

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

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

FISH, HER-2/neu, Paraffin Block

Specimen Type/Source Breast Tissue QCRL
HER-2/neu, FISH SEE NOTE 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

E108000009 WX0000003481 Printed D&T: 11/30/23 14:18 Ordered By: CLIENT CLIENT WX00000000000002063

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 3



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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. Slides from this sample were evaluated by an in-house pathologist and deemed adequate for HER2 FISH analysis by evaluating the invasive tumor per ASCO/CAP guidelines. Controls provided the anticipated results. This case was reviewed by at least 2 observers. Note that improper handling and fixation could affect the results if the cold ischemic time is > 1 hour, or if the fixation time is < 6 hours or > 72 hours. Results from this test are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in patients with invasive breast carcinoma. The performance of this test has not been fully investigated for other tumors. Clinical correlation is recommended. This test is also indicated as an aid in the assessment of patients for whom HER2 targeted therapy (e.g. Herceptin; Trastuzumab) is being considered.

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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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

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