

TSS Pat ID:

100-0-3

Carcinoma, infiltrating duct, NOS

8500/3

SPECIMENS:

- A. SENTINEL LYMPH NODE #1
- B. SENTINEL LYMPH NODE 2 RIGHT AXILLA
- C. SENTINEL LYMPH NODE 3 RIGHT AXILLA
- D. SENTINEL LYMPH NODE 4 RIGHT AXILLA
- E. SENTINEL LYMPH NODE #5
- F. RIGHT BREAST
- G. ADDITIONAL LATERAL TISSUE RIGHT BREAST
- H. ADDITIONAL SUPERIOR RIGHT BREAST TISSUE

Path Site Code: breast, upper-outer quadrant
CQCF Site: breast, NOS C50.9

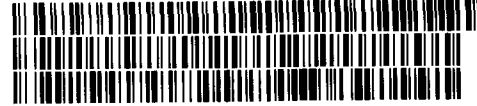
C50.4

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TCGA-E2-A109-01A-PR

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- H. ADDITIONAL SUPERIOR RIGHT BREAST TISSUE

INTRAOPERATIVE CONSULTATION DIAGNOSIS:

TPA, B, C, D, E. Sentinel lymph nodes #1, 2, 3, 4, 5, biopsies: No tumor seen.
By Dr, called to Dr. at . (A,B), . C, D) and at . (E).

GROSS DESCRIPTION:

A. SENTINEL LYMPH NODE #1

Received is a tan-pink fatty lymph node (1.8 x 0.9 x 0.3 cm). The specimen is serially sectioned, touch prep was performed. The specimen is submitted is cassettes A1-A3.

B. SENTINEL LYMPH NODE #2 RIGHT AXILLA

Received is a tan-pink fatty lymph node (1.5 x .6 x .3 cm). The specimen is serially sectioned and touch preps are taken. The specimen is submitted in toto in B.

C. SENTINEL LYMPH NODE #3 RIGHT AXILLA

Received are two tan-pink lymph nodes (1.0 x 0.3 x 0.2 cm and 1.4 x .6 x .5 cm). The specimen is serially sectioned and touch preps are taken. The specimen is submitted as follows:

- C1: one lymph node, trisected
- C2: one lymph node serially sectioned

D. SENTINEL LYMPH NODE #4 RIGHT AXILLA

Received is a tan-pink lymph node (1.0 x .6 x .3 cm). The specimen is serially sectioned and touch preps are taken. The specimen is submitted in toto in cassette D.

E. SENTINEL LYMPH NODE #5

Received is a tan-pink lymph node (.9 x .7 x .2 cm). The specimen is serially sectioned and touch preps are taken. The specimen is submitted in toto in cassette E.

F. RIGHT BREAST

Received fresh labeled with the patient name, designated "right breast", is a simple mastectomy specimen weighing 1181 grams and measuring overall 28 x 23 x 4.5 cm. The specimen is received with orientation, a suture indicating the axillary aspect. The overlying beige-tan ellipse of skin measures 21 x 11 cm. The surface demonstrates three areas of brown hyperpigmentation, the largest measuring 1 x 0.6 cm to the smallest measuring 0.5 x 0.3 cm. A light tan raised lesion is noted at 3 o'clock on the skin measuring 0.5 x 0.5 cm. The light tan areola measures 2.3 cm in diameter, the everted nipple measures 1 cm in diameter. The deep margin is inked black. The specimen is serially sectioned from axilla to medial aspect and shows a firm beige-tan lesion in the upper outer quadrant at approximately 10 o'clock approaching the deep surgical margin at a distance of 4.3 cm. The lesion measures 2.2 x 1.9 x 1.5 cm. An ill defined white firm fibrous area is also demonstrated at approximately 12 o'clock measuring 1.5 x 1.2 x 1 cm. This area is located 5.5 cm from the lesion. An ill defined irregular dense white area is shown in the lower inner quadrant measuring 2.5 x 2 x 2 cm. This area is located approximately 10.5 cm from the lesion. The remainder of the breast parenchyma shows dark yellow adipose tissue. A portion of the specimen was submitted for tissue procurement. Representative sections are submitted as follows:

- F1-F4: the lesion in the upper outer quadrant
- F5: deep margin overlying lesion
- F6-F8: sections of white firm fibrous tissue at 12 o'clock

F9-F16: multiple sections of ill defined firm area in lower inner quadrant
 F17-F18: representative sections of upper inner quadrant
 F19-F21: representative sections of the lower outer quadrant
 F22-F23: additional sections from the upper outer quadrant adjacent to lesion
 F24: section of nipple
 F25: section of skin demonstrating the raised tan lesion at 3 o'clock
 F26: additional section of skin
 F27-F28: possible lymph nodes

G. ADDITIONAL LATERAL TISSUE RIGHT BREAST

Received in formalin in a container labeled with the patient name, designated "additional lateral tissue", is a fragment of dark yellow adipose tissue measuring 8 x 2.2 x 0.5 cm. The exterior surface is inked black. The entire specimen is submitted in cassettes G1-G4.

