

SURGICAL PATHOLOGY (Order Order **SURGICAL PATHOLOGY** Status: Completed Electronically signed by: Ordering user: Authorized by: Frequency: -SURGICAL PATHOLOGY (Order Result Resulted: 11/13/23 1131, Result status: Edited SURGICAL PATHOLOGY Result - FINAL Specimen Information Collected On ID Source Type 11/07/23

Resulted: 11/13/23 1131, Result status: Edited

Result - FINAL

SURGICAL PATHOLOGY

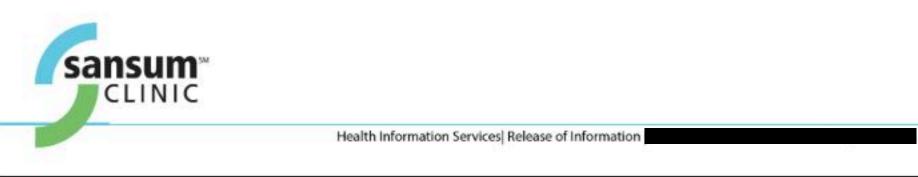
Abrams, Roxann L

MRN DOB:

Visit date:

Legal Sex: F

(Order **SURGICAL PATHOLOGY** Order **SURGICAL PATHOLOGY** Status: Completed Electronically signed by: Ordering user: Epic, Daemon 12/22/23 0000 Authorized by: Frequency: -SURGICAL PATHOLOGY (Order Result Resulted: 12/29/23 1531, Result status: Final SURGICAL PATHOLOGY result Specimen Information Source Collected On ID Type 12/22/23 Resulted: 12/29/23 1531, Result status: Final SURGICAL PATHOLOGY result **Surgical Pathology Exam** Order (Order **Surgical Pathology Exam** Electronically signed by: Status: Completed Ordering user: Authorized by: Frequency: -Surgical Pathology Exam (Order Result Resulted: 03/26/24 1318, Result status: Final Surgical Pathology Exam result Specimen Information Source Collected On ID Type 03/25/24 0859 Resulted: 03/26/24 1318, Result status: Final Surgical Pathology Exam result Surgical Pathology Exam Order (Order Surgical Pathology Exam Status: Completed Electronically signed by: Ordering user: Authorized by: Frequency: -



Abrams, Roxann L DOB: MRN: Visit date:

Legal Sex: F

Status: Completed

Result

Surgical Pathology Exam (Order

Surgical Pathology Exam

result

Specimen Information

Collected On ID Type Source 06/12/24 1325

Resulted: 06/14/24 1049, Result status: Final

Resulted: 06/14/24 1049, Result status: Final

Surgical Pathology Exam

result

Order

Surgical Pathology (Performed at PDL) (Order

Surgical Pathology (Performed at PDL)

Electronically signed by:

Ordering user: Authorized by:

Cosigning events

Electronically cosigned by

Frequency: 01/07/25 -

Diagnoses

Result

Recurrent breast cancer, left (CMS/HCC) [C50.912]

Questionnaire

Question

Answer Other Comment - A: left axilla skin punch bx Specimen Source:

Other Comment - B: left axilla lower skin Other Comment - C: left chest skin bx Other Comment - D:left chest skin bx

Resulting lab: PACIFIC DIAGNOSTIC LAB

CLINICAL HISTORY:

65 yo female Punch Bxs, recent punch skin bx showing

ILC

Ordering provider:

Order comments: A: left axilla skin punch bx B: left axilla lower skin C: left chest skin bx D:left chest skin bx

Surgical Pathology (Performed at PDL) (Order

Resulted: 01/09/25 1051, Result status: Final

Surgical Pathology (Performed at PDL)

Ordering provider:

Narrative:

A: left axilla skin punch bx

B: left axilla lower skin

C: left chest skin bx

D:left chest skin bx

Specimen Source: Other

A: left axilla skin punch bx

Specimen Source: Other

B: left axilla lower skin

Specimen Source: Other

C: left chest skin bx

Specimen Source: Other

D:left chest skin bx

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Sansum Clinic

result



CLINICAL HISTORY: 65 yo female Punch Bxs, recent punch skin bx showing ILC

Surgical Pathology-PDC

Case: 01/07/2025 1330

Authorizing Provider: Ordering Location:

Received: 01/07/2025 2003

Pathologist:

Specimens: A) - Skin, left axilla skin punch bx

- B) Skin, left axilla lower skin
- C) Skin, left chest skin bx
- D) Skin, left chest skin bx
- A. Skin, left axilla, punch biopsy:
- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma
- B. Skin, left axilla, lower, punch biopsy:
- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma
- C. Skin, left chest, punch biopsy:
- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma
- D. Skin, left chest, punch biopsy:
- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma

Comment: Skin biopsies have patchy, minimal superficial peri-vascular chronic inflammatory infiltrate with a few scattered eosinophils. The differential diagnosis includes drug reaction and dermal hypersensitivity reaction. Clinical correlation is recommended.

The history of recurrent lobular carcinoma is noted. There is no carcinoma identified in any of the biopsies, including on keratin immunostains and multiple additional levels.

Electronically signed by

Technical component for the stains listed below was performed by Pacific Diagnostic Laboratories at 454 S Patterson Ave, Santa Barbara, CA 93111

Professional interpretation for the stains listed below was performed in-house by an MPC/SBCH pathologist at 400 W Pueblo St. Santa Barbara, CA 93105

Block(s): A1, B1, C1, D1 Population: All areas

Antibody Patient Results/Comments Keratin AE1/3 Negative

Interpretation: There is no immunohistochemical evidence of involvement by carcinoma.

Internal and external IHC controls were reviewed and are satisfactory. All above stains are single (non-cocktail/multiplex) unless otherwise indicated.

The reported immunochemical stain(s) were developed and their performance characteristics determined by Pacific Diagnostic Laboratories. They 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. This test is used for clinical purposes and should not be regarded as investigational or research. This laboratory is certified under the Clinical Laboratory Improvement Amendment of 1988 (CLIA) as qualified to

perform high complexity clinical testing.

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- A. Received in formalin labeled "LT axilla skin punch Bx is a 0.4 x 0.3 cm skin punch, excised to a depth of 0.3 cm. The epidermis is pale-tan and hyper wrinkled. The specimen is submitted entirely in cassette A1.
- B. Received in formalin labeled "left axilla lower skin punch is a 0.3 cm skin punch, excised to a depth of 0.3 cm. The epidermis is white to pale-pink, hyper wrinkled, and irregular. The specimen is submitted entirely in cassette B1.
- C. Received in formalin labeled "left chest skin Bx is a 0.3 cm skin punch, excised to a depth of 0.4 cm. The epidermis is white to pale-pink and hyper wrinkled. The specimen is submitted entirely in cassette C1.
- D. Received in formalin labeled "left chest skin is a 0.3 cm skin punch, excised to a depth of up to 0.5 cm. The epidermis is white to pale-pink, hyper wrinkled, and irregular. The specimen is submitted entirely in cassette D1. jdk

A: left axilla skin punch bx

B: left axilla lower skin

C: left chest skin bx

D:left chest skin bx

Specimen Source: Other A: left axilla skin punch bx Specimen Source: Other B: left axilla lower skin Specimen Source: Other C: left chest skin bx Specimen Source: Other

CLINICAL HISTORY: 65 yo female Punch Bxs, recent punch skin bx showing ILC

Specimen Information

| ID | Туре | Source | Collected On | |
|----|--------|--------|---------------|--|
| | Tissue | Skin | 01/07/25 1330 | |

Testing Performed By

D:left chest skin bx

| Lab - Abbreviation Name | Director | Address | Valid Date Range |
|-----------------------------|----------|---------|-------------------------|
| 19 - PDL PACIFIC DIAGNOSTIC | CAB LAB | | 12/05/24 1327 - Present |

Resulted: 01/09/25 1051, Result status: Final

Surgical Pathology (Performed at PDL) [59770876]

Ordering provider:

Resulting lab: PACIFIC DIAGNOSTIC LAB

Narrative:

A: left axilla skin punch bx
B: left axilla lower skin
C: left chest skin bx
D:left chest skin bx
Specimen Source: Other
A: left axilla skin punch bx
Specimen Source: Other

Specimen Source: Other B: left axilla lower skin Specimen Source: Other C: left chest skin bx Specimen Source: Other D:left chest skin bx

CLINICAL HISTORY: female Punch Bxs, recent punch skin bx showing ILC

Surgical Pathology-PDC

Authorizing Provider: Collected: 01/07/2025 1330

Ordering Location: LAB INTERFACED ORDERS Received: 01/07/2025 2003

Case:

Pathologist:

Specimens: A) - Skin, left axilla skin punch bx

result



- B) Skin, left axilla lower skin
- C) Skin, left chest skin bx
- D) Skin, left chest skin bx
- A. Skin, left axilla, punch biopsy:
- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma
- B. Skin, left axilla, lower, punch biopsy:
- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma
- C. Skin, left chest, punch biopsy:
- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma
- D. Skin, left chest, punch biopsy:
- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma

Comment: Skin biopsies have patchy, minimal superficial peri-vascular chronic inflammatory infiltrate with a few scattered eosinophils. The differential diagnosis includes drug reaction and dermal hypersensitivity reaction. Clinical correlation is recommended.

The history of recurrent lobular carcinoma is noted. There is no carcinoma identified in any of the biopsies, including on keratin immunostains and multiple additional levels.

Electronically signed by

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Block(s): A1, B1, C1, D1 Population: All areas

Antibody Patient Results/Comments Keratin AE1/3 Negative

Interpretation: There is no immunohistochemical evidence of involvement by carcinoma.

Internal and external IHC controls were reviewed and are satisfactory. All above stains are single (non-cocktail/multiplex) unless otherwise indicated.

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A. Received in formalin labeled "LT axilla skin punch Bx is a 0.4 x 0.3 cm skin punch, excised to a depth of 0.3 cm. The epidermis is pale-tan and hyper wrinkled. The specimen is submitted entirely in cassette A1.

