

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

Physician: Doctor, Example

**Patient: Patient, Example**

**DOB** 12/31/1752  
**Gender:** 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

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

*Unless otherwise indicated, testing performed at:*

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RESULT:  
HER2 (ERBB2) Amplified

HER2/CEP17 Ratio: 2.3  
Average HER2 Signal Number per Cell: 6.1  
Average CEP17 Signal Number per Cell: 2.7  
Number of Cells Scored: 40  
Number of Observers: 2  
Scoring Method: Manual  
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Controls were run and performed as expected. This result has been reviewed and approved by Dan Albertson, M.D.  
(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 non-amplified 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 non-heterogeneous.

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.

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**H=High, L=Low, \*=Abnormal, C=Critical**  
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Unless otherwise indicated, testing performed at:

**ARUP LABORATORIES | 800-522-2787 | aruplab.com**  
500 Chipeta Way, Salt Lake City, UT 84108-1221  
Tracy I. George, MD, Laboratory Director

Patient: Patient, Example  
ARUP Accession: 19-176-148358  
Patient Identifiers: 01234567890ABCD, 012345  
Visit Number (FIN): 01234567890ABCD  
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VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
ERBB2 (HER2) by FISH	19-176-148358	6/25/2019 3:45:00 PM	6/28/2019 4:36:08 PM	6/28/2019 5:21:00 PM

END OF CHART

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

Unless otherwise indicated, testing performed at:

**ARUP LABORATORIES | 800-522-2787 | aruplab.com**  
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