H. ADDITIONAL SUPERIOR RIGHT BREAST TISSUE

Received in formalin in a container labeled with the patient name designated "additional superior right breast tissue", is a fragment of yellow adipose tissue measuring 3 x 2.2 x 1 cm. The entire specimen is submitted in cassettes H1 and H2.

DIAGNOSIS:

- A. SENTINEL LYMPH NODE #1, EXCISION:
 - ONE LYMPH NODE, NEGATIVE FOR TUMOR (0/1).
- B. SENTINEL LYMPH NODE #2, RIGHT AXILLA, EXCISION:
 - ONE LYMPH NODE, NEGATIVE FOR TUMOR (0/1).
- C. SENTINEL LYMPH NODE #3, RIGHT AXILLA, EXCISION:
 - TWO LYMPH NODES, NEGATIVE FOR TUMOR (0/2).
- D. SENTINEL LYMPH NODE #4, RIGHT AXILLA, EXCISION:
 - ONE LYMPH NODE, NEGATIVE FOR TUMOR (0/1).
- E. SENTINEL LYMPH NODE #5, EXCISION:
 - ONE LYMPH NODE, NEGATIVE FOR TUMOR (0/1).
- F. RIGHT BREAST, SIMPLE MASTECTOMY:
 - TWO FOCI OF INVASIVE DUCTAL CARCINOMA, TUMOR SIZE 2.2 x 1.9 x 1.5 CM. AND 1 x 1 CM. RESPECTIVELY, SBR GRADE III IN LARGE TUMOR FOCUS.
 - DUCTAL CARCINOMA IN-SITU, COMEDO AND SOLID TYPES, HIGH NUCLEAR GRADE WITH MICROCALCIFICATIONS.
 - MARKED FIBROCYSTIC DISEASE AND ADENOSIS WITH EXTENSIVE MICROCALCIFICATIONS.
 - SURGICAL RESECTION MARGINS, NEGATIVE FOR TUMOR.
 - FOCAL SEBORRHEIC KERATOSIS OF SKIN.
 - SEE TEMPLATE.

Note: There are two foci of invasive ductal carcinoma identified: the large one is present in the upper outer quadrant measuring 2.2 cm. This focus is SBR grade III. Another small tumor focus is present in the central area at the 12 o'clock position measuring 1 x 1 cm. This focus of tumor is SBR grade I, with tubular formation. Ductal carcinoma in-situ containing microcalcifications is associated with the large focus of invasive carcinoma. In addition microcalcifications are also present in multifoci of adenosis and fibrocystic disease.

G. ADDITIONAL LATERAL TISSUE RIGHT BREAST, EXCISION:

- BENIGN ADIPOSE TISSUE, NEGATIVE FOR TUMOR.

H. ADDITIONAL SUPERIOR RIGHT BREAST TISSUE, EXCISION:

- BENIGN ADIPOSE TISSUE, NEGATIVE FOR TUMOR.

SYNOPTIC REPORT - BREAST

Specimens Involved

Specimens: F: RIGHT BREAST

Specimen Type: Mastectomy

Needle Localization: No

Laterality: Right

Invasive tumor: Present

Multifocality: Yes

WHO CLASSIFICATION

Invasive ductal carcinoma, NOS 8500/3

Specimen size: Size of Invasive focus 2.2cm

Additional dimensions: 1.9cm x 1.5cm
 Tumor Site: Upper outer quadrant
 Central
 Margins: Negative
 Distance from closest margin: 4.3cm
 Tubular score: 3 (<10% tubule)
 Nuclear grade: 3
 Mitotic score (Olympus 40x): 2 (7-13/10)
 Modified Scarff Bloom Richardson Grade: III (8-9 points)
 Necrosis: Absent
 Vascular/Lymphatic Invasion: None identified
 Lobular neoplasia: None
 Lymph nodes: Sentinel lymph node only
 Lymph node status: Negative 0 / 6
 DCIS present
 Margins uninvolved by DCIS
 DCIS Quantity: Estimate % 15
 DCIS type: Comedo
 Solid
 DCIS location: Associated with invasive tumor
 Nuclear grade: High
 Necrosis: Present
 Location of CA++: DCIS
 Benign epithelium
 Pathological staging (pTN): pT 2 N 0

