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FAX TRANSMISSION

Recipient Name: **SIMONMED IMAGING - AMFL84974**
Delivery Date/Time : 10/11/2024 13:31 CDT
Total Cases: **1**
Batch#: **AMP: 78159664**
Courier Route#: **AP20**

LAB INFORMATION

4225 E. Fowler Ave
Suite B
Tampa,FL 33617
Phone1: 800-395-7284
Fax: 813-533-5346

REPORTS INCLUDED

Accession #	**FL24-004150-BR**	Patient Name:	ROMERO TIBABUZO, DIANA MARCELA	Encounter #
Reported:	**10/11/2024**	Physician Name:	USMANI, OMAR	MRN #
Patient ID:	**9416712**	Priority:	ROUTINE	

*** END OF COVER SHEET ***

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PATIENT INFORMATION	PHYSICIAN INFORMATION
ROMERO TIBABUZO, DIANA MARCELA SEX: F AGE: 41Y **DOB:** 03/04/1983 Patient ID: 9416712	**OMAR USMANI, MD** SIMONMED IMAGING - AMFL84974 [AMFL84974] 10125 W COLONIAL DR, STE 114 OCOEE, FL 34761 Phone: 407-531-7100 AP20

SPECIMEN INFORMATION

Collected: 10/4/2024
Received: 10/4/2024
Reported: 10/11/2024

Accession #: **FL24-004150-BR**

SURGICAL PATHOLOGY REPORT

DIAGNOSIS

RIGHT BREAST, 10:00, 5 CM FROM NIPPLE, STEREOTACTIC BIOPSY:

DUCTAL CARCINOMA IN SITU, SOLID AND CRIBRIFORM, INTERMEDIATE TO HIGH NUCLEAR GRADE, ASSOCIATED WITH COMEDONECROSIS AND CALCIFICATIONS.

THE DUCTAL CARCINOMA IN SITU IS PRESENT IN THREE OUT OF THREE BLOCKS WITH THE TUMOR MAXIMUM CONTIGUOUS LINEAR DIMENSION MEASURING 5.0 MM.

PROGNOSTIC MARKERS ARE PENDING ON BLOCK A3.

COMMENT: KEY PORTIONS OF THIS CASE HAVE BEEN REVIEWED BY ONE OR MORE PATHOLOGISTS.

Rawia S. Yassin, MD
Electronic Signature: 11 OCT 2024 01:58 PM

CLINICAL INFORMATION

CLINICAL INFORMATION:
MAMMOGRAM, SUSPICIOUS CALCIFICATIONS

SPECIMEN DATA

GROSS DESCRIPTION:
A. Received in 10% Neutral Buffered Formalin labeled with the patient name and "right breast 10:00 5 cm from nipple" are six cores of tan-yellow fibrofatty tissue ranging from 1.5 x 0.2 x 0.1 cm to 1.8 x 0.2 x 0.1 cm. Entirely submitted in six piece(s) in three cassette(s). Two pieces/cassette from cassette A1 to cassette A3.

Time and date of collection: 10:25 a.m., 10/04/2024.
Time and date placed in formalin: 10:27 a.m., 10/04/2024.
Time and date removed from formalin: 6:00 a.m., 10/05/2024.

The gross examination of this/these specimen(s) is/are performed at Ameripath Florida, 4225 E. Fowler Avenue, Tampa, FL 33617.
Medical Director: Piotr A. Borkowski, CLIA 10D2025224

MICROSCOPIC DESCRIPTION:
A MICROSCOPIC EXAMINATION WAS PERFORMED TO ARRIVE AT THE DIAGNOSTIC CONCLUSION REPORTED.

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PATIENT INFORMATION

ROMERO TIBABUZO, DIANA MARCELA
SEX: F
AGE: 41Y **DOB:** 03/04/1983
Patient ID: 9416712

PHYSICIAN INFORMATION

OMAR USMANI, MD
SIMONMED IMAGING - AMFL84974
[AMFL84974]
10125 W COLONIAL DR, STE 114
OCOEE, FL 34761
Phone: 407-531-7100 AP20

SPECIMEN INFORMATION

Collected: 10/4/2024
Received: 10/4/2024
Reported: 10/11/2024
Accession #: **FL24-004150-BR**

PROGNOSTIC MARKERS

PROCESSING INFORMATION

Specimen Type and Site: RIGHT BREAST, 10:00, 5 CM FROM NIPPLE, STEREOTACTIC BIOPSY
Time of Tissue Acquisition to Fixation: 2 MINUTES
Type of Fixation: FORMALIN
Specimen ID #: A3
Duration of Fixation: 19 HOURS, 33 MINUTES
Processing Type: PARAFFIN BLOCK

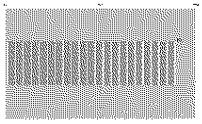
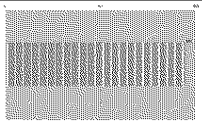
RESULTS

Case Comments

PLEASE SEE THE SURGICAL PATHOLOGY REPORT FOR DIAGNOSIS, GRADING, AND DESCRIPTION OF THE TUMOR.

