SPECIMENS:

A. RIGHT BREAST LESION

- B. ADDITIONAL POSTERIOR MARGIN
- C. LEFT BREAST CANCER
- Carcinoma, infiltrating ductal, NOS 8500/3 Site: breast, NOS C50.9 2/8/11 D. ADDITIONAL POSTERIOR -LATERAL MARGIN
- E. SENTINEL L.N. LEFT AXILLA #1
- F. SENTINEL L.N. LEFT AXILLA #2
- G. SENTINEL L.N. LEFT AXILLA #3
- H. SENTINEL L.N. LEFT AXILLA #4
- I. SENTINEL L.N. LEFT AXILLA #5
- J. ADDITIONAL INFERIOR MARGIN
- K. ADDITIONAL POSTERIOR MARGIN

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- K. ADDITIONAL POSTERIOR MARGIN

INTRAOPERATIVE CONSULTATION DIAGNOSIS:

A. Right breast: An ill-defined firm area about 0.3cm from posterior margin, additional margin B received (gross only).

101-0-3

C. Left breast: $1.7 \times 1.5 \times 1.3$ cm nodule located 0.1-cm from posterior and inferior junction.

. Sentinel lymph nodes, left axilla, #1-5: Lymph nodes, negative for tumor on touch preparation. Diagnoses called to Dr. at i. (A). (C) .. (E-I) by Dr..

GROSS DESCRIPTION:

A. RIGHT BREAST LESION

Received fresh labeled with matching patient identifiers is an oriented (single-anterior, double-lateral, triple-superior) 20g, 5.2 x 4.9 x 1.6 cm lumpectomy with 1.4 x 0.3 cm skin ellipse accompanied by mammograms. The specimen is inked as follows: Anterior-blue, posterior-black, superior-red, inferiororange, medial-green, lateral-yellow. The specimen is serially sectioned from medial to lateral into 5 slices revealing a 1 x 0.5 x 0.5 cm ill-defined firm hemorrhagic area approaching the closest posterior margin at 0.3cm. The entire specimen is submitted for microscopic evaluation: A1: Medial margin

A2-A3: Section 2 entirely submitted

A4-A6: Section 3, A6 demonstrates ill-defined firm area

A7-A9: Section 4 entirely submitted

A10-A13: Lateral margin

B. ADDITIONAL POSTERIOR MARGIN

Received in formalin in a container labeled with matching patient identifiers is a 2.6 x 2.4 x 1.1cm breast tissue with orientation, the suture designating the final posterior margin. This area is inked black. The specimen is serially sectioned and submitted entirely in cassettes B1-B4. C. LEFT BREAST

Received fresh labeled with matching patient identifiers is an oriented (single-anterior, double-lateral, triple-superior, quadruple-posterior) 94g, 9.6 (anterior to posterior) x 7.5 x 4.4 cm lumpectomy. The specimen is inked as follows: Anterior-blue, posterior-black, superior-red, inferior-orange, medial-green, lateral-yellow. The specimen is serially sectioned from anterior to posterior into 7 slices revealing a 1.7 x 1.5 x 1.3 cm firm tan circumscribed round mass closest to the posterior/inferior margin at 0.1cm. A second possible 0.5 x 0.3 x 0.3 cm nodule is palpated 0.5cm from the main mass that approaches the posterior margin at 0.2cm. A portion of the specimen is submitted for tissue procurement. Representatively submitted as follows:

C1: Representative sections anterior margin, slice 1

C2: Representative section, slice 2 superior

C3-C4: Representative sections, slice 3, lateral and inferior

UUID:4F2A288E-8162-4579-BCD2-0FF31B0EEB3C TCGA-E2-A1II-01A-PR Redacted C5-C6: Representative sections, slice 4, medial and inferior

C7-C13: Slice 5 entirely submitted, C10-C11, mass, C12-C13, possible nodule

C14-C19: Slice 6 entirely submitted, C14-C17, mass (procured), C18-C19 posterior

C20-C21: Posterior margin submitted entirely, slice 7

D. ADDITIONAL POSTĚRIOR LATERAL MÁRGIN

Received in formalin in a container labeled with matching patient identifiers is a 4.2 x 2.7 x 1.6 cm breast tissue with orientation, the suture designates the final posterior lateral margin. This area is inked black. The specimen is serially sectioned and submitted entirely in D1-D6.

E. SENTINEL LYMPH NODE LEFT AXILLA #1

Received fresh labeled with matching patient identifiers is a fragment of adipose tissue measuring 2.5 x 2.4 x 0.5 cm. A possible lymph node is identified measuring 1.2 x 0.5 x 0.5 cm. Touch preparation is performed. The lymph node is submitted entirely in cassette E1.

F. SENTINEL LYMPH NODE LEFT AXILLA #2

Received fresh labeled with matching patient identifiers is a fragment of adipose tissue measuring 3.3 x 2.5 x 0.7 cm. A possible lymph node is identified measuring 1.3 x 0.5 x 0.5 cm. Touch preparation is performed. The lymph node is submitted entirely in cassette F1.

G. SENTINEL LYMPH NODE LEFT AXILLA #3

Received fresh labeled with matching patient identifiers is a fragment of adipose tissue measuring 2.9 x 2.5 x 0.4 cm. A possible lymph node is identified measuring 0.5 x 0.5 x 0.5 cm. Touch preparation is performed. The entire specimen is submitted in cassettes G1-G2.

H. SENTINEL LYMPH NODE LEFT AXILLA #4

Received fresh labeled with matching patient identifiers is a portion of tan-yellow possible lymphoid tissue measuring 0.9 x 0.5 x 0.5 cm. The specimen is bisected. Touch preparation is performed. The entire specimen is submitted in cassette H1.

I. SENTINEL LYMPH NODE LEFT AXILLA #5

Received fresh labeled with matching patient identifiers is a portion of tan-yellow possible lymphoid tissue measuring 1.6 x 1 x 0.3 cm. The specimen is bisected. Touch preparation is performed. The entire specimen is submitted in cassette I1.

J. ADDITIONAL INFERIOR MARGIN

Received in formalin in a container labeled with matching patient identifiers is a portion of resected breast tissue measuring 3.2 x 2.6 x 0.6 cm. The specimen is received with orientation, the suture designates the final inferior margin. This area is inked black. The specimen is serially sectioned and submitted entirely in cassettes J1-J3.

K. ADDITIONAL POSTERIOR MARGIN

Received in formalin in a container labeled with matching patient identifiers is a portion of resected breast tissue measuring 4.1 x 1.9 x 0.8 cm. The specimen is received with orientation, the suture designates the final posterior margin. This area is inked black. The specimen is serially sectioned and submitted entirely in cassettes K1-K3.

RESULTS:

SUMMARY OF IMMUNOHISTOCHEMISTRY/SPECIAL STAINS

Material: Block

Population: Tumor Cells

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

Material: Block E1 Population: Tumor Cells

Stain/Marker:Result: Comment:

Negative CYTOKERATIN AE1/3

Material: Block F1 Population: Tumor Cells

Stain/Marker:Result: Comment:

CYTOKERATIN AE1/3

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

it. They have not been cleared or approved by the U.S. Food and Drug Administration. In PDA 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. BREAST, RIGHT, NEEDLE LOCALIZED WIDE LOCAL EXCISION:
 - FOCAL ATYPICAL DUCTAL HYPERPLASIA.
 - FOCAL HEMORRHAGE, COLUMNAR CELL CHANGE, AND INTRADUCTAL MICROCALCIFICATIONS.
 - BENIGN SKIN.
- B. BREAST, RIGHT, ADDITIONAL POSTERIOR MARGIN, EXCISION:
 - BREAST TISSUE WITH FOCAL HEMORRHAGE AND USUAL DUCTAL HYPERPLASIA.
- C. BREAST, LEFT, NEEDLE LOCALIZED WIDE LOCAL EXCISION:
 - INVASIVE DUCTAL CARCINOMA, POORLY DIFFERENTIATED (SBR GRADE 3), WITH MARKED LYMPHOCYTIC INFILTRATE.
 - TUMOR MEASURES 1.7 CM IN GREATEST DIMENSION.
 - TUMOR IS WITHIN 1 MM OF THE POSTERIOR AND INFERIOR MARGINS (SEE NOTE).

NOTE: The final posterior and inferior margins are negative for tumor (see specimens J and K).

- D. BREAST, LEFT, ADDITIONAL POSTERIOR-LATERAL MARGIN, EXCISION: BREAST TISSUE, NEGATIVE FOR CARCINOMA.
- E. SENTINEL LYMPH NODE #1, LEFT AXILLA, BIOPSY:
 - ONE LYMPH NODE, NEGATIVE FOR CARCINOMA (0/1) (SEE NOTE).
- F. SENTINEL LYMPH NODE #2, LEFT AXILLA, BIOPSY:
 - ONE LYMPH NODE, NEGATIVE FOR CARCINOMA (0/1) (SEE NOTE).

NOTE FOR E AND F: Cytokeratin AE1/3 stains were performed and are negative showing no evidence of metastases.

- G. SENTINEL LYMPH NODE #3, LEFT AXILLA, BIOPSY:
 - ONE LYMPH NODE, NEGATIVE FOR CARCINOMA (0/1).
- H. SENTINEL LYMPH NODE #4, LEFT AXILLA, BIOPSY:
 - ONE LYMPH NODE, NEGATIVE FOR CARCINOMA (0/1).
- I. SENTINEL LYMPH NODE #5, LEFT AXILLA, BIOPSY:
 - ONE LYMPH NODE, NEGATIVE FOR CARCINOMA (0/1).
- J. BREAST, LEFT, ADDITIONAL INFERIOR MARGIN, EXCISION:
 - BREAST TISSUE WITH USUAL DUCTAL HYPERPLASIA,

NEGATIVE FOR CARCINOMA.

K. BREAST, LEFT, ADDITIONIAL POSTERIOR MARGIN, EXCISION: - BREAST TISSUE WITH USUAL DUCTAL HYPERPLASIA, NEGATIVE FOR CARCINOMA.

SYNOPTIC REPORT - BREAST Excision Specimen Type: Needle Localization: Yes - For mass

Laterality: Left

Present Invasive Tumor:

Multifocality: No

WHO CLASSIFICATION

Invasive ductal carcinoma, NOS 8500/3

Tumor size: 1.7cm Tumor Site: 3:00 Negative Margins: Tubular Score: 3 Nuclear Grade: Mitotic Score: 2

3 Modified Scarff Bloom Richardson Grade:

Absent Necrosis:

Vascular/Lymphatic Invasion: None identified

Lobular neoplasia:

None Lymph nodes:

Sentinel lymph node only

Lymph node status: Negative 0/5

DCIS not present

ER/PR/HER2 Results

ER: Negative PR: Positive

HER2: Negative by IHC

pT 1c N 0 Pathological staging (pTN):

SYNOPTIC REPORT - BREAST, ER/PR RESULTS

Specimen: Surgical Excision

Block Number:

Allred Score: 0 = Proportion Score 0 + Intensity Score 0 ER: Negative Allred Score: 4 = Proportion Score 2 + Intensity Score 2 PR: Negative

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 following 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: Surgical Excision

Block Number:

Interpretation: **NEGATIVE**

Intensity:

% Tumor Staining: 5% Fish Ordered: No

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 inhouse 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.

CLINICAL HISTORY:

Lesion on core biopsy, right breast; Left breast carcinoma.

PRE-OPERATIVE DIAGNOSIS:

Breast carcinoma

ADDENDUM:

ONCOTYPE DX BREAST CANCER ASSAY

RESULTS: Recurrence Score: 52

CLINICAL EXPERIENCE: Patients with a recurrence score of:

had an average rate of Distant Recurrence at 10 years of 34%

52 in the clinical validation study

ER Score: 3.7 Negative PR Score: 3.3 Negative Her2 Score: 7.6 Negative

Interpretation:

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

Gross Dictation: , M.D., Pathologist,

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

Final Review: , M.D., Pathologist,

Final: , M.D., Pathologist, Addendum: , M.D., Pathologist, Addendum Final: , M.D., Pathologist

_ Criteria	1	,
Diagnosis Discrepancy	Yes	No
Primar / Tumor Site Discrepages	-	1
nir AA Discrepancy		
Prior Malignancy History		
Dual/Synchronous Primary Nated		Z
Case is (circle): QUALIFIED / DISQUA	LikiEP.	
Dale Revie wed:	31:	
W		