MEDGENOME

Medgenome Labs Ltd
Sy No 94/1C and 94/2, Tower-1, Veerasandra Village,
Attibele Hobli, Electronic City, Phase-1, Bangalore,
Karnataka, 560100.

IHC Breast prognostic / Predictive Panel - ER, PR, HER 2 and Ki 67

Patient Name	K.D.H. Anula Jayanthi De Silva	Order ID	1311033
Age / Gender	71 Years / Female	Sample ID	9161398
Physician	Dr. Mahendra Perera	Collection Date	NA
Customer	MCC18718-Aegle Omics Private Limited	Sample Received Date	26-05-2025 03:00 PM
Report Date	29-05-2025 11:41 PM	Report Status	Final
Collection Center/ Partner Lab	0		

Lab/Biopsy No : MBH-2928-25

Clinical Details : C/O Ca. (R) Breast. Now with (L) femoral fracture with metastasis.

Specimen received : 2 blocks. Biopsy blocks (L) femur

Received two paraffin blocks bearing No. YD 17040 - A and B. From Lanka Hospitals Laboratories. For IHC.

Test Requested: ER, PR, HER 2 and Ki 67 Number of blocks provided: 2 Date and Time of fresh specimen collection: Unknown **Test done on block B**	Time Placed in 10% formalin: Unknown Time to Fixation: Less than an hour: Not Provided Type of Fixation: 10% formalin: Not Provided Duration of Fixation: 6-72 hours: Not Provided Type of tissue processing: Routine: Unknown

RESULTS

IHC Markers	% Cells	Intensity	Internal Controls	Interpretation
Estrogen Receptor	20	Weak	Absent	Positive
Progesterone Receptor	10	Weak	Absent	Positive

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.

IHC Markers	Total Score	Interpretation
HER-2/neu	0	Negative
Pattern of staining	Tumor cells show no membranous staining.	

MIB1 (Ki67) proliferating index IHC

Ki 67 : - <1 % in highest proliferating invasive areas.

ADVICE

Note - Low Ki67 score may be attributed to decalcification / fixation related.

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CONTROLS:

Clones used:

ER-Alpha-EP1-Rabbit Monoclonal
PR-EP2-Rabbit Monoclonal Her2/erb2-EP3-Rabbit Monoclonal
Ki-67-MIB-1-Mouse Monoclonal

Interpretative Guide:

ASCO, CAP ER/PgR Testing in Breast Cancer Guideline Update 2020

Table 1 : Optimal algorithm for ER/PgR testing and Interpretation		
ER	Negative	0 / <1% of tumor cell nuclei are immunoreactive
	Low Positive (with an additional recommended comment)	1-10% of tumor cell nuclei are immunoreactive
	Positive	>10% of tumor cell nuclei are immunoreactive
PgR	Negative	0 / <1% of tumor cell nuclei are immunoreactive
	Positive	1-100% of tumor cell nuclei are immunoreactive
ER /PgR	Uninterpretable	If the sample is inadequate (insufficient cancer or severe artifacts present, as determined at the discretion of the pathologist), if external and internal controls (if present) do not stain appropriately, or if preanalytic variables have interfered with the assay's accuracy.

Table 2 : Additional Recommended reporting Comment for ER with	
1%-10% cells staining	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.
No internal controls and ER is 0%-10%	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.

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(5):545-563.

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ASCO CAP HER-2/neu Testing Guidelines Recommendations (Focused Update) 2023

HER-2/neu scoring system on invasive tumor	
0 (Negative)	No staining is observed in tumor cells or membrane staining that is incomplete and is faint/barely perceptible and within <= 10% of tumor cells
1+ (Negative)	Incomplete membrane staining that is faint/barely perceptible and is > 10% of tumor cells
2+ (Equivocal)	Weak to moderate complete membrane staining observed in >10% of tumor cells
3+ (Positive)	Circumferential membrane staining that is complete, intense and within >10% of the invasive tumor cells.

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 despite having some level of protein expression. Patients with breast cancers that are HER2 IHC 1+ or IHC 2+ / ISH not amplified may be eligible for treatment with a cytotoxic drug regimen that targets non- amplified / non-over expressed levels of HER2 (IHC 0 results do not currently result in eligibility).

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. Archives of Pathology & Laboratory Medicine 2018; 142:11, 1364-1382

Wolff, A.C. et al. Human epidermal growth factor receptor 2 testing in breast cancer: American Society of Clinical Oncology- College of American Pathologists Guideline Update. Archives of Pathology & Laboratory Medicine 2023; 147(9):993–1000.

Educational notes [MIB1 (Ki67) proliferating index] : Cellular proliferation is a major determinant of the biologic behaviour of breast cancer. IHC assessment of Ki67 antigen using the recommended MIB1 antibody clone a nuclear marker expressed in all phases of the cell cycle other than G0 phase. The fraction of MIB 1-positive tumor cells (the MIB 1 labelling index) is often correlated with the clinical course of cancer is useful for objective histopathological evaluation of invasive tumor proliferation activity.

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Approved By

Dr. Rakshith V
Consultant Histopathologist
KMC95334

*****End of Report*****

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CONDITIONS OF LABORATORY TESTING AND REPORTING

Medgenome Labs Ltd, Bangalore, Karnataka, India

- Laboratory results should be used with other clinical information to determine a final diagnosis.
- In case of unexpected test results please contact the laboratory. We will investigate and repeat analysis if possible.
- The medical report must be viewed and reproduced as a whole
- This medical report is not intended for medico-legal purposes.
- The medical report is to be interpreted and used by medical personnel only
- Assays are performed and reported in accordance with the stated schedule.
- The results of a laboratory test are dependent on the quality of the sample as well as the assay procedure.
- A requested test may not be carried out if:
- Sample is insufficient or inappropriate
- Sample quality is unsatisfactory
- Request for testing is withdrawn by the ordering doctor or patient
- There is discord between the labelling of the sample container and the name on the test requisition.
- For any query contact customer support : +91(0)8067154932/33
