SPECIMEN(S): A. SLN #1 RIGHT AXILLA
B. LEFT BREAST TISSUE BIOPSY WITH NEEDLE LOCALIZATION
C. RIGHT BREAST TISSUE BIOPSY WITH NEEDLE LOCALIZATION
D. ADDITIONAL MEDIAL SUPERIOR MARGIN RIGHT BREAST
E. RIGHT AXILLARY CONTENTS

ICD-O-3
Carcinoma, infiltrating duct, NOS 8500/3
Site: breast, NOS C50.9 MW 12/3/12

CLINICAL HISTORY:
None Given

PRE-OPERATIVE DIAGNOSIS:
Right breast cancer- left breast atypia.

INTRAOPERATIVE CONSULTATION:
TPA: SLN #1 right axilla- Positive for carcinoma. Diagnosis called to Dr. at by Dr.

DIAGNOSIS:
A. LYMPH NODE, SENTINEL #1, RIGHT AXILLA, EXCISION:
- METASTATIC CARCINOMA TO ONE OF ONE LYMPH NODE (1/1), MEASURING 0.3-CM WITH NO EXTRANODAL EXTENSION.

B. BREAST, LEFT, WIDE LOCAL EXCISION:
- FOCAL FIBROADENOMATOID CHANGES WITH COARSE CALCIFICATIONS
- BIOPSY SITE CHANGES WITH FIBROSIS, GRANULATION TISSUE, FOREIGN BODY GIANT CELL REACTION AND FAT NECROSIS, NO TUMOR SEEN.

C. BREAST, RIGHT, WIDE LOCAL EXCISION:
- INVASIVE DUCTAL CARCINOMA WITH PAPILLARY AND FOCAL MUCINOUS FEATURES, SBR GRADE 2, MEASURING 3-CM
- HIGH NUCLEAR GRADE, DUCTAL CARCINOMA IN SITU, SOLID, MICROPAPILLARY, PAPILLARY AND CRIBRIFORM TYPES WITH CENTRAL NECROSIS AND MICROCALCIFICATIONS
- SURGICAL RESECTION MARGINS NEGATIVE FOR TUMOR
- BIOPSY SITE CHANGES WITH FIBROSIS, GRANULATION TISSUE, FOREIGN BODY GIANT CELL REACTION AND FAT NECROSIS
- SEE SYNOPTIC REPORT AND SEE NOTE.

D. BREAST, RIGHT, ADDITIONAL MEDIAL SUPERIOR MARGIN, EXCISION:
- BREAST TISSUE NO TUMOR SEEN.

E. LYMPH NODES, RIGHT, AXILLARY DISSECTION:

- FIFTEEN LYMPH NODES, NEGATIVE FOR METASTASES (0/15).

NOTE: Invasive ductal carcinoma is identified in 5 consecutive slices from lateral to medial, measuring about 3.0 CM.

HER-2/neu test by FISH is ordered, since the core needle biopsy results were equivocal.

SUMMARY OF IMMUNOHISTOCHEMISTRY/SPECIAL STAINS

Material: Block A1
Population: Lymph Node

Stain/Marker:	Result:	Comment:
CYTOKERATIN AE1/3	Positive	
CYTOKERATIN 7	Negative	
S-100	Negative	
ESTROGEN RECEPTOR	Positive	

Material: Block C7
Population: Tumor Cells

Stain/Marker:	Result:	Comment:
CYTOKERATIN AE1/3	Positive	
CYTOKERATIN 7	Negative	
S-100	Negative	
ESTROGEN RECEPTOR	Positive	

Material: Block C12
Population: Tumor Cells

Stain/Marker:	Result:	Comment:
P63	Negative	
CALP	Negative	
SMOOTH MUSCLE MYOSIN	Negative	

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 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 hey 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/or negative controls.

