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

Physician: Doctor, Example

Patient: Patient, Example

DOB	5/14/1944
Sex:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	01/01/2017 12:34

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

ARUP test code 2008603

ERBB2 (HER2) by FISH

See Note

RESULT:
HER2 (ERBB2) Amplified

HER2/CEP17 Ratio: 3.9
Average HER2 Signal Number per Cell: 10.0
Average CEP17 Signal Number per Cell: 2.6
Number of Cells Scored: 20
Number of Observers: 2
Scoring Method: Manual

Controls were run and performed as expected.
This result has been reviewed and approved by [redacted]

(pathologist signature)

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 by histopathologic review of a matching hematoxylin- and eosin-stained section. Controls performed appropriately.

The Dako HER2 IQFISH test result was interpreted according to 2017 ASCO/CAP guidelines for HER2 in gastroesophageal adenocarcinoma. According to these guidelines, a nonamplified result indicates an ERBB2/CEP17 ratio less than 2.0; an amplified result indicates either (1) an ERBB2/CEP17 ratio of 2.0 or greater or (2) an average ERBB2 copy number of at least 6.0. Tumors with ERBB2/CEP17 ratio less than 2.0 and an average of 3 or more copies of CEP17 with an average ERBB2 copy number of at least 4.0 but less than 6.0 on a minimum of 40 cell count, are considered indeterminate. Genetic heterogeneity is reported when there is an aggregate population of amplified cells comprising greater than 10 percent of the tumor cell population on a slide. Cases with amplification of 50 percent or more of the tumor population are considered nonheterogeneous.

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

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

The 2017 ASCO/CAP guidelines recommend FISH testing be performed only on tumors with equivocal (2+) IHC results. Findings from the Trastuzumab for Gastric Cancer (ToGA) trial and other studies have reported that the FISH positivity alone in the absence of protein expression does not correlate with response to HER2-directed therapy in gastroesophageal adenocarcinomas.

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	22-109-155890	4/19/2022 2:25:00 PM	4/29/2022 12:48:55 PM	5/5/2022 10:04:00 AM

END OF CHART