Invasive breast cancer tissue

**HER2 (ERBB2) testing (IHC or FISH)**

- IHC 0 or 1+
  - HER2 negative; trastuzumab therapy not indicated
  - Reflex to FISH recommended
  - FISH <2.0a
    - HER2 negative; trastuzumab therapy not indicated
    - Equivocal; trastuzumab response uncertain
  - FISH ≥2.0c; <2.0d
    - HER2 positive; patient eligible for trastuzumab therapy
    - Equivocal; trastuzumab response uncertain

- IHC 2+
  - HER2 positive; patient eligible for trastuzumab therapy

- IHC 3+
  - HER2 negative; trastuzumab therapy not indicated
  - Reflex to IHC recommended
  - FISH ≥2.0c or average HER2 ≥6.0 copies/cell
    - HER2 positive; patient eligible for trastuzumab therapy
    - HER2 negative; trastuzumab therapy not indicated
    - Equivocal; trastuzumab response uncertain
  - IHC 0 or 1+

Prior to reporting an equivocal FISH result, additional cells are counted by a second observer and, if the result is still equivocal, the FISH assay is automatically repeated.

This figure was developed by Quest Diagnostics based on reference 1. It is provided for informational purposes only and is not intended as medical advice. A physician’s test selection and interpretation, diagnosis, and patient management decisions should be based on his/her education, clinical expertise, and assessment of the patient.

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**Footnotes:**

a With average HER2 copy number <4.0 signals/cell, and counting at least 20 cells within the area.

b With average HER2 copy number ≥4.0 and <6.0 signals/cell, observed in a homogeneous and contiguous population and counting at least 20 cells within the area.

c Observed in a homogeneous and contiguous population, within >10% of the invasive tumor cells, and counting at least 20 cells within the area.

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