SYNOPTIC REPORT - BREAST

Specimens Involved

Specimens: A: SLN #1 RIGHT AXILLA
C: RIGHT BREAST TISSUE BIOPSY WITH NEEDLE LOCALIZATION
D: ADDITIONAL MEDIAL SUPERIOR MARGIN RIGHT BREAST
E: RIGHT AXILLARY CONTENTS

Specimen Type: Excision
Needle Localization: Yes
Laterality: Right
Invasive Tumor: Present
Multifocality: No

WHO CLASSIFICATION

Invasive ductal carcinoma, NOS 8500/3
Tumor size: 3cm
Margins: Negative
Distance from closest margin: 0.4cm
anterior
Tubular Score: 2
Nuclear Grade: 3
Mitotic Score: 3
Modified Scarff Bloom Richardson Grade: 2
Necrosis: Absent
Vascular/Lymphatic Invasion: None identified
Lobular neoplasia: None
Lymph nodes: Sentinel lymph node
Axillary dissection
Lymph node status: Positive 1 / 16
Micrometastases: No

DCIS present
Margins uninvolved by DCIS
DCIS Quantity: Estimate 10%
DCIS Type: Cribriform
Micropapillary
Papillary
DCIS Location: Associated with invasive tumor
Nuclear grade: High
Necrosis: Present
Location of CA++: DCIS

ER/PR/HER2 Results

ER: Positive
PR: Positive
HER2: Pending by FISH
Performed on Case: ER/PR on case. HER2 by FISH pending on the current case

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Pathological staging (pTN): pT 2 N 1a
Pathological staging is based on the AJCC Cancer Staging Manual, 7th Edition

GROSS DESCRIPTION:

A. SLN #1 RIGHT AXILLA

Received fresh labeled with the patient's identification and 'SLN #1 right axilla' is a tan pink lymph node 1.7 x 0.9 x 0.7cm. The specimen is serially sectioned. A touch prep is taken. Toto A1.

B. LEFT BREAST TISSUE BIOPSY WITH NEEDLE LOCALIZATION

Received in formalin labeled with the patient's identification and 'left breast tissue biopsy with needle localization' are two oriented, previously inked lumpectomy specimens 59g and 53g each – when placed back together by the surgeon, measuring 11.5 x 8 x 4.5cm. Ink code- anterior-yellow, posterior-black, superior-blue, inferior-orange, medial-green, lateral-red. Specimen is serially sectioned in to 15 slices revealing a 0.6 x 0.5 x 0.5cm previous biopsy site with surrounding necrosis, at the anterior margin in slices 4-5-6. The specimen is radiographed and areas of concern are marked by the radiologist. A biopsy clip is identified in slice 5. Representatively submitted:

B1-B2: medial margin slice 1
B3: anterior margin slice 2
B4: anterior margin slice 3
B5: bx site with anterior margin slice 4
B6: inferior margin slice 4
B7: bx site with anterior margin and clip ID slice 5
B8: superior margin slice 5
B9: posterior margin slice 5
B10: inferior margin slice 5
B11: bx site with anterior margin slice 6
B12: superior-posterior margin marked by the radiologist slice 14
B13-B14: inferior margin slice 14
B15: lateral margin marked by the radiologist slice 15

C. RIGHT BREAST TISSUE BIOPSY WITH NEEDLE LOCALIZATION

Received in formalin labeled with the patient's identification and 'right breast tissue biopsy with needle localization' is an oriented, previously inked 201g, 15.2 x 11 x 3.4cm needle localized lumpectomy with two radiographs. Ink code- anterior-yellow, posterior-black, superior-blue, inferior-orange, medial-green, lateral-red. Specimen is serially sectioned in to 11 slices revealing a tan white gelatinous lobulated mass 5.3 x 4 x 2.8cm, 0.1cm from the closest anterior and posterior margins in slices 2-3-4-5-6-7 and 8. A portion of the specimen is submitted for tissue procurement. Representatively submitted:

C1: lateral margin slice 1
C2: mass with anterior margin slice 2
C3: mass with anterior margin slice 3
C4-C5: mass with anterior margin slice 4
C6-C8: mass with anterior margin slice 5
C9: superior margin slice 5
C10-C11: mass with posterior margin slice 6
C12: mass with posterior margin slice 7
C13: anterior – inferior margins slice 7
C14: mass slice 8
C15: inferior margin slice 9

