UUID:1CEBF20D-767A-4A19-AA41-B9EAFCF05176
TCGA-E2-A158-01A-PR Redacted

ICD-0-3
Carcinoma, infiltrating duct, NOS
8500/3 12/8/10

Path Site Code: breast, upper outer quadrant C50.4
CQEF Site: breast, NOS C50.9

TSS:

SPECIMENS:
A. SENTINEL LYMPH NODE #1 LEFT AXILLA
B. SENTINEL LYMPH NODE #2 LEFT AXILLA
C. LEFT BREAST
D. SENTINEL LYMPH NODE #1 RIGHT AXILLA
E. RIGHT BREAST

SPECIMEN(S):
A. SENTINEL LYMPH NODE #1 LEFT AXILLA
B. SENTINEL LYMPH NODE #2 LEFT AXILLA
C. LEFT BREAST
D. SENTINEL LYMPH NODE #1 RIGHT AXILLA
E. RIGHT BREAST

INTRAOPERATIVE CONSULTATION DIAGNOSIS:
TPA, Sentinel lymph node #1, left axilla: Negative for carcinoma
TPB, Sentinel lymph node #2, left axilla: Negative for carcinoma
Diagnosis called at . . by Dr.
TPC, Sentinel lymph node #1, right axilla: negative for carcinoma
Diagnosis called at . by Dr.

GROSS DESCRIPTION:
A. SENTINEL LYMPH NODE #1 LEFT AXILLA
Received fresh labeled with the patient's identification and designated "sentinel lymph node number one left axilla" is a fragment of fibroadipose tissue, 1.4 x 1 x 0.6 cm, consisting of one possible lymph node, 1.4 x 0.7 x 0.4 cm. Touch preparation is performed. The entire lymph node is submitted, A1.
B. SENTINEL LYMPH NODE #2 LEFT AXILLA
Received fresh labeled with the patient's identification and designated "sentinel lymph node number two left axilla" is a fragment of fibroadipose tissue, 2 x 1.4 x 0.8 cm, consisting of one possible lymph node, 2 x 0.9 x 0.5 cm. Touch preparation is performed. The entire lymph node is submitted, B1.
C. LEFT BREAST
Received fresh labeled with the patient's identification and designated "left breast" is an oriented (suture in axilla), 573-g, 25 x 18 x 4.5 cm mastectomy specimen with 3.5 x 2 cm light tan skin ellipse, and 1.4-cm diameter everted nipple. Ink code: Posterior-black, anterior/superior-blue, anterior/inferior-orange. The specimen is serially sectioned from lateral to medial revealing a tan stellate mass in the UOQ (slices 3-4), 3 x 2.8 x 1.5 cm, located 0.2-cm from the nearest anterior margin, and 2.2-cm from the deep margin. A smaller well defined nodule present in the posterior UIQ is seen. A portion the specimen is submitted for tissue procurement. Representatively submitted:
C1-C3: Nipple, C3 contains representative section of skin
C4: Mass with anterior margin, slice 3, UOQ
C5: Mass with anterior margin, slice 4, UOQ
C6-C7: Remainder of mass, slice 4, UOQ
C8: Deep margin, slice 4, UOQ
C9: Additional section, UOQ, slice 5
C10: Representative section, LOQ, slice 5
C11-C12: Representative sections, UIQ, slices 7-8, respectively
C13: Representative section, LIQ, slice 7
C14-C15: nodule in posterior UIQ

D. SENTINEL LYMPH NODE #1 RIGHT AXILLA
Received fresh labeled with matching patient identifiers is a piece of adipose tissue 3.4 x 3 x 1.1 cm containing two lymph nodes, the smaller is 0 .5 cm in diameter, larger one measures 2.4 x 0.8 x 0.8 cm. Touch preps are performed the specimen is submitted entirely/separately in cassettes D1-D2.
E. RIGHT BREAST
Received fresh labeled with the patient's identification and "right breast" is an oriented 454 g, 19 x 16 x 3 cm mastectomy with 3 x 3 cm skin ellipse and 1.8 cm everted nipple. Ink code: Anterior/superior-blue, anterior/inferior-orange, posterior-black. Specimen is serially sectioned into 9 slices from medial to the lateral with nipple in slice 4 revealing 4 lesions.
1- 1.3 x 0.8 x 0.5 cm firm tan mass located in slics 5-6 in the upper outer quadrant; 2.7 cm from the deep margin and 0.2 cm from the anterior margin
2- 1.2 x 0.9 x 0.8 cm firm tan stellate mass with central area of hemorrhage located in the upper mid-quadrant; 2.5 cm from the deep margin, 1.8 cm from the anterior margin, 1.4 cm the medial to lesion #1, and 1.8 cm posterior/superior from nipple
3- 0.6 x 0.3 x 0.3 cm firm tan nodule located in the upper inner quadrant; 1.2 cm from the deep margin, 0.9 cm from the anterior margin and 3.2 cm medial to lesion #2

