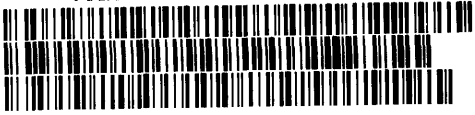

MRN:
Patient: **Sex/DOB:** Female
Admission Date: **Discharge Date:**
Ordering Physician:

Pathology Addendum Report

Collected Date/Time: **Accession Number:**
Received Date/Time:

Addendum Report
ASSAY PERFORMED: HER2 GENE AMPLIFICATION BY DUAL IN SITU HYBRIDIZATION USING THE HER2 Dual ISH DNA PROBE COCKTAIL

ICD-O-3
Carcinoma, infiltrating duct NOS 8500/3
Site ® breast NOS C 50.9
path
® breast, upper outer quadrant C50.4
JW 8/2/13

Number of nuclei scored:	20
Total HER2 signals:	60
Total CHR 17 signals:	39
HER2/CHR 17 ratio:	1.5

INTERPRETATION: - NEGATIVE FOR HER2 GENE AMPLIFICATION.

NOTE: THE ASSAY WAS PERFORMED AS A REFLEX TEST AFTER THE HER2/NEU IMMUNOSTAIN WAS 2+.

SPECIMEN TYPE: The HER2 is performed on a formalin-fixed paraffin-embedded tissue slide from block C3.

DESCRIPTION OF THE ASSAY: The HER2 assay enables the HER2 gene and Chr17 centromere to be co-hybridized and visualized via light microscopy on the same slide. Specifically for this assay, HER2 is detected by a dinitrophenyl (DNP) labeled probe visualized utilizing SISH DNP (silver in situ hybridization) detection kit. The Chr17 centromere is targeted with a digoxigenin (DIG) labeled probe and detected using ISH DIG detection kit. Dual ISH staining results in visualization by light microscopy and which HER2 appears as discrete black signals (SISH) and Chr17 as red signals in nuclei of normal cells serving as internal positive control for staining) as well as in carcinoma cells.

SLIDE SCORING: Once an adequate target area is identified the reader records the scores for HER2 and Chr17 copy numbers that are present in 20 representative nuclei. If the resulting HER2 / Chr17 ratio falls within 1.8-2.2 (EQUIVOCAL) the reader is recommended to score an additional 20 nuclei and the resulting ratio is calculated from the total 40 nuclei. HER2 gene status is reported as non-amplified (HER2/ Chr17 < 2.0) or amplified (HER2/Chr17 ≥ 2.0).

MRN:
Patient:

Sex/DOB: Female

Pathology Addendum Report

Collected Date/Time:
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The performance characteristics of this assay were determined by
This assay has been approved by the U.S. Food and Drug Administration. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high-complexity clinical laboratory testing.

cpt: 88368 x2

(Electronic signature)
Verified:

Collected Date/Time:
Received Date/Time:

Accession Number:

Addendum Report
IMMUNOHISTOCHEMICAL EVALUATION OF ESTROGEN RECEPTORS, PROGESTERONE RECEPTORS, AND HER-2NEU IN INVASIVE MAMMARY CARCINOMA .

ESTROGEN RECEPTORS: 99 %, positive.
PROGESTERONE RECEPTORS: 40 %, positive.
STAINING INTENSITY: moderate

HER-2NEU: SCORE 2+, EQUIVOCAL.

Immunohistochemical studies were performed on formalin fixed paraffin embedded tissue (Block C3) using the following monoclonal antibodies: Estrogen receptor (Clone SP1), Progesterone receptor (Clone 1E2) and Her-2neu Clone 4B5); control sections for HER-2Neu are provided within a kit (score 0 MCF-7, score 1+ T-47D, score 2+ MDA-MB-453, score 3+ BT-474). Detection system used: polymer. Primary antibodies, reagents and control sections for HER-2neu are all provided by

All controls show appropriate reactivity.

Reactivity of Estrogen and Progesterone receptors is determined based on the percentage of positively stained nuclei of tumor cells. Reference values (CAP accreditation program checklist 2010 and guidelines on webpage):
Positive: nuclear staining in 1% or greater than 1% of invasive carcinoma cells
Negative : nuclear staining in less than 1% of invasive carcinoma cells
Staining intensity: is reported as weak, moderate or strong.

HER-2neu reactivity is reported applying the CAP scoring guidelines (CAP accreditation program checklist 2010 and guidelines on webpage):
Score 0 = Negative: No immunoreactivity, or faint weak immunoreactivity in <10% of tumor cells but only a portion of the membrane is positive..
Score 1 = Negative: Faint weak immunoreactivity in 10% or >10% of tumor cells but only a portion of the membrane is positive.
Score 2+ = Equivocal: Weak to moderate complete membrane immunoreactivity in >10% of tumor cells or

MRN:
Patient: Sex/DOB: Female

Pathology Addendum Report

Collected Date/Time: Accession Number:
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circumferential intense membrane staining in <30% of cells.
Score 3+ = Positive: More than 30% of the tumor cells must show circumferential intense and uniform membrane staining. A homogeneous (chicken wire) pattern should be present.

Equivocal results for HER-2neu (Score 2+) will be subsequently followed by a reflex dual-color ISH testing.

The performance characteristics of these antibodies were determined by the
ey 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. These tests are used for clinical purposes. They should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high-complexity clinical laboratory testing.

(Electronic signature)
Verified

Surgical Pathology Report

Collected Date/Time: Accession Number:
Received Date/Time:

Final Diagnosis
A. RIGHT BREAST, CORE BIOPSY:
- INVASIVE DUCTAL CARCINOMA.

B. RIGHT SENTINEL LYMPH NODE, BIOPSY:
- NO EVIDENCE OF CARCINOMA IN ONE LYMPH NODE.
- SEE SPECIAL STAINS SECTION.

C. RIGHT BREAST, TOTAL MASTECTOMY:
- INVASIVE DUCTAL CARCINOMA GRADE 2, 2.5 CM.
- MARGINS OF RESECTION ARE FREE OF CARCINOMA.
- SEE SYNOPTIC REPORT, SPECIAL STAINS SECTIONS AND NOTE.

NOTE: hormonal receptors and Her2-neu status will be reported in an addendum.

(Electronic signature)
Verified:

Synoptic Report
SPECIMEN:
Total breast (including nipple and skin)
PROCEDURE:
Total mastectomy (including nipple and skin)

Surgical Pathology Report

Collected Date/Time: **Accession Number:**
Received Date/Time:

LYMPH NODE SAMPLING:
Sentinel lymph node(s)
SPECIMEN INTEGRITY:
Single intact specimen (margins can be evaluated)
SPECIMEN SIZE:
Greatest dimension: 26 cm
Additional dimensions: 17 x 6 cm
SPECIMEN LATERALITY:
Right
TUMOR SITE: INVASIVE CARCINOMA:
Upper outer quadrant
TUMOR SIZE: SIZE OF LARGEST INVASIVE CARCINOMA:
Greatest dimension of largest focus of invasion over 0.1 cm: 2.5 cm
Additional dimensions: 2.0 x 2.0 cm
TUMOR FOCALITY:
Single focus of invasive carcinoma
MACROSCOPIC AND MICROSCOPIC EXTENT OF TUMOR:
Skin: Invasive carcinoma does not invade into the dermis or epidermis
DUCTAL CARCINOMA IN SITU (DCIS):
DCIS is present
Extensive intraductal component (EIC) negative
SIZE (EXTENT) OF DCIS:
Estimated size (extent) of DCIS (greatest dimension using gross and microscopic evaluation) is at least 0.3 cm (constituting about 5% of the entire tumor mass.)
ARCHITECTURAL PATTERNS:
Comedo
Cribriform
NUCLEAR GRADE:
Grade III (high)
NECROSIS:
Present, central (expansive "comedo" necrosis)
LOBULAR CARCINOMA IN SITU (LCIS):
Not identified
HISTOLOGIC TYPE OF INVASIVE CARCINOMA:
Invasive ductal carcinoma (no special type or not otherwise specified)
GLANDULAR (ACINAR)/TUBULAR DIFFERENTIATION:
Score 2: 10% to 75% of tumor area forming glandular/tubular structures
NUCLEAR PLEOMORPHISM:
Score 3: Vesicular nuclei, often with prominent nucleoli, exhibiting marked variation in size and shape, occasionally with very large and bizarre forms
MITOTIC COUNT:
Score 2
OVERALL GRADE:
Grade 2: scores of 6 or 7
MARGINS:
Margins uninvolved by invasive carcinoma

Surgical Pathology Report

Collected Date/Time: Accession Number:
Received Date/Time:

Distance from closest margin: 25 mm
Distance from posterior margin: 25 mm
Margins uninvolved by DCIS (if present)
Distance from closest margin: posterior mm
Distance from posterior margin: 25 mm
LYMPH-VASCULAR INVASION:
Present
DERMAL LYMPH-VASCULAR INVASION:
Not identified
LYMPH NODES:
Number of sentinel lymph nodes examined: 1 (no tumor seen)
Total number of lymph nodes examined (sentinel and nonsentinel): 1
METHOD OF EVALUATION OF SENTINAL LYMPH NODES:
H&E, multiple levels
Immunohistochemistry
PRIMARY TUMOR (INVASIVE CARCINOMA (pT):
pT2: Tumor >20 mm but less than or equal to 50 mm in greatest dimension
REGIONAL LYMPH NODES (pN):
pN0: No regional lymph node metastasis identified histologically
DISTANT METASTASIS (M):
Not applicable
ADDITIONAL PATHOLOGIC FINDINGS:
intraductal papilloma
MICROCALCIFICATIONS:
Present in DCIS

Source of Specimen

A Core Biopsy, RT Breast
B Lymph Nodes, Sentinel Right
C RT Total Mastectomy

Clinical Information

Palpable mass upper central FNAB positive, patient with right breast mass
PRE-OP DIAGNOSIS: Right breast cancer
POST-OP DIAGNOSIS: Same
TYPE OF PROCEDURE: Right mastectomy and sent to the node biopsy

Gross Description

Specimen is received in 3 parts:

A.The specimen is labeled "CORE BIOPSY" and is received unfixed for frozen section diagnosis. It consists of 2 cylindrical pieces of gray-tan soft tissue each measuring 1.5 cm in length and 0.1 cm diameter. Entirely submitted in cassette FSA 1.
Time specimen was removed from the patient
Time specimen was placed in formalin

Surgical Pathology Report

Collected Date/Time:
Received Date/Time:

Accession Number:

Ischemic time: 20 minutes

B. The specimen is labeled "RIGHT SENTINEL NODE" and is received unfixed for frozen section diagnosis. (Specimen is in formalin mother 6 hour and less than 48 hours). It consists of a ymph node measuring 1.6 x 1 x 0.5 cm. Sectioned and entirely submitted in cassette FSB 1.
Time specimen was removed from the patient:
Time specimen was placed in formalin :
Ischemic time: 22 minutes

C. The specimen is labeled "RIGHT TOTAL MASTECTOMY " and is received in formalin. (The specimen is in the formalin more than 6 hours and less than 48 hours). It consist of mastectomy specimen without lymph nodes weighing 990 grams and measuring 26 x 17 x 6 cm with brown skin ellipse measuring 24 x 12 cm, containing grossly unremarkable 1.5 cm in diameter nipple. The skin is tagged with a black stitch designating lateral breast. The posterior margin is composed of smooth fascia which is inked black. The breast is sliced in sagittal planes revealing a 2.5 x 2 x 2 cm an ill-defined firm area which is 2.5 cm away from the deep margin of resection. The remaining portions reveal unremarkable yellow mammary fat with streaks of white-gray mammary parenchyma. Representative sections submitted as follows:

C1 = nipple
C2-C6 = upper outer quadrant mass
C7 = upper outer quadrant, posterior margin of resection in correspondence of the mass
C8 = representative section upper inner quadrant
C9 = representative section upper outer quadrant
C10 = representative section lower outer quadrant
C11 = representative section lower inner quadreant

Time specimen was removed from the patient.
Time specimen was sectioned and placed in formalin
Ischemic time: 15 minutes

Dictated by

Intra Operative Consultation

A. Right breast cores = carcinoma
B. Right sentinel node = no tumor seen

Special Stains / Slides

Immunohistochemical studies were performed on formalin fixed, paraffin-embedded tissue (Block B1) with adequate positive and negative control sections.
Cytokeratins AE1/AE3 and Cam5.2 fail to reveal metastatic carcinoma.

The performance characteristics of these antibodies were determined by the
ey 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. These tests are used for clinical purposes. They should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high-complexity clinical laboratory testing.

16 H&E, 4 FS, 16 H&E

MRN:
Patient: **Sex/DOB:** Female

Surgical Pathology Report

Collected Date/Time: **Accession Number:**
Received Date/Time:

Tissue Code

Criteria	LW 7/10/13	Yes	No
Diagnosis Discrepancy			✓
Primary Tumor Site Discrepancy			✓
HIPAA Discrepancy			✓
Prior Malignancy History			✓
Dual/Synchronous Primary Noted			
Case is (circle):	QUALIFIED / DISQUALIFIED		
Reviewer Initials: STR	Date Reviewed: 7/10/2013		

Print Date/Time: