



**Staining & Scoring: CDP Breast Cancer Progression TMA
(CDP Stage I Breast Cancer Prognostic TMA (Case Sets 9-13))**

Estrogen Receptor Staining:

Marker: ER
Clone: 6F11
Dilution: 1:35
Company: Novocastra

For Progesterone Staining:

Marker: PR
Clone: PgR1294
Dilution: 1:200
Company: Dako

For Her-2 Staining:

Marker: c-erbB-2/Her-2/neu Ab-8
Clone: e2-400
Dilution: 1:300
Company: Labvision

For ER and PR scoring: ASCO CAP Guidelines

Score 0= <1% expressing cells, (negative)

Score 1= ≥ 1% expressing cells, (positive)

For Her-2 IHC Scoring: (ASCO/CAP Guidelines)

Score 1: Weak, incomplete membrane staining in any proportion of invasive tumor cells, or weak, complete membrane staining in less than 10% of cells.

Score 2: Complete membrane staining that is non-uniform or weak but with obvious circumferential distribution in at least 10% of cells, or intense complete membrane staining in 30% or less of tumor cells

Score 3: Uniform intense membrane staining of more than 30% of invasive tumor cells

Her-2 FISH Results:

For Her-2 FISH evaluation of the results, Her-2 signals and CEP17 signals were obtained, and the ratio method was used to look at the amplification. All cases 2+ and 1+ by IHC were evaluated by FISH.

FISH Positive:



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FISH HER2 / CEP17 ratio 2.2 or greater, or FISH HER2 gene copy number >6.0

FISH Negative:

FISH HER2 / CEP17 <1.8, or

FISH HER2 gene copy number <4.0

Final HER2 assessment:

Negative

IHC 0 (FISH not performed)

IHC 1+ and FISH nonamplified, unavailable, or equivocal

IHC 2+ and FISH nonamplified

IHC not available and FISH nonamplified

Positive:

IHC 3+ (FISH not performed)

IHC 2+ and FISH amplified

IHC 1+ and FISH amplified

IHC not available and FISH amplified