- B. Received in formalin labeled "left axilla lower skin punch is a 0.3 cm skin punch, excised to a depth of 0.3 cm. The epidermis is white to pale-pink, hyper wrinkled, and irregular. The specimen is submitted entirely in cassette B1.
- C. Received in formalin labeled "left chest skin Bx is a 0.3 cm skin punch, excised to a depth of 0.4 cm. The

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epidermis is white to pale-pink and hyper wrinkled. The specimen is submitted entirely in cassette C1.

D. Received in formalin labeled "left chest skin is a 0.3 cm skin punch, excised to a depth of up to 0.5 cm. The epidermis is white to pale-pink, hyper wrinkled, and irregular. The specimen is submitted entirely in cassette D1. jdk

A: left axilla skin punch bx

B: left axilla lower skin

C: left chest skin bx

D:left chest skin bx

Specimen Source: Other A: left axilla skin punch bx Specimen Source: Other

B: left axilla lower skin Specimen Source: Other C: left chest skin bx

Specimen Source: Other D:left chest skin bx

CLINICAL HISTORY: female Punch Bxs, recent punch skin bx showing ILC

View Image (below)



Abrams, Roxann L MRN: L Visit date:

DOB:

Legal Sex: F

PACIFIC DIAGNOSTIC LABORATORIES Guiding Health.



| PRACTICE INFORMATION | REP | ORT INFORMATION | 1 | PATIENT INFORMATION |
|----------------------|------------|--------------------------|-----------|---------------------|
| Provider: | Report sta | Report status: See Below | | |
| Recipient: | Encounter | No.: | Phone: | |
| Phone: O: | Printed: | 1/9/2025 10:51 AM | DOB: 7/5/ | 1959 |
| Code: | | | MRN: | SEX: Female |
| | Comment | | | |
| | | | | |
| Address: | | | | |
| | | | | |

Surgical Pathology-PDC (Final result)

Authorizing Provider: Ordering Provider:

Ordering Location: LAB INTERFACED ORDERS Collected: 01/07/2025 1330 Pathologist: Received: 01/07/2025 2003

Specimens

A Skin, left axilla skin punch bx
B Skin, left axilla lower skin
C Skin, left chest skin bx

D Skin, left chest skin bx

FINAL DIAGNOSIS

A. Skin, left axilla, punch biopsy:

- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma

B. Skin, left axilla, lower, punch biopsy:

- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma

C. Skin, left chest, punch biopsy:

- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma

D. Skin, left chest, punch biopsy:

- -- Skin with minimal superficial peri-vascular inflammation (see comment)
- -- Negative for carcinoma

Comment: Skin biopsies have patchy, minimal superficial peri-vascular chronic inflammatory infiltrate with a few scattered eosinophils. The differential diagnosis includes drug reaction and dermal hypersensitivity reaction. Clinical correlation is recommended.

The history of recurrent lobular carcinoma is noted. There is no carcinoma identified in any of the biopsies, including on keratin immunostains and multiple additional levels.

Electronically signed by

IHC

Technical component for the stains listed below was performed by Pacific Diagnostic Laboratories at 454 S Patterson Ave, Santa Barbara, CA 93111 Professional interpretation for the stains listed below was performed in-house by an MPC/SBCH pathologist at 400 W Pueblo St. Santa Barbara, CA 93105

Block(s): A1, B1, C1, D1 Population: All areas

Page 1 of 3



Abrams, Roxann L DOB: MRN: Legal Sex: F Visit date:





Patient Results/Comments Antibody

Keratin AE1/3 Negative

Interpretation: There is no immunohistochemical evidence of involvement by carcinoma.

Internal and external IHC controls were reviewed and are satisfactory. All above stains are single (non-cocktail/multiplex) unless otherwise indicated.

The reported immunochemical stain(s) were developed and their performance characteristics determined by Pacific Diagnostic Laboratories. They 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. This test is used for clinical purposes and should not be regarded as investigational or research. This laboratory is certified under the Clinical Laboratory Improvement Amendment of 1988 (CLIA) as qualified to perform high complexity clinical testing.

GROSS DESCRIPTION

A. Received in formalin labeled "LT axilla skin punch Bx" is a 0.4 x 0.3 cm skin punch, excised to a depth of 0.3 cm. The epidermis is pale-tan and hyper wrinkled. The specimen is submitted entirely in cassette A1.

- B. Received in formalin labeled "left axilla lower skin punch" is a 0.3 cm skin punch, excised to a depth of 0.3 cm. The epidermis is white to pale-pink, hyper wrinkled, and irregular. The specimen is submitted entirely in cassette B1.
- C. Received in formalin labeled "left chest skin Bx" is a 0.3 cm skin punch, excised to a depth of 0.4 cm. The epidermis is white to pale-pink and hyper wrinkled. The specimen is submitted entirely in cassette C1.
- D. Received in formalin labeled "left chest skin" is a 0.3 cm skin punch, excised to a depth of up to 0.5 cm. The epidermis is white to pale-pink, hyper wrinkled, and irregular. The specimen is submitted entirely in cassette D1. jdk

CLINICAL HISTORY

A: left axilla skin punch bx

B: left axilla lower skin

C: left chest skin bx

D:left chest skin bx

Specimen Source: Other

A: left axilla skin punch bx

Specimen Source: Other

B: left axilla lower skin

Specimen Source: Other C: left chest skin bx

Specimen Source: Other

D:left chest skin bx

CLINICAL HISTORY:

female Punch Bxs, recent punch skin bx showing ILC

Proposed Charges

| Charge Code 88305 (CPT®) | Qty | Charge Code Qty 88341 (CPT®) 1 | Charge Code Qty 88305 (CPT®) 1 |
|-----------------------------|-----|--------------------------------|--------------------------------|
| 88341 (CPT®) | 1 | 88305 (CPT®) 1 | 88341 (CPT®) 1 |
| 88305 (CPT®) | 1 | 88341 (CPT®) 1 | |

Performing Lab CL CLIA License #:

Director:

The interpretations of all normal gynecologic specimens and the technical components for all surgical and autopsy pathology as well as cytology specimens, except for flow cytometry or unless otherwise designated as performed by an outside laboratory, were performed at Pacific Diagnostics Laboratory (PDL) Core Laboratory, 454 S. Patterson Avenue, Santa Barbara, CA 93111. The professional interpretations, including intraoperative, microscopic and macroscopic evaluations for all pathology specimens, except for normal gynecologic cytology specimens, were performed at Santa Barbara Cottage Hospital (CLIA# 05D0584831), 400 W. Pueblo Street, Santa Barbara, CA 93105. The diagnosis was made using microscopic evaluation of representative tissue sections unless otherwise specified. All standard and special cellular stains were developed and their performance characteristics were determined by PDL Core Laboratory. For flow cytometry, the performance characteristics as well as the technical and professional components were performed at Santa Barbara Cottage Hospital (CLIA# 05D0584831). Intraoperative evaluations for Goleta Valley Cottage Hospital radiologist-procured specimens were performed at Goleta Valley Cottage Hospital, 351 S. Patterson Ave. Santa Barbara, CA 93111. The Laboratory Medical Director for all of the aforementioned

Please note that the CPT codes listed may not reflect final billing.

Page 2 of 3





Abrams, Roxann Female,

Legend



| Order | SURGICAL PATHOLOGY (Orde | r |
|---|--------------------------|----------|
| SURGICAL PATHOLOGY Electronically signed by: Ordering user: Authorized by: Cosigning events Electronically cosigned by | Ordering provider: | d |
| | | |



Abrams, Roxann L MRN: DOB:

Visit date:

Legal Sex: F

SURGICAL PATHOLOGY

(continued)

Frequency: 01/16/25 -

Released by:

Diagnoses

Recurrent cancer of left breast (CMS/HCC) [C50.912]

Questionnaire

Question

Specimen Source: Other Comment - left chest wall flank

CLINICAL HISTORY:

possitive punch biopsy for cancer superior is short and

long is lateral

Result

SURGICAL PATHOLOGY (Order

Resulted: 01/27/25 1131, Result status: Edited Result - FINAL

SURGICAL PATHOLOGY
Ordering provider:

Resulting lab: PACIFIC DIAGNOSTIC LAB

Narrative:

Specimen Source: Other left chest wall flank

CLINICAL HISTORY: Female Left Chest Wall flank excison of prior possitive punch biopsy for cancer superior

is short and long is lateral

Surgical Pathology-PDC Case:

Authorizing Provider: Collected: 01/16/2025 1400

Ordering Location: LAB INTERFACED ORDERS Received: 01/16/2025 1819

Pathologist:

Specimen: Skin, left chest wall

Skin, left chest wall flank, excision:

-- Positive for breast carcinoma, focally involving 12-3 and 3-6:00 margins

-- Background skin with scar and tattoo ink

Electronically signed by

Block(s): A3

Population: Carcinoma

Antibody Patient Results/Comments

Keratin 7 Positive GATA3 Positive

Interpretation: Findings support breast carcinoma.

Internal and external IHC controls were reviewed and are satisfactory. All above stains are single (non-cocktail/multiplex) unless otherwise indicated.

ESTROGEN/PROGESTERONE RECEPTOR IMMUNOHISTOCHEMISTRY

Block: A3

Estrogen receptor: POSITIVE (2-3+ intensity, 70-80% of cells staining)

Progesterone receptor: NEGATIVE (<1% of cells staining)

Comment: HER-2/neu and Ki-67 testing are pending, with results to be reported by addendum.

ER/PR internal control: Absent; External control: Satisfactory.

Cold ischemic time: Unknown

Specimen: Formalin fixed 6-72 hours, paraffin embedded tissue.

Patient results interpreted using ASCO-CAP ER/PgR guidelines. Staining intensity is graded 0-3+. Nuclear staining in <1% of tumor cells is scored as negative. Estrogen Antibody - Leica Clone 6F11, Progesterone Antibody - Leica



clone PgR 16.