SYNOPTIC REPORT - BREAST, ER/PR RESULTS

Specimens Involved

Specimens: F: RIGHT BREAST

SPECIMEN:

Other

simple mastectomy

Block Number: F1

ER: Positive - Allred Score: 8 = Proportion score: 5 + Intensity Score 3

PR: Negative - Allred Score: 0 = Proportion Score 0 + Intensity Score 0

COMMENT:

The Allred score for estrogen and progesterone receptors is calculated by adding the sum of the proportion score (0 = no staining, 1 = <1% of cells staining, 2 = 1 - 10% of cells staining, 3 = 11-30% of cells staining, 4 = 31-60% of cells staining, 5 = >60% of cells staining) to the intensity score (1 = weak intensity of staining, 2 = intermediate intensity of staining, 3 = strong intensity of staining), with a scoring range from 0 to 8.

ER/PR positive is defined as an Allred score of >2 and ER/PR negative is defined as an Allred score of less than or equal to 2.

Methodology: Fixation Type and Length: Tissue was fixed in 10% neutral buffered formalin () for no less than 8 and no longer than 24 hours. Antibody and Assay Methodology:

Mouse anti-human ER and PR, ().

Comment: This assay can be used to select invasive breast cancer patients for hormone therapy (1). ER and PR analysis was performed on this case by immunohistochemistry utilizing the ER (ER 1D5, 1:100) and PR (PGR 136, 1:100) antibody provided by following the manufacturer's instructions listed in the package insert. This assay was not modified, and adherence to all instruction and guidelines were strictly followed. Interpretation of the ER/PR immunohistochemical staining characteristics is guided by published results in the medical literature (1), information provided by the reagent manufacturer and by internal review of staining performance within the

1. Harvey JM, et al. Estrogen receptor status by immunohistochemistry is superior to the ligand-binding assay for predicting response to adjuvant endocrine therapy in breast cancer. J Clin Oncol. 17:1474-1481, 1999

CLINICAL HISTORY:

Patient is a year old white female who underwent an ultrasound guided core biopsy on which revealed invasive ductal carcinoma of right breast with extensive pleomorphic malignant appearing microcalcifications on mammogram. The patient opted for a right simple mastectomy and sentinel lymph node biopsy after consideration.

PRE-OPERATIVE DIAGNOSIS:

Right breast cancer.

ADDENDUM:

SYNOPTIC REPORT - BREAST HER-2 RESULTS

Specimens Involved

Specimens: F: RIGHT BREAST

HER2 Status Results, Immunohistochemistry Evaluation

SPECIMEN

Surgical Excision

Block Number: Block

F1

Interpretation: Equivocal

Intensity: 2+

% Tumor Staining: 50%

FISH Ordered YES DATE

METHODOLOGY

Methodology: Fixation Type and Length: Tissue was fixed in 10% neutral buffered formalin () for no less than 8 and no longer than 24 hours. Antibody and Assay Methodology:

Rabbit anti-human HER2, Herceptest™ (FDA-approved test kit), Control

Slides Examined: External kit-slides provided by manufacturer (cell lines with high, low and negative HER2 protein expression), and in-house known HER2 amplified control tissue were evaluated along with the test tissue. These control slides run along side of this patient's sample showed appropriate staining. Adequacy of Specimen: Adequate, well preserved, clear-cut invasive carcinoma identified for HER2 evaluation.

Scoring Criterion and Scoring System:

IHC Level of Expression(Score) /Tumor Cell Membrane Staining Pattern

Negative (0)/Absence of Staining

Negative (1+)/Faint Incomplete membrane Staining, >10% of Cells

Equivocal (2+)/Weak complete membrane Staining, >10% of Cells

Positive (3+)/Strong complete membrane Staining, >10% of Cells

Equivocal Category for HER2 IHC results: A HER2, 2+ staining result that is interpreted as equivocal may not indicate gene amplification. A FISH test for HER2 gene amplification will be ordered for all HER2 IHC 2+ results.

COMMENT

This assay can be used to select invasive breast cancer patients for Trastuzumab (Hereptin) therapy (1,2). Clinical Trials have shown that Trastuzumab substantially increases the likelihood for an objective response and overall survival for patients with metastatic HER2-positive breast cancer, regardless of whether HER2 tumor status was determined as IHC 3+ or FISH positive. Trastuzumab added to adjuvant chemotherapy substantially increase disease-free survival and decreases the risk of disease recurrence by about 50% for patients with early-stage HER2 protein over-expressed or gene amplified invasive breast cancer (3).

