



LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 34 Y

Referral Testing

Collected: 09/08/2022 14:24 Received: 09/08/2022 14:24

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: FISH, HER-2/neu, Paraffin Block. Row 2: Specimen Type/Source: Breast Tissue, Site: QCRL. Row 3: HER-2/neu, FISH: SEE NOTE, Site: QCRL.

Order ID: 21-12345
Specimen Type: Tissue
Clinical Indication: Invasive lobular carcinoma

RESULT:
HER2 GENETIC HETEROGENEITY IS PRESENT (SEE COMMENTS BELOW)

Amplified area:
HER2/D17Z1 ratio: 3.8
Average HER2 copy number: 6.8 signals/cell
Average D17Z1 copy number: 1.8 signals/cell

Non-amplified area:
HER2/D17Z1 ratio: 1.3
Average HER2 copy number: 3.2 signals/cell
Average D17Z1 copy number: 2.5 signals/cell

INTERPRETATION:
This FISH assay revealed HER2 (ERBB2) amplification of aggregated cells in a distinct population representing approximately 10% of the tumor cells. The remaining tumor cells were negative for HER2 amplification. Histopathologic correlation is indicated.

The CAP/ASCO guidelines recommend HER2 testing on every primary invasive breast cancer and on metastatic sites, if tissue is available. Please expect the results of any other concurrent study in a separate report.

Image analysis method: Manual
Cells Counted: 40

SAMPLE INFORMATION:

Block ID:
Specimen site: Right Breast

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED



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Specimen type: Core Biopsy
Cold ischemic time: Less than 1 hour
Type of fixation: Formalin
Duration of fixation: 6-72 hours
Type of tissue processing: Not provided
IHC result for HER2 overexpression: Not available

NOMENCLATURE:

Amplified area: nuc ish(D17Z1x1-3,HER2x3-17) (20)
Non-amplified area: nuc ish(D17Z1x1-4,HER2x2-4) (20)

ASSAY INFORMATION:

According to the CAP/ASCO guidelines (J Clin Oncol. 2018 Jul 10;36(20):2105-2122. PMID: 29846122):

- A ratio of >/=2.0 and an average HER2 copy number >/=4.0 in >10% of tumor cells indicates amplification.
- A ratio of <2.0 and an average HER2 copy number <4.0 indicates absence of amplification.
- Any other FISH result should be reviewed together with the IHC result using sections from the same tissue sample used for FISH.

This fluorescence in situ hybridization (FISH) test was performed using the probes specific for the HER2 (ERBB2; 17q12) and the D17Z1 (CEN-17; centromeric region of chromosome 17) loci (DAKO HER2 IQFISH pharmDx Kit).

The analytical performance characteristics of this assay have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano, CA. The modifications have not been cleared or approved

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Test Name Result Flag Ref-Ranges Units Site
by the U.S. Food and Drug Administration. This assay has been
validated pursuant to the CLIA regulations and is used for clinical
purposes.

Fatih Z. Boyar, MD, FACMG (800) NICHOLS-4307
Alireza Bazooband, MD, FCAP, FASCP

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Clinical info Not provided QCRL

Reported Date: 11/30/2023 14:18 HERFI

Performing Site:

QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

E10800009 Ordered By: CLIENT CLIENT
WX0000003481 WX00000000002063
Printed D&T: 11/30/23 14:18

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1
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