ISO 9001 : 2008 CERTIFIED LAB

KOS Diagnostic Lab
(A Unit of KOS Healthcare)

KOS™
EXCELLENCE IN HEALTHCARE & DIAGNOSTICS

Dr. Vinay Chopra
MD (Pathology & Microbiology)
Chairman & Consultant Pathologist

Dr. Yugam Chopra
MD (Pathology)
CEO & Consultant Pathologist

LABORATORY REPORT

Name	:Mrs BIMLA DEVI	Sex/Age	: Female/ 49 Years	H.ID :	Case ID : 40621604396
Ref By	:DR VINAY CHOPRA	Dis.Loc.	:		Pt ID :
Bill. Loc.	:KOS DIAGNOSTIC LAB				Pt. Loc. :
Registration Date & Time	: 29-Jun-2024 09:12	Sample Type	: block		Ph # :
Sample Date & Time	: 29-Jun-2024 09:12	Sample Coll. By	:		Ref Id :
Report Date & Time	: 05-Jul-2024 16:06	Acc. Remarks	:		Ref Id2 :

Histopathology Report

Specimen :
Block for IHC, ER, PR, Her2Neu study.

Clinical Data :
Not available.

Macroscopic Examination :
Nature of Material: Received single paraffin block labelled as Phe425/24.
Cold Ischemia Time: Unknown **Fixation Time:** unknown
Antigen Retrieval By: Ventana CC1 **Detection System:** Ventana Ultraview Universal DAB kit
Antibody clone : ER - SP1 (Roche- Ventana) , PR- 1 E2- Roche (Ventana) , Her2neu- Polyclonal (Dako)
Testing Performed on Block Number: Phe425/24.
Morphology - Invasive breast carcinoma

Impression :
Immunohistochemistry Evaluation: ER, PR, HER-2

Test	Intensity	% of tumor cell staining	Allred score
Estrogen receptor	0	0	0 (negative)

Grossing By : Dr. Vipal Parmar

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M.D. Pathologist

Dr. Bhavna Mehta
M.D. (P.D.C.C) G-56686
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Progesteron receptor	0	0	0 (negative)
Her2 neu	Negative (score 0)		

Interpretation:

ER,PR ,Her2 neu negative **(Triple negative)**

Remarks: All (internal and external) controls show appropriate reactivity.

---------- End Of Report ----------

Notes:

Test Type: FDA cleared

Primary antibody: ER: SP1, PR: 1E2, HER-2: Polyclonal, ki-67: MIB1

Scoring system: Total Allred score

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Allred Score for Estrogen and Progesterone Receptor Evaluation

Proportion Score	Positive Cells, %	Intensity	Intensity Score
0	0	None	0
1	<1	Weak	1
2	1 to 10	Intermediate	2
3	11 to 33	Strong	3
4	34 to 66		
5	≥67		

Reporting Results of HER2 Testing by Immunohistochemistry (IHC)

Result	Criteria
Negative (Score 0)	No staining observed *or* Membrane stating that is incomplete and is faint/barely perceptible and within ≤10% of tumor cells
Negative (Score 1+)	Incomplete membrane staining that is faint/barely perceptible and within >10% of tumor cells*
Equivocal (Score 2+)†	Weak to moderate complete membrane staining in >10% of tumor cells *or* Complete membrane staining that is intense but within ≤10% of tumor cells*
Positive (Score 3+)	Complete membrane staining that is intense and >10% of tumor cells*

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- **Breast cancers with HER2 IHC score 1+ or HER2 IHC score 2+ and a negative ISH result are eligible for clinically appropriate HER2-targeted therapy and may be reported as "HER2 Low".**

Reasons for false-negative results include the following:

- Exposure of tumor cells to heat (eg, carcinomas transected by using cautery during surgery)
- Prolonged cold ischemic time, which may result in antigenic degradation. One hour or less is preferable
- Under or overfixation; fixation for at least 6 hours in buffered formalin is recommended, and prolonged fixation can also diminish immunoreactivity[4]
- Type of fixative: ER is degraded in acidic fixatives such as Bouin's and B-5; formalin should be buffered to ensure pH range between 7.0 and 7.4
- Decalcification, which may result in loss of immunoreactivity
- Nonoptimized antigen retrieval
- Type of antibody
- Dark hematoxylin counterstain obscuring faintly positive diaminobenzidine (DAB) staining

Studies suggest that patients with higher hormone receptor levels have a higher probability of response to hormonal therapy, but expression as low as 1% positive staining has been associated with clinical response. As a result, the guidelines recommend classifying all cases with at least 1% positive cells as receptor positive. For patients with low ER expression (1% to 10% weakly positive cells), the decision on endocrine therapy should be based on an analysis of its risks and potential benefits.

Invasive carcinoma cases with 1 to 10% of cells staining for ER (not PgR) are reported as "Low Positive" and the following report comment is recommended: "The cancer in this sample has a low level (1-10%) of ER expression by IHC. There are limited data on the overall benefit of endocrine therapies for patients with low level (1-10%) ER expression but they currently suggest possible benefit, so patients are considered eligible for endocrine treatment. There are data that suggest invasive cancers with these results are heterogeneous in both behavior and biology and often have gene expression profiles more similar to ER negative cancers." The Low Positive designation applies only to invasive carcinoma, and is not used for Progesterone receptor or DCIS.

For cases in which no internal controls are present and the ER result is either negative or Low Positive, the following report comment is recommended: "No internal controls are present, but external controls are appropriately positive. If needed, testing another specimen that contains internal controls may be warranted for confirmation of ER status." When a tumor is negative but no internal control cells are present, the pathologist must exercise judgment as to whether the assay can be interpreted as a true negative. This should include consideration of

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histologic type and grade, cold ischemia and fixation times, and the status of external controls. If the pathologist decides that hormone receptor status cannot be determined, the test should be reported as such and repeated on another block or specimen.

Percentage of cells with nuclear positivity may be reported as a specific number or a range if more than 10%.

Technical issues prevent the test from being reported as positive, negative, or equivocal. This may occur if specimen handling was inadequate, if artifacts (crush or edge artifacts) make interpretation difficult, or if the analytic testing failed.

Refferneces :

1. Template for Reporting Results of Biomarker Testing of Specimens from Patients with Carcinoma of the Breast

Version: 1.5.0.0 , Protocol Posting Date: June 2022

2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guideline in Oncology, Version 3.2017. www.nccn.org/professionals/physician_gls/PDF/breast.pdf. Accessed December 18, 2017

3. Allison KH, Hammond MEH, Dowsett M, et al. Estrogen and progesterone receptor testing in breast cancer: ASCO/CAP guideline update. *Arch Pathol Lab Med* doi: 10.5858/arpa.2019-0904-SA.

4. Wolff AC, Hammond MEH, Allison KH, et al. HER2 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.

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