

[99] High Concordance of 6 HER2 In Situ Hybridization Methods with Abbott FISH

James E Boers, Colinda Netjes, Harriette C Meeuwissen, Clemens Prinsen, Cees van Krimpen, Jos Bart, Elise MJ van der Logt, Ed Schuurung. Isala Klinieken, Zwolle, Netherlands; Canisius Wilhelmina Ziekenhuis, Nijmegen, Netherlands; Kennemer Gasthuis, Haarlem, Netherlands; University Medical Center Groningen, Groningen, Netherlands

Background: HER2 *in situ* hybridization (ISH) has become a common test in breast cancer. Abbott FISH was used in most clinical studies showing the efficacy of anti-HER2 treatment in HER2 positive carcinomas. Only reports comparing one or two of newly developed ISH assays with Abbott FISH have been published previously. We conducted a comprehensive concordance study of 6 ISH methods with Abbott FISH in a large series of breast carcinomas.

Design: Tissue Micro Arrays (TMA) were constructed by taking three 0.6 mm tissue cores from formalin-fixed/paraffin-embedded tissue-blocks from 402 primary breast carcinomas diagnosed in 2007 (supported by the Dutch Pathological Society). Up to 384 cases were analyzable in the TMA. ISH was performed after ample experience with 7 ISH assays. Scoring was performed by two independent observers without knowledge of the other ISH data according the ASCO-guidelines for HER2-testing. HER2 and chromosome 17 (Chr17) signals were counted separately, the HER2:Chr17 ratio was calculated and considered positive when the ratio was ≥ 2.0 . In cases with a ratio was between 1.8 and 2.2, additional enumeration was performed. The discordant cases were reviewed and scores were reassigned on consensus of opinion. Concordance and Cohen's kappa score were calculated in relation to FISH, Abbott.

Results: are presented in the table:

Methods	Analyzable cases	HER2 ratio ≥ 2.0	Concordance	Kappa-score
FISH, Abbott	372	45 (12.1%)	X	X
FISH, DAKO	352	40 (11.4%)	98.1%	0.90
FISH, Zytovision	357	45 (12.6%)	99.1%	0.96
single probe SISH, Ventana	357	43 (12.0%)	98.9%	0.95
dual probe SISH, Ventana	371	47 (12.7%)	99.4%	0.97
duoCISH, DAKO	364	38 (10.4%)	97.2%	0.86
duoCISH, Zytovision	344	43 (12.5%)	99.1%	0.96

Concordance / Kappa-score: compared to Abbott FISH

Conclusions: Concordance of 6 HER2 ISH assays with Abbott FISH were shown to be 97.2% or higher. In this study, DAKO assays had a lower kappa score with Abbott FISH than Ventana or Zytovision assays.

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