C16: posterior margin slice 10
C17: medial margin slice 11
D. ADDITIONAL MEDIAL SUPERIOR MARGIN RIGHT BREAST
Received in formalin labeled with the patient's identification and 'additional medial superior margin right breast' is an oriented 37g, 7 x 7 x 3cm fibrofatty tissue. Final margin inked blue. Serial sectioning reveals unremarkable parenchyma. Representatively submitted in D1-D6.
E. RIGHT AXILLARY CONTENTS
Received in formalin labeled with the patient's identification and 'right axillary contents' are multiple tan pink fragments of fibrofatty tissue aggregating to 15 x 8 x 3.5cm. Dissection reveals sixteen lymph nodes ranging from 3.5 x 2.4 x 1.6cm to 0.2 x 0.2 x 0.2cm.
E1: five lymph nodes
E2: five lymph nodes
E3: two lymph nodes
E4: one lymph node
E5-E6: one lymph node
E7-E8: one lymph node
E9-E10: one lymph node

ADDENDUM:

FISH/ISH ANALYSIS REPORT 3

Specimens Involved

Specimens: C: RIGHT BREAST TISSUE BIOPSY WITH NEEDLE LOCALIZATION

HER2/NEU RESULTS

ANALYTICAL INTERPRETATION OF RESULTS
HER-2 NOT AMPLIFIED

Clinical interpretation of the results
A majority of tumors cells displayed moderate polysomy 17 with 2 to 3 chromosome 17 centromere signals and 2 to 4 HER2 signals, with a HER2/CEP 17 Ratio 1.5, consistent with no amplification of the HER2/neu gene.

Probes identification
LSI Her-2/neu 17q11.2-12, spectrumorange
CEP 17, 17 p11.1-q11.1 alpha satellite DNA, spectrumgreen

Image analysis method - Manual

Results interpreted
Yes

ISCN
nuc ish: (CEP17x2),(HER2x3)[200]

Number of invasive tumor cells counted
200

Number of observers
1

Number of Her2 signals/nucleus
3.2

Number of CEP 17 signals/nucleus
2.2

Her2/CEP 17 ratio
1.5

TEST CHARACTERISTICS: 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 Pathology Core Facility, Department of Pathology, under the direction of Dr.. The results of these studies should always be interpreted in the context of the clinical, morphological, and immunophenotypic diagnosis. The 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.

Specimen information

RPCI surgical pathology/cytology case number

Source of case
RPCI

Block number used C7

Specimen site
Breast

Female breast right

Specimen type

Complete excision (less total mastectomy)

Specimen fixative type

Formalin

Duration of fixation (hrs)

6 - 48 hrs

Comment:

Controls: The FISH study was performed with appropriately stained positive and negative controls.

ADDENDUM:

ONCOTYPE DX BREAST CANCER ASSAY

RESULTS: Recurrence Score: 27

CLINICAL EXPERIENCE: Patients with a recurrence score of: 27 in the clinical validation study had an average rate of Distant Recurrence at 10 years of 18%

ER Score: 12 Positive
PR Score: 6.7 Positive
Her2 Score: 9.1 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.

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:		

12/13/12

L biopsy report

left breast bx

SPECIMENS:
A. LEFT BREAST CENTRAL CORE BIOPSY
B. RIGHT BREAST SUBAREOLAR CORE BIOPSY

SPECIMEN(S):
A. LEFT BREAST CENTRAL CORE BIOPSY
B. RIGHT BREAST SUBAREOLAR CORE BIOPSY

DIAGNOSIS:
A. BREAST, LEFT, CENTRAL, BIOPSY:
- MINUTE FRAGMENTS OF ATYPICAL CELLS WITH NECROSIS
- STROMAL CALCIFICATIONS, SEE NOTE.

