ICD-O-3
Carcinoma, infiltrating duct, NOS 8500/3
Site Code: breast, NOS C50.9

12/19/10 W

TSS Pt ID

SPECIMENS:

A. SLN #1 RIGHT AXILLA
B. SLN #2 RIGHT AXILLA
C. SLN #3 RIGHT AXILLA
D. RIGHT BREAST
E. RIGHT AXILLARY CONTENTS LEVELS 1-2
F. ADDITIONAL RIGHT BREAST TISSUE
G. ADDITIONAL INFERIOR MARGIN

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INTRAOPERATIVE CONSULTATION DIAGNOSIS:

TPA-sentinel lymph node #1 right axilla: Positive for carcinoma {Dr. consulted} called by Dr. to Dr. at

GROSS DESCRIPTION:

A. SLN #1 RIGHT AXILLA
Received fresh is one lymph node measuring 0.8 x 0.7 x 0.2 cm. One touch prep is performed. Lymph node is submitted entirely in cassettes A1-A3.
B. SLN#2 RIGHT AXILLA
Received fresh is a lymph node measuring 1 x 0.6 x 0.4 cm. Submitted in cassette B1.
C. SLN#3 RIGHT AXILLA
Received fresh is a piece of yellow-tan soft tissue measuring 3.2 x 1.5 x 0.3 cm. One possible lymph node is identified measuring 0.1-cm. Lymph node is submitted in cassette C1.
D. RIGHT BREAST
Received fresh is an oriented 205g, 15 x 13 x 4.5 cm mastectomy with 4.5 x 3 cm tan skin ellipse, 1.5 cm everted nipple. Superior anterior margin is inked yellow, inferior anterior margin blue, the deep margin black. The specimen is serially sectioned from lateral to medial revealing the following:
1) A granular tan irregular mass {lesion #1} measuring 4.5 x 2.7 x 1.5 cm in the mid to upper inner quadrant. It is 1 cm from the deep margin and abuts the anterior/superior margin.
2) A 1 x 0.8 x 0.7 cm granular pink-tan area {lesion #2} that is 2 cm inferior to lesion #1.
3) 0.5 cm possible biopsy site in upper outer quadrant that is 1.5 cm lateral to lesion #1 and is 2.7 cm from the deep margin.
Representatively submitted as follows:
D1-D2: lesion #1 including anterior/superior margin
D3-D4: complete cross-section extending from anterior/superior to deep, lesion #1
D5: lesion #1 including deep margin
D6: lesion #2 and tissue connecting to lesion #1
D7: lesion #2 and skin
D8: tissue extending from lesion #1 to possible biopsy site
D9-D11: possible biopsy site
D12: granular tissue from superior anterior margin
D13: upper inner quadrant
D14: lower inner quadrant
D15: lower outer quadrant
D16: upper outer quadrant
D17-D18: nipple
D19-D20: soft tissue from axillary tail

E. RIGHT AXILLARY CONTENTS LEVELS 1-2

Received in formalin are multiple tan pink soft tissue fragments aggregating to 5 x 3 x 2cm. Dissection reveals 17 possible lymph nodes ranging from 0.2 x 0.2 x 0.2cm to 2.0 x 2.0 x 1.5cm. Entirely submitted:
E1: 5 lymph nodes
E2: 4 lymph nodes
E3: 4 lymph nodes
E4: 2 lymph nodes
E5: 1 lymph node serially sectioned
E6: 1 lymph node serially sectioned
E7-E8: additional axillary tissue
E9-E13: remainder of tissue
F. ADDITIONAL RIGHT BREAST TISSUE
Received in formalin is an 8g unoriented aggregate of tan pink fibrofatty tissue 5.0 x 4.0 x 2.0cm. The specimen is inked Black and serially sectioned to reveal grossly unremarkable breast parenchyma. Toto F1-F9.
G. ADDITIONAL INFERIOR MARGIN
Stitch at new true margin.
Received in formalin is a 28g oriented tan pink fragment of fibrofatty tissue 11.0 x 5.0 x 1.5cm. The new true margin is inked Black and the specimen is serially sectioned to reveal grossly unremarkable breast parenchyma. Toto G1-G27.

