

TSS ID

**SPECIMENS:**

- A. SLN #1 RIGHT AXILLA
- B. RIGHT BREAST
- C. ADDITIONAL ANTERIOR MARGIN

ICD-0-3

*Carcinoma, infiltrating ductal, NOS 8500/3*  
*Site: breast, NOS C50.9 2/8/11*  
*hr*

**SPECIMEN(S):**

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**INTRAOPERATIVE CONSULTATION DIAGNOSIS:**

TPA, Lymph node, sentinel, right axilla, biopsy: Negative for carcinoma  
Part B, Right breast, Gross examination: Tumor is present at the anterior margin, and at least 0.2-cm from posterior margin  
Diagnoses called at (A) and (B) by Dr.

**GROSS DESCRIPTION:**

**A. SLN #1 RIGHT AXILLA**

Received fresh labeled with the patient's patient and designated "sentinel lymph node number one right axilla" is a fragment of lymphoid tissue measuring 1.9 x 1.2 x 0.8 cm. Touch preparation is performed. Entirely submitted, A1.

**B. RIGHT BREAST**

Received fresh labeled with the patient's identification and designated "right breast" is a previously inked, oriented, 13-g, 4 x 2.5 x 1.5 cm lumpectomy specimen. The short suture designates superior, long-lateral. Ink code: Anterior-yellow, posterior-black, medial-green, lateral-red, superior-blue, inferior-orange. The specimen is serially sectioned from medial to lateral into 6 slices revealing a firm tan mass, 1.2 x 0.9 x 0.7 cm, located 0.1-cm from the nearest anterior margin. A portion of the specimen is submitted for tissue procurement. The remainder of the specimen is entirely submitted:

B1-B2: Perpendicular sections medial margin

B3-B4: Slice 2, B4 demonstrates mass

B5-B6: Slice 3, B6 demonstrates mass

B7-B8: Slice 4, B8 demonstrates mass

B9-B10: Slice 5, B10 demonstrating remainder of mass

B11-B12: Perpendicular sections lateral margin

**C. ADDITIONAL ANTERIOR MARGIN**

Received fresh labeled with the patient's identification and designated "additional anterior margin" are two previously inked (black at final margin) fragments of adipose tissue together weighing 1 g and measuring 2 x 1 x 0.3 cm in aggregate. The entire specimen is submitted, C1.

**DIAGNOSIS:**

**A. LYMPH NODE, SENTINEL #1, RIGHT AXILLA, EXCISION:**  
- ONE LYMPH NODE, NEGATIVE FOR METASTASES (0/1).

**B. BREAST, RIGHT, WIDE LOCAL EXCISION:**

- INVASIVE DUCTAL CARCINOMA, SBR GRADE 3 WITH FOCAL NECROSIS, MEASURING 1.2-CM
- HIGH NUCLEAR GRADE, DUCTAL CARCINOMA IN SITU, SOLID AND CRIBRIFORM TYPES WITH CENTRAL NECROSIS, MICROCALCIFICATIONS, AND LOBULAR EXTENSION
- INVASIVE TUMOR INVOLVES ANTERIOR SURGICAL RESECTION MARGIN (SEE PART C)
- BIOPSY SITE CHANGES WITH FIBROSIS
- SEE SYNOPTIC REPORT.

**C. BREAST, ADDITIONAL ANTERIOR MARGIN, EXCISION:**  
- FATTY BREAST TISSUE, NO TUMOR SEEN.

**SYNOPTIC REPORT - BREAST**

Specimen Type: Excision

Needle Localization: No

Laterality: Right

Invasive Tumor: Present

Multifocality: No

WHO CLASSIFICATION

Invasive ductal carcinoma, NOS 8500/3

Tumor size: 1.2cm

Margins: Negative

Distance from closest margin: 0.3cm  
inferior

Tubular Score: 3

Nuclear Grade: 2

Mitotic Score: 3

Modified Scarff Bloom Richardson Grade: 3

Necrosis: Present

Vascular/Lymphatic Invasion: None identified

Lobular neoplasia: None

Lymph nodes: Sentinel lymph node only

Lymph node status: Negative 0 / 1

DCIS present

Margins uninvolved by DCIS

DCIS Quantity: Estimate 10%

DCIS Type: Solid

Cribriform

DCIS Location: Associated with invasive tumor

Nuclear grade: High

Necrosis: Present

Location of CA++: DCIS

Benign epithelium

ER/PR/HER2 Results

ER: Positive

PR: Positive

HER2: Pending

Performed on Case:

Pathological staging (pTN): pT 1c N 0

Pathological staging is based on the AJCC Cancer Staging Manual, 7th Edition

#### CLINICAL HISTORY:

None given

#### PRE-OPERATIVE DIAGNOSIS:

None given

#### ADDENDUM:

SYNOPTIC REPORT - BREAST HER-2 RESULTS

Specimen: Surgical Excision

Block Number:

Interpretation: EQUIVOCAL

Intensity: 2+

% Tumor Staining: 30%

Fish Ordered: Yes

#### 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. Pathology Department takes full responsibility for this test's performance.  
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 F

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  $\leq 2.0$ , consistent with no amplification of the HER2/neu gene.

Block used Source of case:  
Tissue fixation formalin-fixed tissue Outside Case No: NA  
Tissue source breast Results interpreted: yes

HER2/CEP17 ratio: 1.1

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 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: 18

CLINICAL EXPERIENCE: Patients with a recurrence score of: 18 in the clinical validation study  
had an average rate of Distant Recurrence at 10 years of 11%

ER Score: 10.2 Positive

PR Score: 9.2 Positive

Her2 Score: 9.9 Negative

Interpretation:

ER Negative < 6.5 Positive  $\geq 6.5$

PR Negative < 5.5 Positive  $\geq 5.5$

Her2 Negative < 10.7 Positive  $\geq 11.5$  Equivocal = 10.7 - 11.4

Gross Dictation:

Microscopic/Diagnostic Dictation:

Final Review: M.D., Pathologist

Final: M.D., Pathologist,

Addendum: M.D., Pathologist,

Addendum Final: M.D., Pathologist, (

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Addendum Final, M.D., Pathologist,

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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:	