NOTE: Scattered minute fragments of crushed cells with necrosis are identified. They may represent contents of DCIS. Multiple levels are examined. Excisional biopsy is recommended.

B. BREAST, RIGHT, SUBAREOLAR, BIOPSY:
- INVASIVE DUCTAL CARCINOMA, SBR GRADE 2, SEE NOTE.

NOTE: Maximum invasive tumor size measures 0.8-cm. This measurement may not reflect the actual size of the tumor.

Breast biomarkers are ordered.

GROSS DESCRIPTION:
A. LEFT BREAST CENTRAL CORE BIOPSY
Received in formalin labeled with the patient's identification and 'left breast central core biopsy' are multiple tan vellow cores of tissue ranging from 4.3 x 0.2cm to 0.5 x 0.2cm. Toto A1-A2. Time placed in formalin-
B. RIGHT BREAST SUBAREOLAR CORE BIOPSY
Received in formalin labeled with the patient's identification and 'right breast subareolar core biopsy' are four tan yellow cores of tissue ranging from 1.1 x 0.1cm to 0.5 x 0.1cm. Toto B1. Time placed in formalin-

CLINICAL HISTORY:
A) Suspicious calcification in central left breast. B) New mass - highly suspicious for cancer.

PRE-OPERATIVE DIAGNOSIS:
A) Rule out DCIS

ADDENDUM:
SYNOPTIC REPORT - BREAST, ER/PR RESULTS
Specimen: Breast Core Needle Biopsy
Block Number:

ER: Positive Allred Score: 8 = Proportion Score 5 + Intensity Score 3
PR: Positive Allred Score: 5 = Proportion Score 2 + 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.
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:
Tissue was fixed in 10% neutral buffered formalin for no less than 8 and no longer than 24 hours. Immunohistochemistry was performed using the mouse anti-human ER (ER 1D5, 1:100) and PR (PGR 136, 1:100) provided by ollowing the manufacturer s instructions. This assay was not modified. Interpretation of the ER/PR immunohistochemical stain is guided by published results in the medical literature, information provided by the reagent manufacturer and by internal review of staining performance.

SYNOPTIC REPORT - BREAST HER-2 RESULTS
Specimen: Breast Core Needle Biopsy
Block Number:

Interpretation: EQUIVOCAL
Intensity: 2+
% Tumor Staining: 10%
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 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 joint recommendations and guidelines from ASCO and CAP and from the NCCN HER2 testing in Breast Cancer Task Force. The athology Department takes full responsibility for this test's performance.
FISH/ISH ANALYSIS REPORT 3
Specimens Involved
Specimens: B: RIGHT BREAST SUBAREOLAR CORE BIOPSY

HER2/NEU RESULTS

ANALYTICAL INTERPRETATION OF RESULTS
INDETERMINATE (EQUIVOCAL) FOR HER-2 AMPLIFICATION

Clinical interpretation of the results
A majority of tumors cells displayed 2 to CEP17 signals and 4 to 5 HER-2 signals, with a HER-2/CEP 17 Ratio of 2. A HER-2/CEP 17 Ratio of >2.2 is generally considered amplification, while a ratio of 1.8 to <2.2 is generally considered indeterminate. This specimen is a biopsy and recommendation is to repeat HER2 FISH test on resection specimen.
Probes identification
SI Her-2/neu 17q11.2-12, spectrumorange
CEP 17, 17 p11.1-q11.1 alpha satellite DNA, spectrumgreen
Image analysis method - Manual
Results interpreted
Yes
Number of invasive tumor cells counted
100
Number of observers
1
Number of Her2 signals/nucleus
4.0
Number of CEP 17 signals/nucleus
2.0
Her2/CEP 17 ratio
2.0
TEST CHARACTERISTICS: 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 Pathology

Core Facility, Department of Pathology, ... under the direction of Dr.. The results of these studies should always be interpreted in the context of the clinical, morphological, and immunophenotypic diagnosis.

The 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.

Specimen information

Block number used

Comment:

Controls: The FISH study was performed with appropriately stained positive and negative controls.