AMPATH
Central Reference Lal
Door No. 1-100/1/CCH
Serilingampally
Hyderabad

MC-2751

NAME	**: MRS H SWAROOPA B1904251**	REFERRED BY	:	VISIT NO	: VAMP25478648
AGE	: 52Y 0M 0D	SAGEPATH LABS PRIVATE LIMITED		COLLECTED ON	: 29-12-2025 12:00
GENDER	: Female	**LAB MR#**	**: AAMP01354435**	RECEIVED ON	: 30-12-2025 09:02
OP / IP / DG #	:			APPROVED ON	: 03-01-2026 13:50
				REPORT STATUS	: Final Report

CYTOGENETICS

FISH for HER2/neu - Paraffin Block *(Paraffin embedded tissue blocks)*

CYTOGENETICS LAB REF NO: FS 924/25

FISH (Fluorescent in Situ Hybridization) for HER2/Neu (ERBB2) gene.

SPECIMEN TYPE: Paraffin Block.

CLINICAL HISTORY/INDICATIONS: Not available,

IMMUNOHISTOCHEMISTRY REPORT: Not available,

BLOCK/ SLIDE USED FOR HER2/Neu BY FISH: Block no:10832E/25

Impression : The Specimen processed and analyzed FISH for Her2neu is negative with amplification ratio of 1.59 with (Group-5)

Results Table

S.no	Results	No. of cells	No. of signal	Copy number
1	Total number of HER2 signals (Red)	40	140	3.50
2	Total number of CEP17 signals (Green)	40	88	2.20
3	Her 2 neu copy number	3.50		
4	HER2neu/CEP17 Ratio	1.59		

Interphase/Nuclear in situhybridization [ISCN 2024]

Sr. No	Result (ISCN2024)	No of Cells	Her2:CEP17 Ratio	Result
1	nuc ish (D17Z1×2,ERBB2×2~4)	40	1.59	negative

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Reference Table:

Her2/neu Ratio	Her2/neu Copy number	IHC score	Group	Result
≥2	≥4	-	1	Positive
≥2	<4	3+	2	Positive
≥2	<4	2+	2	Negative
<2	≥6	2+ and 3+	3	Positive
<2	≥4 & ≥6	3+	4	Positive
<2	≥4 & ≥6	2+	4	Negative
<2	<4	-	5	Negative

PROBES UTILIZED:

Probe Details: Wuhan ERBB2 (HER2/NEU) amp probe detects amplifications in the long arm of chromosome 17. The orange labeled probe is designed to hybridize to the ERBB2 (HER2/NEU) locus at 17q12. A green labeled probe hybridizes to the 17-centromere region and functions as a control probe.

Note: Tumor area is marked by Pathologist

Additional work up process :

FIHC testing for HER2 should be performed using sections from the same tissue sample used for FISH and the slides from both FISH and IHC be reviewed together to guide the selection of areas to score by FISH.

Group2 comment for negative

Evidence is limited on the efficacy of HER2-targeted therapy in the small subset of cases with HER2/CEP17 ratio ≥2.0 and an average HER2 copy number < 4.0/cell. In the first generation of adjuvant trastuzumab trials, patients in this subgroup who were randomized to the trastuzumab arm did not appear to derive an improvement in disease free or overall survival, but there were too few such cases to draw definitive conclusions. IHC expression for HER2 should be used to complement ISH and define HER2 status. If IHC result is not 3+ positive, it is recommended that the specimen be considered HER2 negative because of the low HER2 copy number by ISH and lack of protein overexpression.

Group4 comment for negative

It is uncertain whether patients with ≥4.0 and < 6.0 average HER2 signals/cell and HER2/CEP17 ratio< 2.0 benefit from HER2 targeted therapy in the absence of protein overexpression (IHC 3+). If the specimen test result is close to the ISH ratio threshold for positive, there is a higher likelihood that repeat testing will result in different results by chance alone. Therefore, when IHC results are not 3+ positive, it is recommended that the sample be considered HER2 negative without additional testing on the same specimen.

References:

1.The 2023 “Human Epidermal Growth Factor Receptor 2 (HER2) Breast Testing Guideline Update” reaffirms the 2018 “HER2 Breast Testing Guideline Focused Update.”
2.Guideline Reference. Burstein HJ, Somerfield MR, Barton DL, et al: Endocrine Treatment and Targeted Therapy for Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Metastatic Breast Cancer: ASCO Guideline Update. J Clin Oncol 39:3959-3977, 2021.
3.Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer American Society of Clinical Oncology–College of American Pathologists Guideline Update Antonio C. Wolff, MD; Mark R. Somerfield, PhD; Mitchell Dowsett, PhD; M. Elizabeth H. Hammond, MD; Daniel F. Hayes, MD; Lisa M. McShane, PhD; Thomas J. Saphner, MD; Patricia A. Spears, BS; Kimberly H. Allison, MD.
4.Burstein HJ, DeMichele A, Somerfield MR, et al: Testing for ESR1 Mutations to Guide Therapy for Hormone Receptor—Positive, Human Epidermal Growth Factor Receptor 2—Negative Metastatic Breast Cancer: ASCO Guideline Rapid Recommendation Update. J Clin Oncol 41:3423-3425, 2023.

Sin No: 15662670

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5.Guideline From the College of American Pathologists, American Society for Clinical Pathology, and American Society of Clinical Oncology. Arch Pathol Lab Med. 2016;140(12):1345-1363. doi:10.5858/arpa.2016-0331-CP
6.Cancer Protocol Templates- Biomarker Reporting. College of American Pathologists. https://www.cap.org/protocols-and- guidelines/cancer-reporting-tools/cancer-protocol-templates. Accessed November 24, 2020.

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Disclaimer:
1. All results released pertain to the specimen as received by the lab for testing and under the assumption that the patient indicated or identified on the bill/test requisition form is the owner of the specimen.
2. Clinical details and consent forms, especially in Genetic testing, histopathology, as well as wherever applicable, are mandatory to be accompanied with the test requisition form. The non-availability of such information may lead to delay in reporting as well as misinterpretation of test results. The lab will not be responsible for any such delays or misinterpretations thereof.
3. Test results are dependent on the quality of the sample received by the lab. In case the samples are preprocessed elsewhere (e.g., paraffin blocks), results may be compromised.
4. Tests are performed as per the schedule given in the test listing and in any unforeseen circumstances, report delivery may be affected.
5. Test results may show inter-laboratory as well as intra-laboratory variations as per the acceptable norms.
6. Genetic reports as well as reports of other tests should be correlated with clinical details and other available test reports by a qualified medical practitioner. Genetic counselling is advised in genetic test reports by a qualified genetic counsellor, medical practitioner or both.
7. Samples will be discarded post processing after a specified period as per the laboratory's retention policy. Kindly get in touch with the lab for more information.
8. If accidental damage, loss, or destruction of the specimen is not attributable to any direct or negligent act or omission on the part of Ampath Labs or its employees, Ampath shall in no event be liable. Ampath lab's liability for a lack of services, or other mistakes and omissions, shall be restricted to the amount of the patient's payment for the pertinent laboratory services.