Reference: Allison KH et al. Estrogen and Progesterone Receptor Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Guideline Update. Arch Pathol Lab Med 2020; 144: p545-563.

Technical component for the stains listed above was performed by Pacific Diagnostic Laboratories at 454 S Patterson Ave, Santa Barbara, CA 93111

Professional interpretation for the stains listed above was performed by manual morphometric analysis in-house by an MPC/SBCH pathologist at 400 W Pueblo St. Santa Barbara, CA 93105

The reported immunochemical stain(s) were developed and their performance characteristics determined by Pacific Diagnostic Laboratories. They 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. This test is used for clinical purposes and should not be regarded as investigational or research. This laboratory is certified under the Clinical Laboratory Improvement Amendment of 1988 (CLIA) as qualified to

perform high complexity clinical testing.

Addendum issued to report IHC results for HER2 and Ki-67

HER2 Breast IHC results: Score 2+ (please see attachment)

Ki-67: 2% average whole tumor staining

Comment: Patients with breast cancers that are HER2 IHC 3+ or IHC 2+/ISH amplified may be eligible for several therapies that disrupt HER2 signaling pathways. Invasive breast cancers that test 'HER2-negative' (IHC 0, 1+ or 2+/ISH not-amplified) are more

specifically considered HER2-negative for protein overexpression/gene amplification since non-overexpressed levels of the HER2 protein may be present in these cases. Patients with breast cancers that are HER2 IHC 1+ or IHC 2+/ISH not amplified may be

eligible for a treatment that targets non-amplified/non-overexpressed levels of HER2 expression for cytotoxic drug delivery (IHC 0 results do not result in eligibility currently).

Addendum Billing Summary

Immunohistochemistry:

Professional interpretation for HER-2/neu was performed in-house by an MPC/SBCH pathologist at 400 W Pueblo St. Santa Barbara, CA 93105 (CPT 88361 x 2)

Technical component was performed by NeoGenomics Laboratory, 31 Columbia, Aliso Viejo, CA 92656

Addendum electronically signed by

Addendum issued to report HER2 FISH results: Negative (please see attachment)

Addendum Billing Summary

FISH Studies:

Professional component is performed in-house by an MPC Pathologist, 400 W Pueblo, Santa Barbara CA 93105 (CPT 88377 x 1)

Technical component is performed by NeoGenomics (see attached report for address/details)

Addendum electronically signed by Lauren E Jacobson, MD on 1/27/2025 at 11:31 AM

Received in formalin, labeled with the patient's name and designated on the requisition as "left chest wall flank" is a 3.4 x 1.2 cm oriented skin ellipse, excised to a depth of up to 1.4 cm. The epidermis is pale-tan and hyper wrinkled with a

centralized 0.5 cm pale-tan to blue and irregular lesion. There is a long suture at 1 tip designating lateral, and a short suture on a broad margin designating superior. The short superior submitted is re designated by the prosector as 12 o'clock,

making the long lateral suture 3 o'clock. The resection surface is inked according to the normal inking scheme as follows: 12-3 o'clock = yellow, 3-6 o'clock = blue, 6-9 o'clock = black, and 9-12 o'clock = red. The skin is sectioned to reveal pale-tan

to blue-black cut surfaces with subcutaneous fat. The specimen is submitted entirely in cassettes A1-A5 (tips in

Printed on 3/18/25 3:19 PM Sansum Clinic Page 13



A1). jdk

Specimen Source: Other left chest wall flank

CLINICAL HISTORY: Female Left Chest Wall flank excison of prior possitive punch biopsy for cancer superior

is short and long is lateral

Specimen Information

ID Type Source Collected On Tissue Skin 01/16/25 1400

Testing Performed By

Lab - Abbreviation Name Director Address Valid Date Range
19 - PDL PACIFIC
DIAGNOSTIC LAB

Director Address Valid Date Range
12/05/24 1327 - Present

Resulted: 01/27/25 1131, Result status: Edited

Result - FINAL

SURGICAL PATHOLOGY

Resulting lab: PACIFIC DIAGNOSTIC LAB

Ordering provider: Narrative:

Specimen Source: Other left chest wall flank

CLINICAL HISTORY: Female Left Chest Wall flank excison of prior possitive punch biopsy for cancer superior

is short and long is lateral

Surgical Pathology-PDC

Authorizing Provider: Collected: 01/16/2025 1400

Ordering Location: LAB INTERFACED ORDERS Received: 01/16/2025 1819

Case:

Pathologist:

Specimen: Skin, left chest wall

Skin, left chest wall flank, excision:

- -- Positive for breast carcinoma, focally involving 12-3 and 3-6:00 margins
- -- Background skin with scar and tattoo ink

Electronically signed by

Block(s): A3

Population: Carcinoma

Antibody Patient Results/Comments

Keratin 7 Positive GATA3 Positive

Interpretation: Findings support breast carcinoma.

Internal and external IHC controls were reviewed and are satisfactory. All above stains are single (non-cocktail/multiplex) unless otherwise indicated.

ESTROGEN/PROGESTERONE RECEPTOR IMMUNOHISTOCHEMISTRY

Block: A3

Estrogen receptor: POSITIVE (2-3+ intensity, 70-80% of cells staining)

Progesterone receptor: NEGATIVE (<1% of cells staining)

Comment: HER-2/neu and Ki-67 testing are pending, with results to be reported by addendum.



ER/PR internal control: Absent; External control: Satisfactory.

Cold ischemic time: Unknown

Specimen: Formalin fixed 6-72 hours, paraffin embedded tissue.

Patient results interpreted using ASCO-CAP ER/PgR guidelines. Staining intensity is graded 0-3+. Nuclear staining in <1% of tumor cells is scored as negative. Estrogen Antibody - Leica Clone 6F11, Progesterone Antibody - Leica clone PgR 16.

Reference: Allison KH et al. Estrogen and Progesterone Receptor Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Guideline Update. Arch Pathol Lab Med 2020; 144: p545-563.

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Addendum issued to report IHC results for HER2 and Ki-67

HER2 Breast IHC results: Score 2+ (please see attachment)

Ki-67: 2% average whole tumor staining

Comment: Patients with breast cancers that are HER2 IHC 3+ or IHC 2+/ISH amplified may be eligible for several therapies that disrupt HER2 signaling pathways. Invasive breast cancers that test 'HER2-negative' (IHC 0, 1+ or 2+/ISH not-amplified) are more

specifically considered HER2-negative for protein overexpression/gene amplification since non-overexpressed levels of the HER2 protein may be present in these cases. Patients with breast cancers that are HER2 IHC 1+ or IHC 2+/ISH not amplified may be

eligible for a treatment that targets non-amplified/non-overexpressed levels of HER2 expression for cytotoxic drug delivery (IHC 0 results do not result in eligibility currently).

Addendum Billing Summary

Immunohistochemistry:

Professional interpretation for HER-2/neu was performed in-house by an MPC/SBCH pathologist at 400 W Pueblo St. Santa Barbara, CA 93105 (CPT 88361 x 2)

Technical component was performed by NeoGenomics Laboratory, 31 Columbia, Aliso Viejo, CA 92656 Addendum electronically signed by Lauren E Jacobson, MD on 1/24/2025 at 2:37 PM

Addendum issued to report HER2 FISH results: Negative (please see attachment)

Addendum Billing Summary

FISH Studies:

Professional component is performed in-house by an MPC Pathologist, 400 W Pueblo, Santa Barbara CA 93105 (CPT 88377 x 1)

Technical component is performed by NeoGenomics (see attached report for address/details)

Addendum electronically signed by Lauren E Jacobson, MD on 1/27/2025 at 11:31 AM

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as 12 o'clock,

making the long lateral suture 3 o'clock. The resection surface is inked according to the normal inking scheme as follows: 12-3 o'clock = yellow, 3-6 o'clock = blue, 6-9 o'clock = black, and 9-12 o'clock = red. The skin is sectioned to reveal pale-tan

to blue-black cut surfaces with subcutaneous fat. The specimen is submitted entirely in cassettes A1-A5 (tips in A1). jdk

