

Fluorescent In Situ Hybridization (FISH) REPORT: FISH for ERBB2(HER2) Gene Amplification for Breast Cancer only

Patient Name	A N Somasekaram	Requesting Clinician	Dr. Umagowry Saravanamuttu
Gender	Female	Hospital Information	Aegle Omics Private Limited
Age/Date of Birth	40 Years	Sample Received	One FFPE block labelled as YH19519D
Sample ID	9403981	Time of Fixation	Not Available.
Order ID(s)	1452429	Samples Received(Date & Time)	19-09-2025 5:15 pm
Clinical Indication	Case of Breast carcinoma.	Report Date	26-09-2025 3:56 pm
Collection Center/ Partner Lab	0		

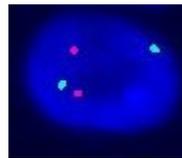
RESULT SUMMARY

Assay Name	Probe	ISCN 2024
ERBB2(HER2) gene Amplification	ERBB2(HER2) DNA probe	nuc ish(D17Z1x1≈3,D17S1215x1≈3) [60]

Interpretation:

Tumor cells are negative for ERBB2(HER2) gene amplification.

DETAILED REPORT



Representative image of a tumor cell showing two spectrum green(CEP 17) and two spectrum orange ERBB2(HER2) signals.

Spectrum Green (G)	17p11.1-q11.1/CEP17	Spectrum Orange (O)	17q11.1-q12/ERBB2(HER2) gene
Loci Analysed	Ratio	Average ERBB2(HER2) Copy number	Result
ERBB2(HER2) / CEP 17	1.13	2.61	Negative

Testing methodology: FISH is a molecular cytogenetic technique used to detect the presence or absence and location of specific gene sequences. FISH involves co-denaturation and hybridization of fluorescent labelled specific DNA probes to target DNA sequence in the interphase cells. Paraffin-embedded tissue specimen should be deparaffinized and pretreated to enhance tissue permeability. The excess unbound probe is removed during post hybridization washes. The sample is stained with DAPI (4', 6-Diamidino-2-phenylindole) a counter-stain to demarcate the nuclei. Each fluorescent labelled probe that hybridizes to region of interest in interphase cells are visualized as signal using suitable optical filters under Epi fluorescent microscope. 60 interphase cells are counted for each probe manually by two readers. Interpretation of results is done based on the signal patterns observed and the results of the test is reported. Appropriate controls are run in each batch along with the patient samples.

Comments: The ERBB2(HER2) DNA probe kit and it is designed to detect amplification of the ERBB2(HER2) gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer tissue specimens. Results from this Kit are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in stage II, node-positive breast cancer patients. This Kit is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node-positive breast cancer treated with adjuvant cyclophosphamide, doxorubicin and 5-fluorouracil (CAF) chemotherapy. This Kit is indicated as an aid in the assessment of patients for whom HERCEPTIN (Trastuzumab) treatment is being considered. The result interpretation is done according to ASCO-CAP 2018 update.

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Table 1: ERBB2(HER2) Result interpretation as per ASCO-CAP 2018 update by Dual Probe ISH assay

Group	ERBB2(HER2)/CEP17 Ratio	Copy number (signals/cell)	Result
1	≥ 2.0	≥ 4	Positive
2	≥ 2.0	< 4	Additional work-up required
3	< 2.0	≥ 6	Additional work-up required
4	< 2.0	≥ 4 and < 6	Additional work-up required
5	< 2.0	< 4	Negative

*** NOTE: Regarding Groups 2, 3, and 4, If not already assessed by the institution/lab performing the ISH test, IHC testing for ERBB2(HER2) should be performed using sections from the same tissue sample used for ISH and the slides from both ISH and IHC be reviewed together to guide the selection of areas to score by ISH.**

References:

1. Wuhan Health care probe kit insert.
2. Wolff AC, Hammond ME, Hicks DG, et al. Recommendations for human epidermal growth factor receptor 2 testing in breast cancer; American Society of Clinical Oncology/College of American Pathologists. Arch Pathol Lab Med 2014;138(2):241-256.
3. ASCO CAP guidelines 2018.

Disclaimers:

1. The performance characteristics have been evaluated by Medgenome lab.
2. The findings of this test must be correlated with clinical diagnosis.
3. CAP recommends that the Specimens subjected to ERBB2(HER2)testing should be fixed in 10% neutral buffered formalin for at least six hours and up to 72 hours. The volume of formalin should be at least 10 times the volume of the specimen. Decalcification solutions with strong acids should not be used.

Enclosed : One block.



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Lab Director

End of Report



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