4- 0.6 x 0.4 x 0.2 cm firm tan nodule located in the lower inner quadrant; 1.2 cm from the deep margin, 0.6 cm from the anterior margin, and 6.2 cm inferior to lesion #1
Representatively submitted.
E1: slice 1, upper inner
E2-E3: slice 2, lesion #3(posterior to anterior)
E4: slice 3, tissue connecting lesion #3 and #2
E5-E7: slice 4, lesion #2 submitted anterior to posterior
E8: slice 5, lesion #1
E9: slice, 6, lesion #1
E10: slice 7, upper outer (lateral to lesion #1)
E11: slice 7, lower outer
E12: slice 6, lower outer
E13-E14: slice 5, lesion #4 (anterior to posterior)
E15-E16: slice 5, tissue connecting lesions #1 and #4
E17: slice 3, lower inner
E18: slice 2, lower inner
E19-E21: nipple, perpendicular sections
E22: skin

DIAGNOSIS:

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

B. LYMPH NODE, SENTINEL #2, LEFT AXILLA, EXCISION:
- METASTATIC CARCINOMA TO ONE OF ONE LYMPH NODE (1/1), MEASURING 0.1-CM (MICROMETASTASES) WITH NO EXTRANODAL EXTENSION, SEE NOTE.

C. BREAST, LEFT, MASTECTOMY:
- TWO FOCI OF INVASIVE DUCTAL CARCINOMA
- SBR GRADE 3, MEASURING 1.6-CM
- SBR GRADE 1, MEASURING 0.5-CM
- INTERMEDIATE NUCLEAR GRADE, DUCTAL CARCINOMA IN SITU, SOLID TYPE WITH CENTRAL NECROSIS AND MICROCALCIFICATIONS
- SURGICAL RESECTION MARGINS NEGATIVE FOR TUMOR
- BIOPSY SITE CHANGES WITH FIBROSIS AND GRANULATION TISSUE
- SEE SYNOPTIC REPORT AND SEE NOTE.

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

E. BREAST, RIGHT, MASTECTOMY:
- TWO FOCI OF INVASIVE DUCTAL CARCINOMA,
- SBR GRADE 3, MEASURING 1.1-CM
- SBR GRADE 2, MEASURING 0.6-CM
- INTERMEDIATE NUCLEAR GRADE, DUCTAL CARCINOMA IN SITU, SOLID AND CRIBRIFORM TYPES
- SURGICAL RESECTION MARGINS NEGATIVE FOR TUMOR
- BIOPSY SITE CHANGES WITH FIBROSIS
- FIBROADENOMA AND SCLEROSING ADENOSIS
- SEE SYNOPTIC REPORT AND SEE NOTE.

NOTE: Left axillary sentinel lymph node #2 touch preparation is negative. Therefore, the false- negativity is due to sampling error. The morphology of metastatic tumor is similar to the larger grade 3 tumor (see below).

In the left mastectomy specimen, 2 nodules are grossly identified, larger nodule located in UOQ measuring 1.6 and is of grade 3; and a smaller nodule, located in posterior UIQ, measuring 0.5-cm and is of grade 1. Breast biomarkers on both nodules are pending.

In the right mastectomy specimen, 4 nodules are grossly identified, one is fibroadenoma, one is sclerosing adenosis, and the other two are separate foci of invasive ductal carcinoma. The largest invasive tumor measures 1.1-cm and it is of grade 3. Breast biomarkers are as follows, ER negative, PR negative and HER-2/neu equivocal (2+, FISH pending). The smaller nodule measures 0.6-cm and it is of grade 2. The breast biomarkers are as follows ER positive, PR positive and HER-2/neu equivocal (2+, FISH pending).

Also, the morphology of grade 3 tumors (right and left) is different. It seems that there are 4 different primary tumors, 2 in each breast.

SYNOPTIC REPORT - BREAST

Specimens Involved
Specimens: B: SENTINEL LYMPH NODE #2 LEFT AXILLA
C: LEFT BREAST

Specimen Type: Mastectomy
Needle Localization: No
Laterality: Left
Invasive Tumor: Present
Multifocality: Yes
WHO CLASSIFICATION
Invasive ductal carcinoma, NOS 8500/3
Tumor size: 1.6cm
Tumor Site: Upper outer quadrant
Upper inner quadrant
Margins: Negative
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: Positive 1 / 2
Micrometastases: Yes

DCIS present
Margins uninvolved by DCIS
DCIS Quantity: Estimate 5%
DCIS Type: Solid
DCIS Location: Associated with invasive tumor
Nuclear grade: Intermediate
Necrosis: Present

ER/PR/HER2 Results
Performed on Case: see note

Pathological staging (pTN): pT 1c N 1mic

SYNOPTIC REPORT - BREAST
Specimens Involved
Specimens: D: SENTINEL LYMPH NODE #1 RIGHT AXILLA
E: RIGHT BREAST