Specimen Source: Other

left chest wall flank

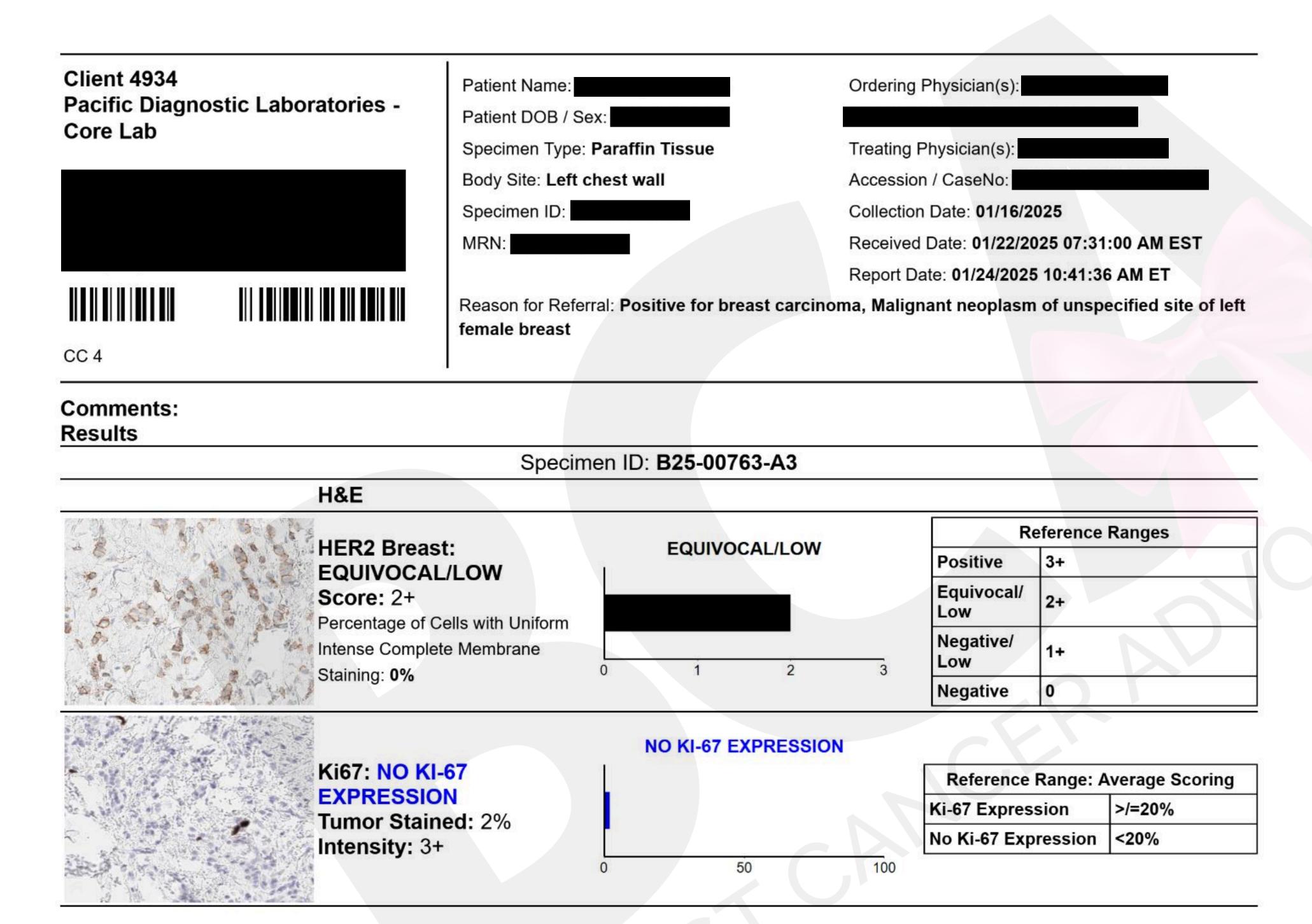
CLINICAL HISTORY: Female Left Chest Wall flank excison of prior possitive punch biopsy for cancer superior

is short and long is lateral

View Image (below)



Histology Image Analysis Multiple Marker Panel



Tissue Fixative:

Specimens for predictive IHC and/or FISH testing should be submitted following CAP guidelines: Incisional and excisional biopsy samples should have a cold ischemia time of no longer than 1 hour and be fixed in 10% neutral buffered formalin (NBF) for intervals ranging from at least 6 hours to no more than 72 hours when testing. The fixative, fixation time and/or cold ischemic time were not provided. A negative result can be a potential false negative due to the possibility of prolonged cold ischemic time, inadequate fixative and/or fixation time. Results should be interpreted with caution.

Cytology specimens should also be fixed in 10% NBF. Please note that body fluid cytology specimens do not have specific cold ischemic time documentation requirements in this setting and are an exception to this statement.

Cold Ischemic Duration: Unknown min(s) Fixative: 10% Neutral Buffered Formalin Fixation Duration: Unknown hours

Intended Use:

Whole slide image capture was performed with the Aperio ScanScope and quantitative computer-assisted image analysis using Indica Labs software.

The digitized slide(s) was/were adequate for quantitative image analysis. All controls were reviewed and showed appropriate positive and negative immunoreactivity.

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Page 1 of 3



Patient Name:
Patient DOB / Sex:
Accession / CaseNo:

Ki67:

Ki-67 is a nuclear protein found in cells in all phases of the cell cycle, except the resting phase (phase G0), and is useful as a marker of cell proliferation. The percentage of Ki-67 positive tumor cells is used to stratify patients into good and poor prognostic groups, but there is lack of consensus guidelines for scoring and best cutoffs for prognosis. Studies that have evaluated proliferation index using Ki-67 by IHC in breast cancer have shown a significant correlation between high proliferation rates and shorter disease free and overall survival.

Scoring and interpretation: The Ki-67 proliferation index is assessed by counting at least three regions, and is reported as percent positive cells based on nuclear expression. The cut-off to define a high Ki-67 proliferation index is not well-established or universally agreed upon. In our laboratory, we use a scoring criteria of <20% of tumor cells with unequivocal nuclear staining of any intensity (>/=1+) is considered diagnostic negative for Ki-67 expression and >/= 20% of tumor cells with unequivocal nuclear staining of any intensity (>/=1+) is considered diagnostic positive for Ki-67 expression with a minimum of 200 viable tumor cells. The scoring criteria of "no Ki-67 expression" versus "Ki-67 expression" represent the level of Ki-67 expression based on these established cut-offs and do not apply to the overall number of positive cells or guidelines for prognostic purposes. The New York State Department of Health has not evaluated any test claims nor reviewed the accuracy of this test.

References:

1. Ki-67LDT as a predictive assay in therapy; A correlation study comparing NeoGenomics LDT to Agilent Ki-67 pharmDx assay. NeoGenomics White Paper. 2022.

HER2 Breast:

HER2, a member of the epidermal growth factor receptor family, is a transmembrane protein with tyrosine kinase activity. Gene amplification and protein overexpression of HER2 have been found in a variety of tumors, including breast carcinomas. The expected overexpression rate varies based on the grade and type of breast cancer. Patients with breast cancers that are HER2 IHC 3+ or IHC 2+/ISH amplified may be eligible for several therapies that disrupt HER2 signaling pathways. Invasive breast cancers that test 'HER2-negative' (IHC 0, 1+ or 2+/ISH not-amplified) are more specifically considered "HER2-negative for protein overexpression/gene amplification" since non-overexpressed levels of the HER2 protein may be present in these cases. Patients with breast cancers that are HER2 IHC 1+ or IHC 2+/ISH not amplified (so-called HER2 Low) may be eligible for a treatment that targets non-amplified/non-overexpressed levels of HER2 expression for cytotoxic drug delivery (IHC 0 results do not result in eligibility currently). The New York State Department of Health has not evaluated any test claims nor reviewed the accuracy of this test. The performance characteristics of this assay have not been validated on decalcified specimens. Results should be interpreted with caution given the likelihood of false negativity on decalcified specimens. Antigenicity of cut tissue sections may diminish over time and is compromised within 6 weeks after cutting from the paraffin block.

Methodology:

Ki67:

Zeta clone MIB1 was used to detect Ki67 in formalin-fixed paraffin-embedded tissue sections. A multimer-technology based system was used for detection.

HER2 Breast:

HER2 staining was performed utilizing the FDA approved Ventana Pathway anti-HER-2/neu antibody (clone 4B5) staining procedure of FFPE specimens using a multimer-based detection system on the Ventana Ultra. Scoring is performed using the 2023 ASCO/CAP HER2 breast guidelines (1). Known artifacts such as edge artifact, tissue retraction and tissue crush may give the false impression of over expression. Care should be taken to avoid assessing these areas, especially in needle core biopsies which generally harbor all of these artifacts (2). Only membrane staining should be assessed in the invasive component of the specimen. The 2023 ASCO/CAP guideline recommendations state that a new HER2 test may be ordered on the excision specimen if the initial HER2 test result in a core needle biopsy specimen of a primary breast cancer is negative and any of the following is observed: the tumor is grade 3, the amount of invasive tumor on the core is small, the resection specimen contains high-grade carcinoma that is morphologically distinct from that in the core, the core biopsy result is equivocal for HER2 after testing by both ISH and IHC, or there is doubt about the specimen handling of the core biopsy (long ischemic time, short time in fixative, different fixative) or the test is suspected by the pathologist to be negative on the basis of testing error. References:

- 1. Wolff AC, Hammond MEH, Allison KH, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. Arch Pathol Lab Med. 2023. 147 (9):993-1000.
- 2. VENTANA PATHWAY anti-HER-2/neu (4B5) package insert

Page 2 of 3

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Patient Name:
Patient DOB / Sex:
Accession / CaseNo:

| Stain | CPT Code | Quantity |
|-------------------|----------|----------|
| Ki67, HER2 Breast | 88361 | 2 |

Electronic Signature

The Accessioning Component, Technical Component Processing and Analysis of this test was completed at NeoGenomics California, 31 Columbia, Aliso Viejo, // CLIA # 05D1021650 / Laboratory Director(s): The Professional Component of this test was completed at Santa Barbara Cottage Hospital, 400 W. Pueblo Attn: Anatomic Pathology Dept, Santa Barbara, CA 93105 / Phone: Fax:

The performance characteristics of the IHC/ISH assays have been validated on formalin-fixed paraffin embedded tissues only. This test was developed and its performance characteristics determined by NeoGenomics Laboratories, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing. For the classification of IHC antibodies, please contact the Client Services team.

Images that may be included within this report are representative of the patient but not all testing in its entirety and should not be used to render a result.

The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.



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Page 3 of 3

View Image (below)





FISH Analysis HER2 Breast

Client 4934 Patient Name: Ordering Physician(s): Pacific Diagnostic Laboratories -Patient DOB / Sex: Core Lab Treating Physician(s): Specimen Type: Paraffin Tissue Body Site: Left chest wall Accession / CaseNo: Specimen ID: Collection Date: 01/16/2025 MRN: Received Date: 01/22/2025 07:31:00 AM EST Report Date: 01/27/2025 12:32:53 PM ET Reason for Referral: Positive for breast carcinoma, Malignant neoplasm of unspecified site of left female breast CC 4

Results: Negative

Interpretation:

Average HER2 signals/nucleus: 1.8
Average CEN 17 signals/nucleus: 1.6
HER2/CEN 17 signal ratio: 1.1
Number of Observers: 1

Results show no evidence of HER2 amplification and a HER2/CEN17 ratio of <2.0 with an average HER2 copy number <4.0 signals per cell. This is a NEGATIVE result.