HER2 analysis was performed on this case by immunohistochemistry utilizing the FDA approved (TM) test kit following the manufacturer's instructions listed in the package insert. This assay was not modified, and adherence to all instruction and guidelines were strictly followed. Interpretation of the HER2 immunohistochemical staining characteristics is guided by published results in the medical literature (4), information provided by the reagent manufacturer and by internal review of staining performance within the Institute Pathology Department.

HER2 TEST VALIDATION

This HER2 immunohistochemical assay has been validated according to the recently revised recommendations and guidelines from the NCCN HER2 testing in Breast Cancer Task Force, and the jointly issued recommendations and guidelines from ASCO and the CAP (5). 80 randomly selected breast cancer samples were tested for HER2 by IHC as outline above and interpreted as, negative (score 0/1+) equivocal (score 2+) and positive (score 3+) without knowledge of the previous reported results.

These cases were also blindly read using two different FISH assay as amplified or non-amplified and the HER2/CEP17 ratios were recorded. After analyzing these results, there was 100% concordance between the IHC and FISH results for cases that were interpreted as either positive or negative by IHC. 9 of the 80 cases were interpreted as equivocal by IHC and of these 3/9 (33%) were non-amplified by FISH and 6/9 (66%) were found to be amplified.

Pathology Department Immunohistochemistry laboratory takes full responsibility for this tests performance and has programs in place to regularly monitor the proficiency and the interpretation of HER2 assays. The laboratory also participates in external quality assurance HER2 programs including the CAP proficiency testing program.

REFERENCE

1. Carlson RW, Anderson BO, Burstein HJ, et al., NCCN breast cancer clinical practice guidelines in oncology. J Natl Compr Canc Netw. 2005;3:238-289.
2. Carlson RW, Brown E, Burstein HJ, et al., NCCN Task Force Report: adjuvant therapy for breast cancer. J Natl Compr Canc Netw. 2006;4:S1-S26.
3. Romond EH, Perez EA, Bryant J, et al. Trastuzumab plus adjuvant chemotherapy for operable HER2-positive breast cancer. N Eng J Med 2005;353(16):1673-84

4. Leong ASY, Formby M, Haffajee Z, et al. Refinement of immunohistologic parameters for Her2/neu scoring validation by FISH and CISH. Appl Immunohistochem Mol Morphol. 2006;14:384-389.
5. Wolff AC, Hammond EH, Schwartz JN, et al., American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Human Epidermal Growth Factor Recepto 2 Testing in Breast Cancer. Arch of Path and Lab Med 2007; 131:18-43.
The followings are ER and PR results of the second tumor focus measuring 1 cm. at the central area of breast tissue.

SYNOPTIC REPORT - BREAST, ER/PR RESULTS

Specimens Involved
Specimens: F: RIGHT BREAST

SPECIMEN:

Surgical Excision

Block Number: F7

ER: Positive - Allred Score: 8 = Proportion score: 5 + Intensity Score 3

PR: Positive - Allred Score: 7 = Proportion Score 4 + Intensity Score 3

COMMENT:

The Allred score for estrogen and progesterone receptors is calculated by adding the sum of the proportion score (0 = no staining, 1 = <1% of cells staining, 2 = 1 - 10% of cells staining, 3 = 11-30% of cells staining, 4 = 31-60% of cells staining, 5 = >60% of cells staining) to the intensity score (1 = weak intensity of staining, 2 = intermediate intensity of staining, 3 = strong intensity of staining), with a scoring range from 0 to 8.

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Methodology: Fixation Type and Length: Tissue was fixed in 10% neutral buffered formalin () for no less than 8 and no longer than 24 hours. Antibody and Assay Methodology:

Mouse anti-human ER and PR, (Dako, Carpinteria, CA).

Comment: This assay can be used to select invasive breast cancer patients for hormone therapy (1). ER and PR analysis was performed on this case by immunohistochemistry utilizing the ER (ER 1D5, 1:100) and PR (PGR 136, 1:100) antibody provided by following the manufacturer's instructions listed in the package insert. This assay was not modified, and adherence to all instruction and guidelines were strictly followed. Interpretation of the ER/PR immunohistochemical staining characteristics is guided by published results in the medical literature (1), information provided by the reagent manufacturer and by internal review of staining performance within the Institute Pathology Department.