Specimen Type: Mastectomy
Needle Localization: No
Laterality: Right
Invasive Tumor: Present
Multifocality: Yes
WHO CLASSIFICATION
Invasive ductal carcinoma, NOS 8500/3
Tumor size: 1.1cm
Margins: Negative
Tubular Score: 3
Nuclear Grade: 3
Mitotic Score: 2
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 2%
DCIS Type: Solid
Cribriform
DCIS Location: Associated with invasive tumor

Nuclear grade: Intermediate
Necrosis: Absent

ER/PR/HER2 Results
Performed on Case: see note

Pathological staging (pTN): pT 1c N 0

SYNOPTIC REPORT - BREAST, ER/PR RESULTS
Specimens Involved
Specimens: E: RIGHT BREAST

Specimen: Surgical Excision
Block Number: E5, larger tumor

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

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 Dako) 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
Specimens Involved
Specimens: E: RIGHT BREAST

Specimen: Surgical Excision
Block Number: E5 larger tumor

Interpretation: EQUIVOCAL
Intensity: 2+
% Tumor Staining: 10%
Fish Ordered: Yes , on Date

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 (Dako, Carpenteria, CA) 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. The Pathology Department takes full responsibility for this test's performance.

SYNOPTIC REPORT - BREAST, ER/PR RESULTS
Specimens Involved
Specimens: E: RIGHT BREAST

Specimen: Surgical Excision
Block Number: E13 smaller tumor

ER: Positive Allred Score: 8 = Proportion Score 5 + Intensity Score 3
PR: Positive Allred Score: 8 = Proportion Score 5 + 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 Dako) 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
Specimens Involved
Specimens: E: RIGHT BREAST

Specimen: Surgical Excision
Block Number: E13 larger tumor

Interpretation: EQUIVOCAL
Intensity: 2+
% Tumor Staining: 50%
Fish Ordered: Yes , on Date

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

CLINICAL HISTORY:

Bilateral invasive breast carcinoma)

PRE-OPERATIVE DIAGNOSIS:

Same

INTRAOPERATIVE CONSULTATION DIAGNOSIS:

TPD, Sentinel lymph node #1, right axilla: negative for carcinoma
Diagnosis called at .m. by Dr

ADDENDUM:

Results for touch prep on specimen D was incorrectly designated in the Intraoperative Consultation Diagnosis above as "TPC". Correct information is as follows:
SYNOPTIC REPORT - BREAST, ER/PR RESULTS
Specimens Involved
Specimens: C: LEFT BREAST

Specimen: Surgical Excision
Block Number: C4 larger tumor

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

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 Dako 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
Specimens Involved
Specimens: C: LEFT BREAST

Specimen: Surgical Excision
Block Number: C4 larger tumor

Interpretation: NEGATIVE
Intensity: 1+
% 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 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. The Pathology Department takes full responsibility for this test's performance.

SYNOPTIC REPORT - BREAST, ER/PR RESULTS
Specimens Involved
Specimens: C: LEFT BREAST

Specimen: Surgical Excision
Block Number: C14 smaller tumor

ER: Positive Allred Score: 8 = Proportion Score 5 + Intensity Score 3
PR: Positive Allred Score: 8 = Proportion Score 5 + 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 Dako 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
Specimens Involved
Specimens: C: LEFT BREAST

Specimen: Surgical Excision
Block Number: C14 smaller tumor

Interpretation: EQUIVOCAL
Intensity: 2+
% Tumor Staining: 10%
Fish Ordered: Yes , on Date

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 (Dako, Carpenteria, CA) 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. The 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 by Dr. A majority of tumors cells displayed 2 chromosome 17 signals and 2 HER-2 signals, with a HER-2/CEP 17 Ratio </=2.0, consistent with no amplification of the HER2/neu gene.

Block used E5 Source of case:

Tissue fixation formalin-fixed tissue Outside Case No: NA

Tissue source breast Results interpreted: yes

HER2/CEP17 ratio: 1.03

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

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 by Dr. A majority of tumors cells displayed 2 chromosome 17 signals and 2 HER-2 signals, with a HER-2/CEP 17 Ratio </=2.0, consistent with no amplification of the HER2/neu gene.

Block used E13 Source of case:

Tissue fixation formalin-fixed tissue Outside Case No: NA

Tissue source breast Results interpreted: yes

HER2/CEP17 ratio: 0.91

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

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 by Dr. A majority of tumors cells displayed 2 chromosome 17 signals and 2 HER-2 signals, with a HER-2/CEP 17 Ratio </=2.0, consistent with no amplification of the HER2/neu gene.
Block used C14 Source of case:
Tissue fixation formalin-fixed tissue Outside Case No: NA
Tissue source breast Results interpreted: yes
HER2/CEP17 ratio: 0.94

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

Gross Dictation:
Microscopic/Diagnostic Dictation:
Final Review: Pathologist,
Final Review: Pathologist,
Final: Pathologist,
Addendum Review: Pathologist
Addendum Final: Pathologist,
Addendum: Pathologist,
Addendum Final: M.D., Pathologist,
Addendum: Pathologist,
Addendum Final: Pathologist,
Addendum: Pathologist,
Addendum Final: 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: 11/2/10