

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

Physician: Doctor, Example

Patient: Patient, Example

DOB: 2/11/1952
Gender: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

ERBB2 (HER2/neu) (HercepTest) with Interpretation by Immunohistochemistry, Tissue

ARUP test code 0049174

ERBB2 (HercepTest) by IHC

2+ Equivocal

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

Unless otherwise indicated, testing performed at:

ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Laboratory Director

Patient: Patient, Example
ARUP Accession: 25-273-400790
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
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4848

Clinical Interpretation: This result has been reviewed and approved by

INTERPRETIVE INFORMATION: HercepTest

Tumors Other Than Breast or Gastric:

The predictive value of HER2 expression, if detected by this assay, is uncertain in tumors other than breast and gastric.

The result of the HercepTest by Dako (Agilent) is interpreted in a semi-quantitative manner. Test is FDA-approved for breast and gastric cancer only, and performed on formalin-fixed, paraffin-embedded tissue. Antibody clone is polyclonal and uses a proprietary detection system.

No guidelines exist for the interpretation of HercepTest in tumors other than breast and gastric.

ARUP Laboratories uses the 2018 ASCO/CAP guidelines for interpretation of ERBB2 (HER2) protein expression in breast cancers, and the 2017 CAP recommendations for interpretation in gastric carcinomas. Tissue should be fixed in formalin for 6-72 hours with a cold ischemic time of less than 1 hour. Tissue not meeting these requirements or tissue placed in decalcification solution should be interpreted with caution due to the likelihood of false negative results.

For breast cancer, positive cases are those with uniform, intense, complete circumferential membrane staining of more than 10 percent of invasive tumor cells (score 3+). Negative cases are defined as a) no staining (score 0), or b) staining that is incomplete and faint or barely perceptible and is within more than 10 percent of the invasive tumor cells (score 1+). Equivocal cases are those with weak to moderate complete membrane staining observed in greater than 10 percent of tumor cells (score 2+). It is recommended that an Equivocal result be reflexed to another method of testing.

For surgical gastric specimens, positive cases are those with moderate to strong complete, basolateral or lateral membranous reactivity in at least 10 percent of tumor cells (score 3+). Negative cases are defined as a) those with no reactivity or membranous reactivity in less than 10 percent of cells observed (score 0) or b) those with faint, barely perceptible membranous reactivity in at least 10 percent of cells (score 1+). Equivocal cases are those with weak to moderate complete, basolateral or lateral membranous reactivity in at least 10 percent of tumor cells (score 2+).

For gastric biopsy specimens, positive cases are tumor cell clusters (defined as at least 5 cells) with a strong complete, basolateral, or lateral membranous reactivity irrespective of percentage of tumor cells stained (score 3+). Negative cases are defined as a) those with no reactivity or no membranous reactivity in any, or less than 5 clustered tumor cells (score 0) or b) those with a faint or barely perceptible membranous reactivity irrespective of percentage of cells stained (score 1+). Equivocal cases are defined as a tumor cell cluster with weak to moderate complete, basolateral, or lateral membranous reactivity irrespective of percentage of tumor cells stained (score 2+).

For more information refer to the ASCO/CAP guidelines found at www.jco.org , or the CAP guidelines found at CAP.org .

Controls stained appropriately.

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Percent of Cells/Circumferential	5
Intensity of Staining	Moderate
Homogenous Pattern	Linear
Fixative Used	Formalin
Time from Bx to Fixative	Not provided
Duration of Fixation	Not provided
Sample Adequacy	Adequate
HER2 Reference Number	WS:SR25-2869 A1
HER2 Tissue Source	Tail of Pancreas

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4848

VERIFIED/REPORTED DATES				
Procedure	Accession	Collected	Received	Verified/Reported
ERBB2 (HercepTest) by IHC	25-273-400790	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Percent of Cells/Circumferential	25-273-400790	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Intensity of Staining	25-273-400790	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Homogenous Pattern	25-273-400790	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Fixative Used	25-273-400790	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Time from Bx to Fixative	25-273-400790	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Duration of Fixation	25-273-400790	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Sample Adequacy	25-273-400790	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
HER2 Reference Number	25-273-400790	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
HER2 Tissue Source	25-273-400790	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

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

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