

Breast Biomarkers Can Be Reliably Tested on Tissue Fixed and Processed by Same Day Automated Microwave-Assisted Method



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Background

- Recommendations to validate any modification in breast cancer biomarker testing have been endorsed by CAP and other regulatory bodies to ensure accurate testing (Fitzgibbon et al 2010).
- Accordingly, any proposed modification has to be tested against a previously validated technique. For modifications in preanalytical variables this entails creating a validation set of paired samples, consisting of a combination of positive (P), low positive (LP, <10%) and negative (N) cases that have been prepared under the same conditions and differing only with respect to the modified variable.
- Microwave-assisted rapid tissue fixation and processing (MWARTFP) significantly reduces tissue processing time.

Design

- A set of 62 breast cancer resection specimens (enriched for HER2+ cases) was prospectively selected for validation.
- Upon receipt from the OR, a core-sized sample of fresh tissue was acquired and immediately processed using a 2 hr protocol for MWARTFP (Pathos, Delta, Milestone).

- The remaining blocks were fixed for a minimum of 8 hours and processed by conventional overnight tissue processing (CTP).
- Parallel blocks from each case were placed on the same run on the immunostainer and read by the same pathologist.

Results

- ¹ fluorescent in situ hybridization (FISH)
- ² One CTP HER2 IHC 1+ scored 2+ on 2 hr protocol but wasn't amplified.
- ³ One CTP ISH equivocal case scored negative on 2 hr protocol.

Biomarker	Status, CTP	Concordant	% Agreement
ER (SP1)	P(LP)	46(2)/48(4)	95.8 (50)
	N	14/14	100
PgR (1E2)	P(LP)	35(7)/35(7)	100 (100)
	N	27/27	100
HER2 IHC (4B5)	P	21/21	100
	N	29 ² /29	100
HER2 FISH ¹	Amplified	18/18	100
	Non-amplified	18/18	100
	Equivocal	1 ³ /2	50

Conclusions

- Hormone receptors and HER2 status tested on MWARTFP and CTP are highly concordant.
- Discrepancy between MWARTFP and CTP on cases with very low positive ER could be attributed to smaller surface area tested on the study cores compared with the clinical blocks.
- This technology can be applied in pathology labs to provide comprehensive and efficient service for rapid (same day) diagnostic units including reliable biomarkers testing.