KEY

- Favorable
- Unfavorable
- Intermediate/ Equivocal

Test	Interpretation; %Positive; Stain Intensity Avg	Comments
ER Estrogen Receptor	 (0 - 100%) **Positive 90% Strong Intensity**	Specimen is adequate for interpretation. Internal controls stained appropriately.
PR Progesterone Receptor	 (0 - 100%) **Positive 95% Strong Intensity**	Specimen is adequate for interpretation. Internal controls stained appropriately.

Rawia S. Yassin, MD
Electronic Signature: 11 OCT 2024 02:30 PM

Copy-To-Physicians: TATE-SOLOMON, DANA, MD

The CPT codes provided are for information purposes only, and are based on AMA guidelines without regard to specific payor requirements.

CPT Codes : 88360x2, 88305

APPENDIX A: Breast Cancer Analysis Using IHC / ISH with Pathologist Review

ER Antibody: This antibody is intended for in vitro diagnostic (IVD) use. CONFIRM anti-ER(SP1), an FDA 510(k) cleared Ventana monoclonal rabbit antibody recognizing ER alpha, has been shown to react with 66 kD protein from MCF-7 cells via Western blotting and the protein size is in agreement with that predicted from the cloning of the gene for ER. According to the current CAP/ASCO guidelines for breast cancer[1] a case is considered ER positive if there is staining of the nucleus greater than 10% of tumor cells and ER low positive if there is staining of the nucleus between 1 – 10%[2].

PR Antibody: This antibody is intended for in vitro diagnostic (IVD) use. CONFIRM anti-PR(1E2), an FDA 510(k) cleared Ventana monoclonal rabbit antibody recognizing the A and B forms of human PR, has been shown to react with 60 kD, 87 kD and 110 kD proteins from T47D cells via Western blotting. The protein sizes are in agreement with the predicted molecular weight of progesterone receptor forms A, B and C. A case is considered PR positive if there is staining of the nucleus in equal to or greater than 1% of tumor cells[2].

Her2/neu Antibody: This antibody is intended for in vitro diagnostic (IVD) use. Ventana PATHWAY anti-HER2/neu(4B5) is an FDA-approved rabbit monoclonal antibody produced against the internal domain of the c-erb-2 oncoprotein (HER2) and is intended for laboratory use for the semi-quantitative detection of HER2 antigen by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded normal and neoplastic breast tissue. This IHC device is indicated for identifying breast cancer patients who are eligible for treatment with Herceptin® (IHC 3+ or IHC 2+/ISH amplified), KADCYLA® (IHC 3+ or IHC 2+/ISH amplified) or ENHERTU® (IHC 1+ or IHC 2+/ISH non-amplified)[2]. 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).

Ki-67 Antibody: This antibody is intended for in vitro diagnostic (IVD) use. FLEX Monoclonal Mouse Anti-Human Ki-67(MIB-1) Antigen (Dako Omnis), is intended for use in immunohistochemistry (IHC) together with the Dako Omnis instrument. This antibody is useful for the identification of the Ki-67 antigen in normal and neoplastic cells.[3]

P53 Antibody: This antibody is intended for in vitro diagnostic (IVD) use. DAKO Flex p53 (DO-7) is an IVD-approved monoclonal mouse antibody that labels wild-type and mutant-type p53 protein and is useful in the investigation of p53 accumulation in human neoplasias[2].

Specimens have been fixed for more than 6 hours and less than 72 hours per regulatory guidelines. ER, PR, and Her2/neu assays were performed on formalin-fixed paraffin embedded tissue using the Ventana Ultraview DAB Detection System on the fully automated Ventana Ultra BenchMark Series Autostainer according to the manufacturer's guidelines. Ki-67 and P53 assays (when present) were performed on formalin-fixed paraffin embedded tissue using the fully automated Dako Omnis Autostainer according to the manufacturer's guidelines. The Ki-67 and p53 assays are not routinely performed as part of this breast cancer profile based on the lack of recommendation by ASCO and the National Comprehensive Cancer Network (NCCN)[1]. If clinically necessary, these assays are available to be ordered separately. Validated IHC is the recommended standard for predicting benefit from endocrine therapy. No other assay types are recommended as the primary screening test for this purpose.

Her2 Dual ISH: This product is intended for in vitro diagnostic (IVD) use. The Ventana Her2 Dual ISH DNA Probe Cocktail Assay is intended to determine Her2 gene amplification status by enumeration of the ratio of the Her2 gene to Chromosome 17 by light microscopy. These probes are detected using a two-color chromogenic *in-situ* (ISH) hybridization method on formalin fixed, paraffin embedded tissues[1].

REFERENCE RANGES for Her2 Dual ISH[4]:
< 2.0 Her-2/neu Gene Amplification Negative (non-amplified)
≥ 2.0 Her-2/neu Gene Amplification Positive (amplified)

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1 American Society of Clinical Oncology/College of American Pathologists guideline update [published online January 13, 2020]. Arch Pathol Lab Med. doi:10.5858/arpa.2019-0904-SA

a. CAP biomarker reporting protocol 2020; version 1.4.0.0.

b. ASCO Clinical Practice Guideline [J Clin Oncol 2016 34:1134-1150].

c. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Version 3.2020.

2 Literature provided by Ventana Medical Systems (Roche Diagnostics) product specification sheet for this antibody.

3 Literature provided by DAKO (Agilent Technologies) product specification sheet for this antibody.

4 J Clin Oncol. 2018 Jul 10;36(20):2105-2122. PMID: 29846122