RESULTS:
SUMMARY OF IMMUNOHISTOCHEMISTRY/SPECIAL STAINS

Material: Block A1
Population: Tumor Cells

Stain/Marker:	Result:	Comment:
CYTOKERATIN AE1/3	Positive	

Material: Block A2
Population: Tumor Cells

Stain/Marker:	Result:	Comment:
CYTOKERATIN AE1/3	Negative	

Material: Block A3
Population: Tumor Cells

Stain/Marker:	Result:	Comment:
CYTOKERATIN AE1/3	Positive	

The interpretation of the above immunohistochemistry stain or stains is guided by published results in the medical literature, provided package information from the manufacturer and by internal review of staining performance and assay validation within the Immunohistochemistry Laboratory of The use of one or more reagents in the above tests is regulated as an analyte specific reagent (ASR). These tests were developed and their performance characteristic determined by the Department of Pathology Laboratory at. They have not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

Special stains and/or immunohistochemical stains were performed with appropriately stained positive and negative controls.

DIAGNOSIS:

A. SENTINEL LYMPH NODE #1, RIGHT AXILLA, BIOPSY:
- MICROMETASTATIC CARCINOMA TO ONE LYMPH NODE, WITH NO EXTRANODAL EXTENSION (1/1) (SEE NOTE).

NOTE: There are two foci of micrometastasis, each measuring less than 1 mm in size. A cytokeratin AE1/3 stain was performed that highlights the micrometastases and also shows a few scattered cytokeratin positive cells in the parenchyma.

B. SENTINEL LYMPH NODE #2, RIGHT AXILLA, BIOPSY:
- ONE LYMPH NODE, NO TUMOR SEEN (0/1).

C. SENTINEL LYMPH NODE #3, RIGHT AXILLA, BIOPSY:
- ONE LYMPH NODE, NO TUMOR SEEN (0/1).

D. BREAST, RIGHT, MASTECTOMY:
- MULTICENTRIC INVASIVE DUCTAL CARCINOMA, MODERATELY DIFFERENTIATED (SBR GRADE 2) (SEE NOTE).
  - TUMOR MEASURES 1.2 CM IN GREATEST DIMENSION.
  - INVASIVE CARCINOMA IS WITHIN 1 MM OF THE ANTERIOR MARGIN IN THE UPPER INNER QUADRANT.
- EXTENSIVE DUCTAL CARCINOMA IN SITU (DCIS), CRIBRIFORM, SOLID AND MICROPAPILLARY TYPES, NUCLEAR GRADES 2 AND 3, WITH NECROSIS AND MICROCALCIFICATIONS, INVOLVING LOBULES
  - DCIS IS PRESENT AT THE ANTERIOR MARGIN IN THE UPPER INNER QUADRANT.
  - DCIS INVOLVES LACTIFEROUS DUCTS.
- SKIN AND NIPPLE, NO TUMOR SEEN.

NOTE: In the upper outer quadrant, a biopsy site is noted with adjacent DCIS. Near the biopsy site, a 2 mm focus of invasive ductal carcinoma is seen. In the upper inner quadrant, there is invasive ductal carcinoma with DCIS, with the largest focus of invasion measuring 1.2 cm and with at least one other focus of invasion that measures 0.1 cm. The DCIS in the upper inner quadrant is mass forming and spans at least 4 cm in greatest dimension.

E. AXILLARY CONTENTS, RIGHT, LEVELS 1-2, DISSECTION:
- 13 LYMPH NODES, NO TUMOR SEEN (0/13).

F. BREAST, RIGHT, ADDITIONAL TISSUE, EXCISION:
- DUCTAL CARCINOMA IN SITU, PRESENT AT INKED ASPECT (SEE NOTE).

NOTE: There is a 3 millimeter focus of DCIS. The tissue was not oriented but was inked entirely black and DCIS is present at the inked aspect.

G. BREAST, RIGHT, ADDITIONAL INFERIOR MARGIN, EXCISION:
- FOCAL COLUMNAR CELL CHANGE WITH CYTOLOGIC ATYPIA (FLAT EPITHELIAL ATYPIA).
- NO EVIDENCE OF CARCINOMA.

SYNOPTIC REPORT - BREAST
Specimen Type: Mastectomy
Needle Localization: No
Laterality: Right
Invasive Tumor: Present
Multifocality: Yes
WHO CLASSIFICATION
Invasive ductal carcinoma, NOS 8500/3
Tumor size: 1.2cm

Tumor Site: Upper outer quadrant
Upper inner quadrant
Margins: Negative
Distance from closest margin: Less than 0.1cm
anterior
Tubular Score: 3
Nuclear Grade: 2
Mitotic Score: 1
Modified Scarff Bloom Richardson Grade: 2
Necrosis: Absent
Vascular/Lymphatic Invasion: Present
Extent: Focal
Lobular neoplasia: None
Lymph nodes: Sentinel lymph node and axillary dissection
Lymph node status: Positive 1 / 16
Micrometastases: Yes
Non-neoplastic areas: columnar cell change with flat epithelial atypia

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DCIS present
Margins involved by DCIS: anterior
DCIS Quantity: Estimate 75%
DCIS Type: Solid
Cribriform
Micropapillary
DCIS Location: Both associated and separate from invasive tumor mass
Nuclear grade: High
Necrosis: Present
Location of CA++: DCIS

ER/PR/HER2 Results
ER: Positive
PR: Positive
HER2: by FISH

Pathological staging (pTN): pT 1c N 1mi

SYNOPTIC REPORT - BREAST HER-2 RESULTS
Specimen: Surgical Excision
Block Number: D2

Interpretation: EQUIVOCAL
Intensity: 2+
% Tumor Staining: 10%
Fish Ordered: Yes , on Date

METHODOLOGY:

Tissue was fixed in 10% neutral buffered formalin for no less than 8 and no longer than 24 hours. Her2 analysis was performed using the FDA approved Dako HercepTest (TM) test kit (, using rabbit anti-human HER2. This assay was not modified. External kit-slides provided by the 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. Adequate, well preserved, clear-cut invasive carcinoma was identified for HER2 evaluation. Interpretation of the HER2 immunohistochemical stain is guided by published results in the medical literature, information provided by the reagent manufacturer and by internal review of staining performance.

This assay has been validated according to the 2007 joint recommendations and guidelines from ASCO and CAP and from the NCCN HER2 testing in Breast Cancer Task Force. The Pathology Department takes full responsibility for this test's performance.

CLINICAL HISTORY:

-year-old female with abnormal screening mammogram of right breast at right upper outer quadrant. Needle biopsy showed invasive ductal carcinoma. Patient then had MRI which showed enhancement of

upper outer quadrant and upper inner quadrant; anteriorly there was enhancement 2 cm from clip and close to nipple. PET, CT and bone scan show no evidence of metastatic disease. Invasive ductal carcinoma SBR grade 2, ER positive, PR positive, Her2/neu negative. Tumor size 0.4 cm, also with high grade DCIS solid and cribriform with necrosis and extension to lobules.

PRE-OPERATIVE DIAGNOSIS:

Right Breast Cancer

ADDENDUM:

PathVysion HER-2 DNA Probe Kit

Case No

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 2 chromosome 17 signals and 2 HER-2 signals, with a HER-2/CEP 17 Ratio </=2.0, consistent with no amplification of the HER2/neu gene.

Block used A1 Source of case: RPCI

Tissue fixation formalin-fixed tissue Outside Case No: NA

Tissue source breast Results interpreted: yes

HER2/CEP17 ratio: 1.05

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.

ONCOTYPE DX BREAST CANCER ASSAY

RESULTS: Recurrence Score: 16

CLINICAL EXPERIENCE: Patients with a recurrence score of: 16 in the clinical validation study had an average rate of Distant Recurrence at 10 years of 10%

ER Score: 10.1 Positive

PR Score: 7.7 Positive

Her2 Score: 9.8 Negative

Interpretation:

ER Negative < 6.5 Positive >= 6.5

PR Negative < 5.5 Positive >= 5.5

Her2 Negative <10.7 Positive >=11.5 Equivocal = 10.7 - 11.4

See separate report for further information.

Test performed at:

Inc.

Gross Dictation:., Pathologist,
Microscopic/Diagnostic Dictation:, M.D., Pathologist,
Final Review: M.D., Pathologist,
Final Review:, M.D., Pathologist,
Final:, M.D., Pathologist,
Addendum:., Pathologist,
Addendum Final: Pathologist,
Addendum:., Pathologist,
Addendum Final:., Pathologist,

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