Methodology: Along with fluorescence in situ hybridization (FISH), an H&E stained slide was reviewed by a pathologist to identify the target area containing invasive tumor. FISH analysis of 50 interphase nuclei was performed within the marked target area using a dual-probe FISH assay. Controls performed appropriately.

Reference: Wolff AC, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer; American Society of Clinical Oncology/ College of American Pathologists Clinical Practice Guideline Focused Update. Arch Pathol Lab Med. 2018;142(11):1364-1382.

Reference Ranges:

HER2 Breast: Based on 2018 CAP/ASCO guidelines, a case is considered POSITIVE when the HER2/CEN17 ratio is >= 2.0 with >= 4.0 HER2 signals/cell [Group 1] and NEGATIVE when the HER2 to CEN17 ratio is <2.0 and <4.0 HER2 signals/cell [Group 5]. If HER2/CEN17 ratio >= 2.0 with average HER2 <4.0 [Group 2], or HER2/CEN17 ratio <2.0 with >= 6.0 HER2 signals/cell [Group 3], or HER2/CEN17 <2.0 with >= 4.0 and <6.0 HER2 signals/cell [Group 4] a definitive diagnosis will be rendered on additional work-up using the HER2 IHC staining with a concomitant workup.

[Groups 2 and 4] If the IHC result is 3+, the case is considered HER2 POSITIVE. If the IHC result is 0 or 1+, the case is considered HER2 NEGATIVE. If the IHC is 2+ the FISH is recounted for an additional 20 cells in the area of invasive cancer with IHC 2+ staining. If reviewing the additional count remains within the bounds of Group 2 or Group 4, then the case is considered NEGATIVE. If the review results in a different ISH category a total of 50 additional cells will be recounted and the result is adjudicated to that final category.

[Group 3] If the IHC result is 3+, the case is considered HER2 POSITIVE. If the IHC result is 0 or 1+, the case is considered HER2 NEGATIVE. If the IHC is 2+ the FISH is recounted for an additional 20 cells in the area of invasive cancer with IHC 2+ staining. If reviewing the additional count remains within the bounds of Group 3, then the case is considered POSITIVE. If the review results in a different ISH category a total of 50 additional cells will be recounted and the result is adjudicated to that final category.

Probe Set Detail:

HER2 Breast: Results show a HER2 to centromere 17 ratio of less than 2.0 and an average HER2 copy number of <4.0 signals per cell following a HER2 breast FISH protocol. This is a NEGATIVE result according to the 2018 ASCO/CAP guidelines.

Comments:

Specimens for predictive IHC and/or FISH testing should be submitted following CAP guidelines: Incisional and excisional biopsy samples should have a cold ischemia time of no longer than 1 hour and be fixed in 10% neutral buffered formalin (NBF) for intervals ranging from at least 6 hours to no more than 72 hours when testing. The fixative, fixation time and/or cold ischemic time were not provided. A negative result can be a potential false negative due to the possibility of prolonged cold ischemic time, inadequate fixative and/or fixation time.

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Health Information Services| Release of Information

Abrams, Roxann L

MRN: DOB: Legal Sex: F

Visit date:

Patient Name:
Patient DOB / Sex:
Accession / CaseNo:

Results should be interpreted with caution.

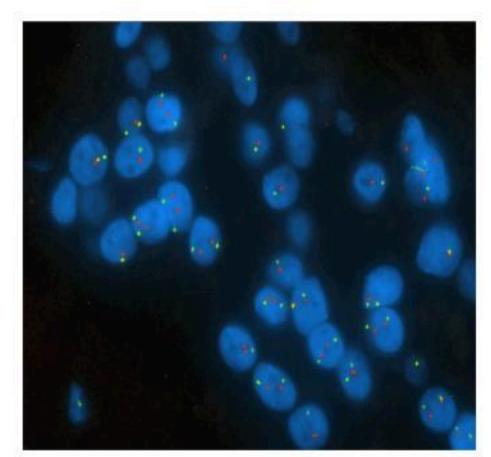
Cytology specimens should also be fixed in 10% NBF. Please note that body fluid cytology specimens do not have specific cold ischemic time documentation requirements in this setting and are an exception to this statement.

Cold Ischemic Duration: Unknown min(s)
Fixative: 10% Neutral Buffered Formalin
Fixation Duration: Unknown hours

Invasive Tumor Nuclei Scored: 50

| Probe set | Scoring method | CPT Code | # of Units |
|-------------|----------------|----------|------------|
| HER2 Breast | Manual | 88377 | 1 |

| HER2 Breast | Mean # of Red Signals | Mean # of Green Signals | Invasive Tumor Nuclei Analyzed |
|---------------|--------------------------|-------------------------------|--------------------------------------|
| Total Counts: | 1.84 | 1.64 | 50 |



FST25-004477 Abrams Roxann L HER2 ALL C.jpg

Electronic Signature

questions regarding coding to the payer being billed.

All controls were within expected ranges.

The Accessioning Component and Technical Component Processing of this test was completed at NeoGenomics California, 31 Columbia, Aliso Viejo, CA / 92656 / 866-776-5907 / CLIA # 05D1021650 / Laboratory Director(s):

The Technical Component Analysis of this test was completed at NeoGenomics Salk Avenue, 2173 Salk Ave., Suite 300, Carlsbad, CA / 92008 / 866-776-5907 / CLIA # 05D1018666 / Laboratory Director(s):

The Professional Component of this test was completed at Santa Barbara Cottage Hospital, 400 W. Pueblo Attn: Anatomic Pathology Dept, Santa Barbara, CA 93105 / Phone:

Analysis Code(s): IF9RYENWW

The HER2 Breast Cancer FISH Test uses a two probe cocktail comprising a HER2 (ERBB2 at 17q12) probe in red and a centromere 17 (D17Z1) probe in green. This test was developed and its performance characteristics determined by the performing laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. This laboratory is regulated under CLIA '88 as qualified to perform high complexity testing. Interphase FISH does not include examination of the entire chromosomal complement.

Images that may be included within this report are representative of the patient but not all testing in its entirety and should not be used to render a result.

The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any

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Page 2 of 2

View Image (below)



Abrams, Roxann L
MRN: DOB:
Visit date:

Legal Sex: F





| PRACTICE INFORMATION | REPO | ORT INFORMATION | P/ | ATIENT INFORMATION |
|----------------------|--------------|--------------------------|--------|--------------------|
| Provider: | Report statu | Report status: See Below | | |
| Recipient: | Encounter N | No.: | Phone: | |
| Phone: O: | Printed: | 1/27/2025 11:31 AM | DOB: | AGE: |
| Code: | | | MRN: | SEX: Female |
| | Comment: | | | |
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| Addross: | | | | |
| Address: | | | | |
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Addended Report: TISSUE EXAM

Surgical Pathology-PDC (Final result)

Authorizing Provider:

Ordering Location:
Pathologist:

Ordering Provider:

Collected:
Received:

O1/16/2025 1400
01/16/2025 1819

Specimens

A Skin, left chest wall

FINAL DIAGNOSIS

Skin, left chest wall flank, excision:

- -- Positive for breast carcinoma, focally involving 12-3 and 3-6:00 margins
- -- Background skin with scar and tattoo ink

Electronically signed by

IHC

Block(s): A3

Population: Carcinoma

Antibody Patient Results/Comments

Keratin 7 Positive GATA3 Positive

Interpretation: Findings support breast carcinoma.

Internal and external IHC controls were reviewed and are satisfactory. All above stains are single (non-cocktail/multiplex) unless otherwise indicated.

ESTROGEN/PROGESTERONE RECEPTOR IMMUNOHISTOCHEMISTRY

Block: A3

Estrogen receptor: POSITIVE (2-3+ intensity, 70-80% of cells staining)

Progesterone receptor: **NEGATIVE** (<1% of cells staining)

Comment: HER-2/neu and Ki-67 testing are pending, with results to be reported by addendum.

ER/PR internal control: Absent; External control: Satisfactory.

Cold ischemic time: Unknown

Specimen: Formalin fixed 6-72 hours, paraffin embedded tissue.

Patient results interpreted using ASCO-CAP ER/PgR guidelines. Staining intensity is graded 0-3+. Nuclear staining in <1% of tumor cells is scored as negative. Estrogen Antibody - Leica Clone 6F11, Progesterone Antibody - Leica clone PgR 16.

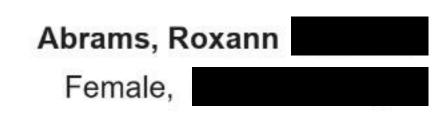
Reference: Allison KH et al. Estrogen and Progesterone Receptor Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Guideline Update. Arch Pathol Lab Med 2020; 144: p545-563.

Technical component for the stains listed above was performed by Pacific Diagnostic Laboratories at 454 S Patterson Ave, Santa Barbara, CA 93111

Page 1 of 10







Professional interpretation for the stains listed above was performed by manual morphometric analysis in-house by an MPC/SBCH pathologist at 400 W Pueblo St. Santa Barbara, CA 93105

The reported immunochemical stain(s) were developed and their performance characteristics determined by Pacific Diagnostic Laboratories. They 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. This test is used for clinical purposes and should not be regarded as investigational or research. This laboratory is certified under the Clinical Laboratory Improvement Amendment of 1988 (CLIA) as qualified to perform high complexity clinical testing.

ADDENDUM

Addendum issued to report IHC results for HER2 and Ki-67

HER2 Breast IHC results: **Score 2+** (please see attachment) Ki-67: 2% average whole tumor staining

Comment: Patients with breast cancers that are HER2 IHC 3+ or IHC 2+/ISH amplified may be eligible for several therapies that disrupt HER2 signaling pathways. Invasive breast cancers that test 'HER2-negative' (IHC 0, 1+ or 2+/ISH not-amplified) are more specifically considered "HER2-negative for protein overexpression/gene amplification" since non-overexpressed levels of the HER2 protein may be present in these cases. Patients with breast cancers that are HER2 IHC 1+ or IHC 2+/ISH not amplified may be eligible for a treatment that targets non-amplified/non-overexpressed levels of HER2 expression for cytotoxic drug delivery (IHC 0 results do not result in eligibility currently).

