Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB	8/15/1952
Sex:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	01/01/2017 12:34

H=High, L=Low, *=Abnormal, C=Critical

ERBB2 (HER2/neu) Gene Amplification by FISH with Reflex, Tissue

ARUP test code 2008603

ERBB2 (HER2) by FISH	See Note

nuc ish(CEP17x2-6,ERBB2x3-13)[50/50]

IHC GUIDED:
HER2 (ERBB2) Amplified

HER2/CEP17 Ratio: 2.0
Average HER2 Signal Number per Cell: 7.2
Average CEP17 Signal Number per Cell: 3.7
Number of Cells Scored: 50
Number of Observers: 2
Scoring Method: Manual

HERCEP IHC Result (performed at ARUP): 2+

Hercep IHC for this case was reviewed and approved by [redacted] See separate report for detailed interpretation.

Controls were run and performed as expected. This result has been reviewed and approved by Dan Albertson, M.D.
2000 Circle of Hope, RM 3100
Salt Lake City, UT 84112
(pathologist signature)

ERBB2 FISH METHODOLOGY AND INTERPRETIVE DATA:
Fluorescence in situ hybridization (FISH) analysis for ERBB2 (HER2) gene amplification was performed on a section from a

paraffin embedded tissue block using the Dako HER2 IQFISH PharmDx DNA Probe kit. Cells were evaluated from regions of tumor identified on histopathologic review of a matching hematoxylin and eosin stained section. Controls performed appropriately.

The Dako HER2 IQFISH test result was interpreted according to the American Society of Clinical Oncology / College of American Pathologists (ASCO/CAP) 2018 Guideline Recommendations for breast cancer fixed in formalin for 6-72 hours. Accordingly, an amplified result indicates an ERBB2/CEP17 ratio of 2.0 or greater with an average copy number of 4.0 or greater (group 1). A non-amplified result indicates an ERBB2/CEP17 ratio less than 2.0 with an average ERBB2 copy number less than 4.0 (group 5). Groups 2-4 encompass findings previously designated as either positive or equivocal. Specifically, group 2 indicates an ERBB2/CEP17 ratio of 2.0 or greater with an average ERBB2 copy number of less than 4.0. Group 3 indicates an ERBB2/CEP17 ratio of less than 2.0 with an average ERBB2 copy number of 6.0 or greater. Group 4 indicates an ERBB2/CEP17 ratio of less than 2.0 with an average ERBB2 copy number of at least 4.0 but less than 6.0.

For groups 2-4, concomitant review of HER2 IHC is performed according to the 2018 Guidelines, when such slides are available. If the IHC score is 3+, then the final result is considered positive for amplification. If 0 or 1+, then the final result is negative for amplification. If the IHC score is 2+, then additional tumor nuclei are enumerated with FISH from the area of highest IHC intensity by an individual blinded to the original results. If the results remain consistent with groups 2 or 4, then the final interpretation is considered negative. An amplified result is reserved for cases in which the recounted population remains consistent with the original results of group 3 (ERBB2/CEP17 ratio of less than 2.0 with an average ERBB2 copy number of 6.0 or greater).

Genetic heterogeneity is reported when there is an aggregate population of amplified cells comprising >10 percent of the tumor cell population on a slide. Cases with amplification of 50 percent or more of the tumor population are considered non-heterogeneous.

Based on the assay performance during test validation, the test is expected to detect HER2 amplification status correctly in 100% of patients. Assay range and limit of detection were generated using normal and known positive cases respectively.

The Dako HER2 IQFISH PharmDx test kit is validated and FDA-approved for the evaluation of ERBB2 (HER2) gene amplification in formalin fixed, paraffin embedded breast and gastroesophageal adenocarcinomas. In the absence of guidelines for interpretation of ERBB2 (HER2) amplification in all other specimen types the test results are interpreted according to 2017 ASCO/CAP guidelines for HER2 in gastroesophageal adenocarcinoma. The results should be interpreted within the appropriate clinical context.

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
ERBB2 (HER2) by FISH	22-123-400423	4/22/2022 4:13:00 PM	5/6/2022 3:04:31 PM	5/11/2022 3:25:00 PM
ERBB2(HercepTest)Rflx to FISH if 2+	22-123-400423	4/22/2022 4:13:00 PM	5/4/2022 11:50:00 AM	5/6/2022 3:04:00 PM
Percent of Cells/Circumferential	22-123-400423	4/22/2022 4:13:00 PM	5/4/2022 11:50:00 AM	5/6/2022 3:04:00 PM

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Intensity of Staining	22-123-400423	4/22/2022 4:13:00 PM	5/4/2022 11:50:00 AM	5/6/2022 3:04:00 PM
Homogenous Pattern	22-123-400423	4/22/2022 4:13:00 PM	5/4/2022 11:50:00 AM	5/6/2022 3:04:00 PM

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical