



Sample #

FINAL PATHOLOGIC DIAGNOSIS

A. Lymph node, right sentinel #1, excision:

- Lymph node with several micrometastases, largest measuring 0.5 mm in extent (1/1)

B. Breast, right central, partial mastectomy:

- Invasive ductal carcinoma, grade II/III with mucinous features, 1.9 cm in greatest dimension, focally involving nipple/areolar complex, surgical margins widely free (see pathologic parameters below)

- Previous biopsy site identified

C. Skin, lateral and medial corners of incision, excision:

-Skin and underlying breast tissue with no significant histopathologic changes

*IAD-3
Carcinoma, mucinous 8480/3
Site @ Breast NDS C50.9
5/16/13 JW*

Breast Pathologic Parameters

1. Invasive carcinoma:

A. Gross measurement: 1.9 cm

B. Composite histologic (modified SBR) grade: II/III

2. Excisional biopsy margins: Free of tumor

- Invasive carcinoma >2.0 cm from all surgical margins

3. Blood vessel and lymphatic invasion: Present in breast parenchyma

4. Axillary lymph nodes:

- One sentinel lymph node with several foci of micrometastases (1/1)

- Size of largest metastatic deposit: Approximately 0.5 mm

- Extranodal extension: Absent

5. Special studies:

- ER: Strong expression in >90% of invasive tumor nuclei

- PR: Strong expression in >80% of invasive tumor nuclei

- Her2/neu antigen (FISH): Pending

6. pTNM (AJCC, 7th edition, 2010): pT1c, N1mi, MX

Effective _____ this Checklist utilizes the 7th edition TNM staging system for breast of the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC).

Comment

Her2/neu (FISH) is pending and will be reported as an addendum.

Interpretation performed by the Attending Pathologist and reviewed with the

Resident/Fellow, _____ M.D.

Electronically Signed Out by

PROCEDURE/ADDENDA

Addendum

Date Ordered: Status: Signed Out

Date Completed:

Addendum Diagnosis

RECEIVED FROM

Breast Cancer Assay Description

Breast Cancer Assay uses RT-PCR to determine the expression of a panel of 21 genes in tumor tissue. The Recurrence Score is calculated from the gene expression results. The Recurrence Score range is from 0-100.

Results

Breast Cancer Recurrence Score = 6

The findings summarized in the Clinical Experience sections of this report are applicable to the patient populations defined in each section. It is unknown whether the findings apply to patients outside these criteria.

Clinical Experience: Prognosis for node negative, ER-positive patients

The Clinical Validation study included female patients with Stage I or II, Node Negative, ER-Positive breast cancer treated with 5 years of tamoxifen. Those patients who had a Recurrence Score of 6 had an Average Rate of Distant Recurrence of 5% (95% CI: 3%-7%)

Quantitative Single Gene Report

ER Score = 11.4 Positive

PR Score = 7.9 Positive

HER2 Score = 9.5 Negative

Laboratory Director:

ORIGINAL REPORT ON FILE IN SURGICAL PATHOLOGY LABORATORY

Addendum Comment

A request for molecular studies was received on _____ from Dr.

The test is to be performed on tissue from case _____. The case report, slides and blocks for the cited accession were retrieved from archives. The pathologist whose signature appears below reviewed the original pathology report, examined candidate H&E slides, and selected block B5) and forwarded it to _____ where the subject molecular test will be performed.

An addendum report will be issued when the results of this molecular test are available.

Addendum

Date Ordered: Status: Signed Out

Date Completed:

Addendum Diagnosis

RECEIVED FROM

HER2 Amp, Breast Cancer, FISH

Specimen Tissue-Paraffin

Specimen ID

Source

Right breast

Order Date

Reason For Referral

r/o HER2 gene amplification

Fixative Formalin

METHODS:

FISH using probes for HER2 (17q12) and a chromosome 17

Centromere (D17Z1) control probe

. Two technologists score signals in 60

Total nuclei from invasive or metastatic tumor and

Concurrent controls.

Results

Nuc ish(D17Z1,HER2)x2

The HER2:D17Z1 ratio is 1.03.

Average HER2 signals per nucleus is 1.8.

Average D17Z1 signals per nucleus is 1.7.

Interpretation

The invasive tumor nuclei have no evidence of HER2 gene

Amplification (per ASCO/CAP guidelines) in this breast

Excision specimen. The HER2:D17Z1 ratio is 1.03.

This result suggests the tumor has two chromosomes 17 with a
Normal HER2 gene copy number.

ASCO/CAP reporting guidelines (Wolff et al., Arch Path Lab
Med 131: 18-43, 2007):

A HER2:D17Z1 ratio less than 1.8 indicates absence of
HER2 gene amplification.

A HER2:D17Z1 ratio from 1.8 2.2 is equivocal for HER2
Gene amplification.

A HER2:D17Z1 ratio greater than 2.2 indicates HER2 gene
Amplification when there are greater than 6 HER2 signals per nucleus.

DISCLAIMER: This test was developed and its performance
Characteristics determined by

It is intended as an

Adjunct to existing prognostic clinical and pathologic
Information for breast cancer patients. This test is not
Intended to diagnose or screen for breast cancer. Per
ASCO/CAP guidelines, HER2 FISH test results are valid for
Non-decalcified paraffin embedded specimens fixed in 10%
Neutral buffered formalin between 6 and 48 hours. Results
From specimens fixed outside these parameters should be
Interpreted accordingly.

Consultant

Report Date :

*Performing Site:

ORIGINAL REPORT ON FILE IN SURGICAL PATHOLOGY LABORATORY

Clinical History:

The patient is a -year-old female with breast cancer undergoing lumpectomy.

Specimens Received:

A: Right sentinel node #1

B: Right breast central partial mastectomy; lumpectomy

C: Additional tissue from lateral and medial corners of incision

Gross Description:

The specimens are received in three containers each labeled with the patient's name and medical record number.

A. The first container is additionally identified as, 'right sentinel node #1'.

Received fresh and placed in formalin is a 1.4 cm rubbery, bluish discolored lymph node that is bisected and submitted in A1.

B. The second container is additionally identified as, 'right breast central partial mastectomy'. Received fresh and placed in formalin is a 90.2 gm partial mastectomy specimen measuring 7.3 cm from medial to lateral, 7.8 cm from superior to inferior and 3.3 cm from anterior to posterior. There is a 6 x 4.8 cm areola with a 1.3 x 1 cm flat nipple, with a short suture designating the superior pole and a long suture designating the lateral pole. The specimen is

inked as follows:

anterior - black

posterior - red

superior - blue

inferior - green

medial - yellow

lateral - violet

The specimen is serially sectioned from medial to lateral into 9 slices (slice 6 at nipple). There is a solid, white-tan, retroareolar mass located in slices 6-7 measuring 1.9 x 1.8 x 1.2 cm. It is located 2.4 cm from the superior margin, 2.5 cm from the lateral margin, 3.0 cm from the inferior margin, 3.3 cm from the medial margin, and 3.5 cm from the deep margin. Representative sections are submitted as follows:

B1: Medial margin

B2: Lateral margin

B3-B9: Slice #7, lesion and margins

B10-B11: Representative skin and nipple, slice #6

B12: Representative uninvolved, slice #5

B13: Representative uninvolved, slice #8

Tissue fixed for at least 6 hours in 10% NBF and no more than 72 hours.

C. The third container is additionally identified as, 'additional tissue from lateral and medial corners of incision'. Received fresh and placed in formalin are 2 pieces of skin and subcutaneous tissue. One piece measures 4 x 2.3 x 0.5 cm and has a stitch that designates the medial corner; this margin is inked blue, and the remainder is inked black. The other portion of skin measures 3.8 x 2.8 x 0.8 cm; the deep surface is inked black. The specimens are sectioned and no discrete lesions are identified. Representative sections are submitted as follows:

C1: Representative sections of piece with stitch

C2: Representative section of other piece

, M.D.

Pathologist Sign Out:

Criteria	lw 4/24/13	Yes	No
Diagnosis Discrepancy			✓
Primary Tumor Site Discrepancy			✓
HIPAA Discrepancy			✓
Prior Malignancy History			✓
Dual/Synchronous Primary Noted			✓
Case is (single):	QUALIFIED / DISQUALIFIED		
Reviewer Initials	Date Reviewed:	4/11/13	