Addendum Billing Summary

Immunohistochemistry:

Professional interpretation for HER-2/neu was performed in-house by an MPC/SBCH pathologist at 400 W Pueblo St. Santa Barbara, CA 93105 (CPT 88361 x 2)

Technical component was performed by NeoGenomics Laboratory, 31 Columbia, Aliso Viejo, CA 92656

Addendum electronically signed by

ADDENDUM

Addendum issued to report HER2 FISH results: Negative (please see attachment)

Addendum Billing Summary

FISH Studies:

Professional component is performed in-house by an MPC Pathologist, 400 W Pueblo, Santa Barbara CA 93105 (CPT 88377 x 1) Technical component is performed by NeoGenomics (see attached report for address/details)

Addendum electronically signed by

GROSS DESCRIPTION

Received in formalin, labeled with the patient's name and designated on the requisition as "left chest wall flank" is a 3.4 x 1.2 cm oriented skin ellipse, excised to a depth of up to 1.4 cm. The epidermis is pale-tan and hyper wrinkled with a centralized 0.5 cm pale-tan to blue and irregular lesion. There is a long suture at 1 tip designating lateral, and a short suture on a broad margin designating superior. The short superior submitted is re designated by the prosector as 12 o'clock, making the long lateral suture 3 o'clock. The resection surface is inked according to the normal inking scheme as follows: 12-3 o'clock = yellow, 3-6 o'clock = blue, 6-9 o'clock = black, and 9-12 o'clock = red. The skin is sectioned to reveal pale-tan to blue-black cut surfaces with subcutaneous fat. The specimen is submitted entirely in cassettes A1-A5 (tips in A1). jdk

CLINICAL HISTORY

Specimen Source: Other left chest wall flank

CLINICAL HISTORY: Female Left Chest Wall flank excison of prior possitive punch biopsy for cancer superior is

short and long is lateral

Proposed Charges

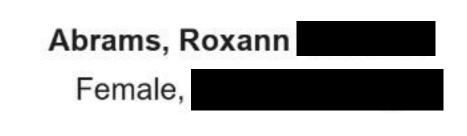
Charge Code Qty Charge Code Qty Charge Code Qty 88305 (CPT®) 1 88341 (CPT®) 1 88341 (CPT®) 1

Page 2 of 10









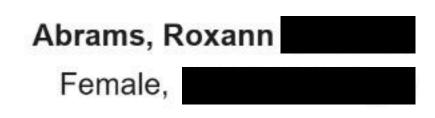
| Charge Cod | le Qty | Charge Code | Qty | Charge Code | Qty | |
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| 88360 (CPT®) | 1 | 88360 (CPT®) | 1 | 88361 (CPT®) | 1 | |
| 88377 (CPT®) | 1 | 88361 (CPT®) | 1 | | | |

Document on 1/24/2025 1331 by Leilany Lynch: Histology Image Analysis Multiple Marker Panel - NeoG B25-00763.pdf:



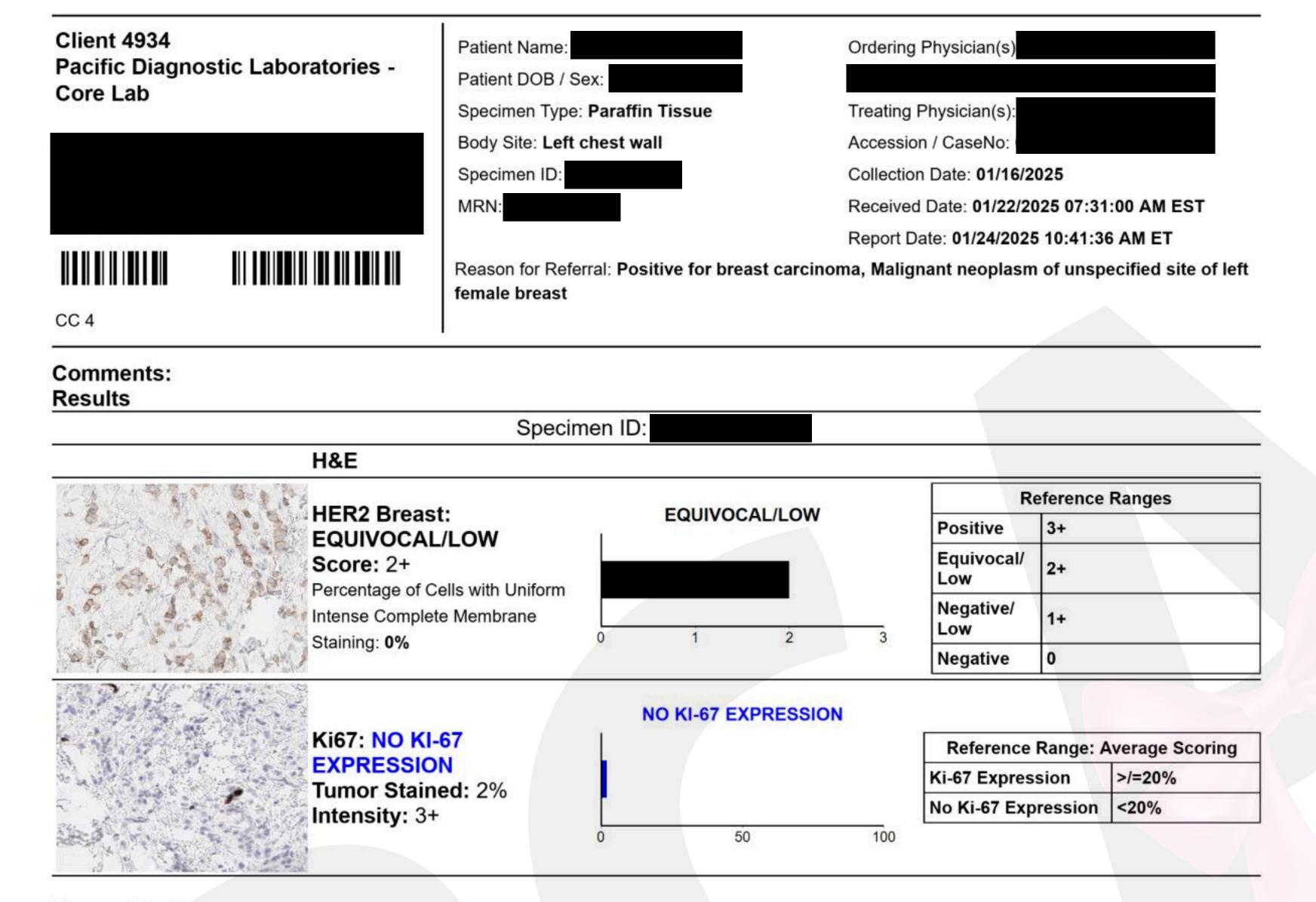
Page 3 of 10







Histology Image Analysis Multiple Marker Panel



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Fixation Duration: Unknown hours

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Health Information Services | Release of Information

Abrams, Roxann L
MRN: DOB: Legal Sex: F
Visit date:



| Abrams, Roxa | nn |
|--------------|----|
| Female, | |

| Patient Name: Abrams, Roxann | |
|------------------------------|--|
| Patient DOB / Sex: | |
| Accession / CaseNo: | |

Ki67:

Ki-67 is a nuclear protein found in cells in all phases of the cell cycle, except the resting phase (phase G0), and is useful as a marker of cell proliferation. The percentage of Ki-67 positive tumor cells is used to stratify patients into good and poor prognostic groups, but there is lack of consensus guidelines for scoring and best cutoffs for prognosis. Studies that have evaluated proliferation index using Ki-67 by IHC in breast cancer have shown a significant correlation between high proliferation rates and shorter disease free and overall survival.

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Methodology:

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References:

- Wolff AC, Hammond MEH, Allison KH, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. Arch Pathol Lab Med. 2023. 147 (9):993-1000.
- 2. VENTANA PATHWAY anti-HER-2/neu (4B5) package insert

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Abrams, Roxann L
MRN: DOB:
Visit date:

Legal Sex: F





Patient Name: **Abrams, Roxann**Patient DOB / Sex:
Accession / CaseNo:

| Stain | CPT Code | Quantity |
|-------------------|----------|----------|
| Ki67, HER2 Breast | 88361 | 2 |

Electronic Signature

The performance characteristics of the IHC/ISH assays have been validated on formalin-fixed paraffin embedded tissues only. This test was developed and its performance characteristics determined by NeoGenomics Laboratories, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing. For the classification of IHC antibodies, please contact the Client Services team.

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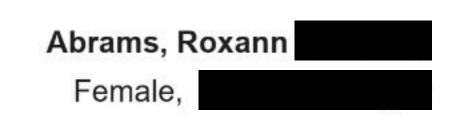
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Document on 1/27/2025 1106 by Angela Lind: FISH Analysis HER2 Breast - NeoG B25-00763.pdf:









FISH Analysis HER2 Breast

Client 4934 Patient Name: Abrams, Roxann L Ordering Physician(s): Pacific Diagnostic Laboratories -Patient DOB / Sex: Core Lab Specimen Type: Paraffin Tissue Treating Physician(s) Body Site: Left chest wall Accession / CaseNo: Specimen ID: Collection Date: 01/16/2025 MRN: Received Date: 01/22/2025 07:31:00 AM EST Report Date: 01/27/2025 12:32:53 PM ET Reason for Referral: Positive for breast carcinoma, Malignant neoplasm of unspecified site of left female breast CC 4

Results: Negative

Interpretation:

Average HER2 signals/nucleus: 1.8
Average CEN 17 signals/nucleus: 1.6
HER2/CEN 17 signal ratio: 1.1
Number of Observers: 1

Results show no evidence of HER2 amplification and a HER2/CEN17 ratio of <2.0 with an average HER2 copy number <4.0 signals per cell. This is a NEGATIVE result.

Methodology: Along with fluorescence in situ hybridization (FISH), an H&E stained slide was reviewed by a pathologist to identify the target area containing invasive tumor. FISH analysis of 50 interphase nuclei was performed within the marked target area using a dual-probe FISH assay. Controls performed appropriately.

Reference: Wolff AC, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer; American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. Arch Pathol Lab Med. 2018;142(11):1364-1382.

Reference Ranges:

HER2 Breast: Based on 2018 CAP/ASCO guidelines, a case is considered POSITIVE when the HER2/CEN17 ratio is >= 2.0 with >= 4.0 HER2 signals/cell [Group 1] and NEGATIVE when the HER2 to CEN17 ratio is <2.0 and <4.0 HER2 signals/cell [Group 5]. If HER2/CEN17 ratio >= 2.0 with average HER2 <4.0 [Group 2], or HER2/CEN17 ratio <2.0 with >= 6.0 HER2 signals/cell [Group 3], or HER2/CEN17 <2.0 with >= 4.0 and <6.0 HER2 signals/cell [Group 4] a definitive diagnosis will be rendered on additional work-up using the HER2 IHC staining with a concomitant workup.

[Groups 2 and 4] If the IHC result is 3+, the case is considered HER2 POSITIVE. If the IHC result is 0 or 1+, the case is considered HER2 NEGATIVE. If the IHC is 2+ the FISH is recounted for an additional 20 cells in the area of invasive cancer with IHC 2+ staining. If reviewing the additional count remains within the bounds of Group 2 or Group 4, then the case is considered NEGATIVE. If the review results in a different ISH category a total of 50 additional cells will be recounted and the result is adjudicated to that final category.

[Group 3] If the IHC result is 3+, the case is considered HER2 POSITIVE. If the IHC result is 0 or 1+, the case is considered HER2 NEGATIVE. If the IHC is 2+ the FISH is recounted for an additional 20 cells in the area of invasive cancer with IHC 2+ staining. If reviewing the additional count remains within the bounds of Group 3, then the case is considered POSITIVE. If the review results in a different ISH category a total of 50 additional cells will be recounted and the result is adjudicated to that final category.

Probe Set Detail:

HER2 Breast: Results show a HER2 to centromere 17 ratio of less than 2.0 and an average HER2 copy number of <4.0 signals per cell following a HER2 breast FISH protocol. This is a NEGATIVE result according to the 2018 ASCO/CAP guidelines.

Comments:

Specimens for predictive IHC and/or FISH testing should be submitted following CAP guidelines: Incisional and excisional biopsy samples should have a cold ischemia time of no longer than 1 hour and be fixed in 10% neutral buffered formalin (NBF) for intervals ranging from at least 6 hours to no more than 72 hours when testing. The fixative, fixation time and/or cold ischemic time were not provided. A negative result can be a potential false negative due to the possibility of prolonged cold ischemic time, inadequate fixative and/or fixation time.

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Page 1 of 2

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| Abrams, Ro | oxann |
|------------|-------|
| Female, | |

Patient Name: Abrams, Roxann
Patient DOB / Sex:
Accession / CaseNo:

Results should be interpreted with caution.

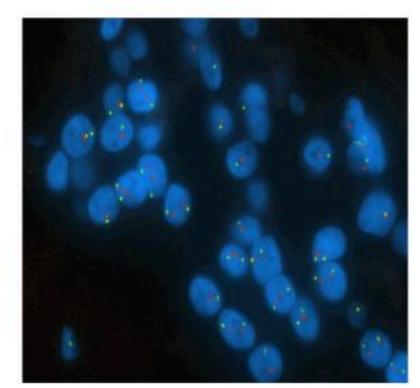
Cytology specimens should also be fixed in 10% NBF. Please note that body fluid cytology specimens do not have specific cold ischemic time documentation requirements in this setting and are an exception to this statement.

Cold Ischemic Duration: Unknown min(s)
Fixative: 10% Neutral Buffered Formalin
Fixation Duration: Unknown hours

Invasive Tumor Nuclei Scored: 50

| Probe set | Scoring method | CPT Code | # of Units |
|-------------|----------------|----------|------------|
| HER2 Breast | Manual | 88377 | 1 |

| HER2 Breast | Mean # of Red Signals | Mean # of Green Signals | Invasive Tumor Nuclei Analyzed |
|---------------|--------------------------|-------------------------------|--------------------------------------|
| Total Counts: | 1.84 | 1.64 | 50 |



FST25-004477 Abrams Roxann L HER2 ALL C.jpg

Electronic Signature

All controls were within expected ranges.

The Accessioning Component and Technical Component Processing of this test was completed at NeoGenomics California, 31 Columbia, Aliso Viejo, CA / 92656 / 866-776-5907 / CLIA # 05D1021650 / Laboratory Director(s):

The Technical Component Analysis of this test was completed at NeoGenomics Salk Avenue, 2173 Salk Ave., Suite 300, Carlsbad, CA / 92008 / 866-776-5907 / CLIA # 05D1018666 / Laboratory Director(s):

The Professional Component of this test was completed at Santa Barbara Cottage Hospital, 400 W. Pueblo Attn: Anatomic Pathology Dept, Santa Barbara, CA 93105 / Phone:

Analysis Code(s): IF9RYENWW

The HER2 Breast Cancer FISH Test uses a two probe cocktail comprising a HER2 (ERBB2 at 17q12) probe in red and a centromere 17 (D17Z1) probe in green. This test was developed and its performance characteristics determined by the performing laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. This laboratory is regulated under CLIA '88 as qualified to perform high complexity testing. Interphase FISH does not include examination of the entire chromosomal complement.

Images that may be included within this report are representative of the patient but not all testing in its entirety and should not be used to render a result.

The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

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Performing Lab CL CLIA License #:

Director:

The interpretations of all normal gynecologic specimens and the technical components for all surgical and autopsy pathology as well as cytology specimens, except for flow cytometry or unless otherwise designated as performed by an outside laboratory, were performed at Pacific Diagnostics Laboratory (PDL) Core Laboratory, 454 S. Patterson Avenue, Santa Barbara, CA 93111. The professional interpretations, including intraoperative, microscopic and macroscopic evaluations for all pathology specimens, except for normal gynecologic cytology specimens, were performed at Santa Barbara Cottage Hospital (CLIA# 05D0584831), 400 W. Pueblo Street, Santa Barbara, CA 93105. The diagnosis was made using microscopic evaluation of representative tissue sections unless otherwise specified. All standard and special cellular stains were developed and their performance characteristics were determined by PDL Core Laboratory. For flow cytometry, the performance characteristics as well as the technical and professional components were performed at Santa Barbara Cottage Hospital (CLIA# 05D0584831). Intraoperative evaluations for Goleta Valley Cottage Hospital radiologist-procured specimens were performed at Goleta Valley Cottage Hospital, 351 S. Patterson Ave. Santa Barbara, CA 93111. The Laboratory Medical Director for all of the aforementioned facilities is

Please note that the CPT codes listed may not reflect final billing.

Legend



Page 10 of 10

| Order | SURGICAL PATHOLOGY | (Order |
|---|-------------------------------------|-----------|
| SURGICAL PATHOLOGY Electronically signed by: Mode: Ordering in Per protocol mode Ordering user: Authorized by: Frequency: 02/13/25 - | Communicated by: Ordering provider: | Completed |



SURGICAL PATHOLOGY

(continued)

Diagnoses

Recurrent breast cancer, left (CMS/HCC) [C50.912]

Questionnaire

Question

Answer

Specimen Source:

Other Comment - left lateral flank

Order comments: A:Left flank skin wide excision suture: short=superior, long=lateral TOB:0846 Form:0848

Result SURGICAL PATHOLOGY (Order

Resulted: 02/18/25 1727, Result status: Final

result

SURGICAL PATHOLOGY

Ordering provider:

Resulting lab: PACIFIC DIAGNOSTIC LAB

Narrative:

A:Left flank skin wide excision suture: short=superior, long=lateral TOB:0846 Form:0848

Specimen Source: Other

left lateral flank

Surgical Pathology-PDC

Authorizing Provider:

Case:

Collected: 02/13/2025 0846

Received:

Ordering Location: LAB INTERFACED ORDERS

02/13/2025 0952

Pathologist:

Specimen: Skin, Left flank skin wide excision suture: short=superior, long=lateral

Skin, left flank, wide excision:

-- Residual invasive lobular carcinoma, <0.5 mm to anterior medial margin

-- Background surgical site changes

Electronically signed by

Technical component for the stains listed below was performed by Pacific Diagnostic Laboratories at 454 S Patterson Ave, Santa Barbara, CA 93111

Professional interpretation for the stains listed below was performed in-house by an MPC/SBCH pathologist at 400 W Pueblo St. Santa Barbara, CA 93105

Block(s): A1

Population: Areas of interest

Antibody Patient Results/Comments

Keratin AE1/3 Negative

Block(s): A2

Population: Areas of interest

Antibody Patient Results/Comments

Keratin 7 Positive

Interpretation: Keratins highlight residual invasive lobular carcinoma in block A2, and relationship to margins.

Internal and external IHC controls were reviewed and are satisfactory. All above stains are single (non-cocktail/multiplex) unless otherwise indicated.

The reported immunochemical stain(s) were developed and their performance characteristics determined by Pacific Diagnostic Laboratories. They 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. This test is used for clinical purposes and should not be regarded as investigational or research. This laboratory is certified under the Clinical Laboratory Improvement Amendment of 1988 (CLIA) as qualified to

perform high complexity clinical testing.



Received in formalin labeled "left flank skin" is a 16 g ellipse of skin with a short suture designating the superior broad margin and a long suture designating the lateral tip. The specimen measures as follows:

Medial-lateral 7.1 cm Superior-inferior 3.2 cm Anterior-posterior 1.6 cm Anterior skin ellipse 6.6 x 2.4 cm

The epidermis is pale-tan with a 4.2 cm partially healed, curvilinear scar running from the medial tip through the center of the specimen. The margins are received inked by the surgeon as follows:

Superior Red Inferior Green Medial Blue Lateral Yellow Anterior Orange Posterior Black

The specimen is serially sectioned from medial to lateral into 22 slices to reveal fibrosis, fat necrosis and embedded sutures deep to the scar. No residual tumor is grossly visualized or palpated. The scar and fat necrosis involve slices 1-15, and the

fat necrosis extends to a depth of 1.1 cm into the subcutaneous fat, 0.4 cm from the deep margin. Representative sections are submitted, sequentially, as labeled:

Cassette summary

Block 1 = slices 1 and 22, medial and lateral tips

Block 2 = slice 3

Block 3 =slice 5

Block 4 = slice 7

Blocks 5-6 =slice 9, bisected

Blocks 7-8 = slice 11, bisected

Blocks 9-10 = slice 13, bisected

Blocks 11-12 = slice 15, bisected, lateral most aspect of the scar

Blocks 13-14 = slice 16, bisected, tissue immediately lateral to the scar

Block 15 =slice 19

Block 16 = slice 2

Block 17 = slice 4

The specimen is removed from the body at 08:46 on 02/13/2025 and placed into formalin at 08:48. The specimen is sectioned returned to formalin at 10:19 on the same day, making the total cold ischemic time roughly 1 hour and 37 minutes. The specimen is

submitted for processing on the evening of 02/13/2025.

/ame

A:Left flank skin wide excision suture: short=superior, long=lateral TOB:0846 Form:0848

Specimen Source: Other

left lateral flank

Specimen Information

| ID | Туре | Source | Collected On | |
|----|--------|--------|---------------|--|
| | Tissue | Skin | 02/13/25 0846 | |

Testing Performed By

| Lab - Abbreviation | Name | Director | Address | Valid Date Range |
|--------------------|---------------------------|----------|---------|-------------------------|
| 19 - PDL | PACIFIC DIAGNOSTIC LAB | | | 12/05/24 1327 - Present |



Abrams, Roxann L DOB: Legal Sex: F MRN: Visit date:

SANTA BARBARA CA 93111

Resulted: 02/18/25 1727, Result status: Final

result

SURGICAL PATHOLOGY

Resulting lab: PACIFIC DIAGNOSTIC LAB

Narrative:

A:Left flank skin wide excision suture: short=superior, long=lateral TOB:0846

Specimen Source: Other

left lateral flank

Ordering provider:

Surgical Pathology-PDC

Case:

Authorizing Provider: Collected: 02/13/2025 0846

Ordering Location: LAB INTERFACED ORDERS Received: 02/13/2025 0952

Pathologist:

Skin, Left flank skin wide excision suture: short=superior, long=lateral Specimen:

Skin, left flank, wide excision:

- -- Residual invasive lobular carcinoma, <0.5 mm to anterior medial margin
- -- Background surgical site changes

Electronically signed by

Technical component for the stains listed below was performed by Pacific Diagnostic Laboratories at 454 S Patterson Ave, Santa Barbara, CA 93111

Professional interpretation for the stains listed below was performed in-house by an MPC/SBCH pathologist at 400 W Pueblo St. Santa Barbara, CA 93105

Block(s): A1

Population: Areas of interest

Antibody Patient Results/Comments

Keratin AE1/3 Negative

Block(s): A2

Population: Areas of interest

Antibody Patient Results/Comments

Keratin 7 Positive

Interpretation: Keratins highlight residual invasive lobular carcinoma in block A2, and relationship to margins.

Internal and external IHC controls were reviewed and are satisfactory. All above stains are single (noncocktail/multiplex) unless otherwise indicated.

The reported immunochemical stain(s) were developed and their performance characteristics determined by Pacific Diagnostic Laboratories. They have not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such

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Superior Red Inferior Green Medial Blue Lateral Yellow Anterior Orange Posterior Black

The specimen is serially sectioned from medial to lateral into 22 slices to reveal fibrosis, fat necrosis and embedded sutures deep to the scar. No residual tumor is grossly visualized or palpated. The scar and fat necrosis involve slices 1-15, and the

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submitted for processing on the evening of 02/13/2025.

/ame

A:Left flank skin wide excision suture: short=superior, long=lateral TOB:0846 Form:0848

Specimen Source: Other

left lateral flank

View Image (below)



Health Information Services| Release of Information

Abrams, Roxann L

MRN: DOB: Legal Sex: F

Visit date:





| The second secon | PORT INFORMATION | 334 | PATIENT INFORMATION |
|--|-----------------------|---|-------------------------|
| Report sta | atus: See Below | Name: | |
| Encounter | No.: | Phone: | |
| Printed: | 2/18/2025 5:27 PM | DOB: | AGE: |
| | | MRN: | SEX: Female |
| Comment | | | |
| | | | |
| | | | |
| | | | |
| | Encounter Printed: | Report status: See Below Encounter No.: Printed: 2/18/2025 5:27 PM Comment: | Encounter No.: Phone: |

Surgical Pathology-PDC (Final result)

Authorizing Provider:
Ordering Location:
Pathologist:

Ordering Provider:

Collected:
Co

Specimens

A Skin, Left flank skin wide excision suture: short=superior, long=lateral

FINAL DIAGNOSIS

Skin, left flank, wide excision:

- -- Residual invasive lobular carcinoma, <0.5 mm to anterior medial margin
- -- Background surgical site changes

Electronically signed by

IHC

Technical component for the stains listed below was performed by Pacific Diagnostic Laboratories at 454 S Patterson Ave, Santa Barbara, CA 93111 Professional interpretation for the stains listed below was performed in-house by an MPC/SBCH pathologist at 400 W Pueblo St. Santa Barbara, CA 93105

Block(s): A1

Population: Areas of interest

Antibody Patient Results/Comments
Keratin AE1/3 Negative

Block(s): A2 Population: Areas of interest

Antibody Patient Results/Comments

Keratin 7 Positive

Interpretation: Keratins highlight residual invasive lobular carcinoma in block A2, and relationship to margins.

Internal and external IHC controls were reviewed and are satisfactory. All above stains are single (non-cocktail/multiplex) unless otherwise indicated.

The reported immunochemical stain(s) were developed and their performance characteristics determined by Pacific Diagnostic Laboratories. They 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. This test is used for clinical purposes and should not be regarded as investigational or research. This laboratory is certified under the Clinical Laboratory Improvement Amendment of 1988 (CLIA) as qualified to perform high complexity clinical testing.

GROSS DESCRIPTION

Received in formalin labeled "left flank skin" is a 16 g ellipse of skin with a short suture designating the superior broad margin and a long suture designating the lateral tip. The specimen measures as follows:

Page 1 of 3



| Abrams, Rox | xann L |
|-------------|--------|
| MRN: | DOB: |
| Visit date: | |

Legal Sex: F





| Medial-lateral | 7.1 cm |
|-----------------------|--------------|
| Superior-inferior | 3.2 cm |
| Anterior-posterior | 1.6 cm |
| Anterior skin ellipse | 6.6 x 2.4 cm |

The epidermis is pale-tan with a 4.2 cm partially healed, curvilinear scar running from the medial tip through the center of the specimen. The margins are received inked by the surgeon as follows:

| Superior | Red |
|-----------|--------|
| Inferior | Green |
| Medial | Blue |
| Lateral | Yellow |
| Anterior | Orange |
| Posterior | Black |

The specimen is serially sectioned from medial to lateral into 22 slices to reveal fibrosis, fat necrosis and embedded sutures deep to the scar. No residual tumor is grossly visualized or palpated. The scar and fat necrosis involve slices 1-15, and the fat necrosis extends to a depth of 1.1 cm into the subcutaneous fat, 0.4 cm from the deep margin. Representative sections are submitted, sequentially, as labeled:

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// Ame

CLINICAL HISTORY

A:Left flank skin wide excision suture: short=superior, long=lateral TOB:0846 Form:0848 Specimen Source: Other left lateral flank

Proposed Charges

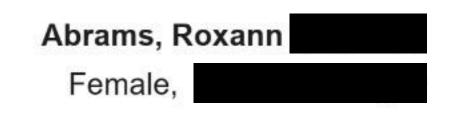
| Charge Cod | le Qty | Charge Code | Qty | Charge Code | Qty | |
|----------------|--------------------|--------------|-----|--------------|-----|--|
| 88305 (CPT®) | 1 | 88341 (CPT®) | 1 | 88341 (CPT®) | 1 | |
| Performing Lab | CL CLIA License #: | Director: | | | | |

The interpretations of all normal gynecologic specimens and the technical components for all surgical and autopsy pathology as well as cytology specimens, except for flow cytometry or unless otherwise designated as performed by an outside laboratory, were performed at Pacific Diagnostics Laboratory (PDL) Core Laboratory, 454 S. Patterson Avenue, Santa Barbara, CA 93111. The professional interpretations, including intraoperative, microscopic and macroscopic evaluations for all pathology specimens, except for normal gynecologic cytology specimens, were performed at Santa Barbara Cottage Hospital (CLIA# 05D0584831), 400 W. Pueblo Street, Santa Barbara, CA 93105. The diagnosis was made using microscopic evaluation of representative tissue sections unless otherwise specified. All standard and special cellular stains were developed and

Page 2 of 3







their performance characteristics were determined by PDL Core Laboratory. For flow cytometry, the performance characteristics as well as the technical and professional components were performed at Santa Barbara Cottage Hospital (CLIA# 05D0584831). Intraoperative evaluations for Goleta Valley Cottage Hospital radiologist-procured specimens were performed at Goleta Valley Cottage Hospital, 351 S. Patterson Ave. Santa Barbara, CA 93111. The Laboratory Medical Director for all of the aforementioned facilities is

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Legend



END OF REPORT