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SYNOPTIC REPORT - BREAST HER-2 RESULTS

Specimens Involved
Specimens: F: RIGHT BREAST

HER2 Status Results, Immunohistochemistry Evaluation

SPECIMEN

Surgical Excision

Block Number: Block

F7

Interpretation: Negative

Intensity: 1+

% Tumor Staining: 10%

FISH Ordered NO DATE

METHODOLOGY

Methodology: Fixation Type and Length: Tissue was fixed in 10% neutral buffered formalin (Pharmco Inc. Brookfield, CT) for no less than 8 and no longer than 24 hours. Antibody and Assay Methodology:

Rabbit anti-human HER2, Herceptest™ (FDA-approved test kit), (Control

Slides Examined: External kit-slides provided by manufacturer (cell lines with high, low and negative HER2 protein expression), and in-house known HER2 amplified control tissue were evaluated along with the test tissue. These control slides run along side of this patient's sample showed appropriate staining. Adequacy of Specimen: Adequate, well preserved, clear-cut invasive carcinoma identified for HER2 evaluation.

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2. Carlson RW, Brown E, Burstein HJ, et al., NCCN Task Force Report: adjuvant therapy for breast cancer. J Natl Compr Canc Netw. 2006;4:S1-S26.
3. Romond EH, Perez EA, Bryant J, et al. Trastuzumab plus adjuvant chemotherapy for operable HER2-positive breast cancer. N Eng J Med 2005;353(16):1673-84
4. Leong ASY, Formby M, Haffajee Z, et al. Refinement of immunohistologic parameters for Her2/neu scoring validation by FISH and CISH. Appl Immunohistochem Mol Morphol. 2006;14:384-389.
5. Wolff AC, Hammond EH, Schwartz JN, et al., American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Human Epidermal Growth Factor Recepto 2 Testing in Breast Cancer. Arch of Path and Lab Med 2007; 131:18-43.

PathVysion HER-2 DNA Probe Kit

Analytical Interpretation of Results: HER-2 NOT AMPLIFIED

Clinical Interpretation of results

Amplification of the HER-2 gene was evaluated with interphase fluorescence in-situ hybridization (FISH) on formalin-fixed paraffin embedded tissue sections using a chromosome 17 centromeric probe and a HER-2 probe that spans the entire HER-2 gene in the Pathology Core Facility by Dr.. A majority of tumors cells displayed moderate polysomy 17 with 2 to 4 chromosome 17 signals and 2 to 4 HER-2 signals, with a HER-2/CEP 17 Ratio ≤ 2.0 , consistent with no amplification of the HER2/neu gene.

Block used F1 Source of case: RPCI

Tissue fixation formalin-fixed tissue Outside Case No:NA

Tissue source breast Results interpreted: yes

HER2/CEP17 ratio: 1.46

This ratio is derived by dividing the total number of LSI HER-2/neu signals by the total number of CEP17 signals in at least 20 interphase nuclei with nonoverlapping nuclei in the neoplastic mammary epithelial cells. Cells with no signals or with signals of only one color are disregarded.

Method of ratio enumeration: manual count

Limitations

The Vysis PathVysion Kit is not intended for use to screen for or diagnose breast cancer. It is intended to be used as an adjunct to other prognostic factors currently used to predict disease-free and overall survival in stage II, node-positive breast cancer patients. In making decisions regarding adjuvant CAF treatment, all other available clinical information should also be taken into consideration, such as tumor size, number of involved lymph nodes, and steroid receptor status.

No

treatment decision for stage II, node-positive breast cancer patients should be based on HER-2/neu

gene amplification status alone.

Overview of this test

FDA APPROVED REAGENT

PathVysion HER-2 DNA Probe Kit is FDA approved for selection of patients for whom Herceptin® therapy is being considered. These tests were performed in the
, under the direction

of Dr.. The results of these studies should always be interpreted in the context of the clinical, morphological, and immunophenotypic diagnosis.

Gross Dictation: M.D., Pathologist,

Microscopic/Diagnostic Dictation: M.D., Pathologist,

Final Review: M.D., Pathologist,

Final: M.D., Pathologist, 1

Addendum: M.D., Pathologist, 1

Addendum Final: M.D., Pathologist,

Addendum: M.D., Pathologist, 1

Addendum Final: M.D., Pathologist,

Addendum: M.D., Pathologist,

Addendum Final: M.D., Pathologist, 1

Addendum: M.D., Pathologist,

Addendum Final: M.D., Pathologist,

Addendum: M.D., Pathologist,

Addendum Final: M.D., Pathologist,

Criteria	Yes	No
Diagnosis Discrepancy		/
Primary Tumor Site Discrepancy		/
HIPAA Discrepancy		/
Prior Malignancy History		/
Dual/Synchronous Primary Noted		/
Case is (circle):	QUALIFIED	DISQUALIFIED
Reviewer Initials	Date Reviewed: 1/1/10	