MAX Lab

Laboratory Investigation Report

Patient Name	Centre
Age/Gender	OP/IP No/UHID
MaxID/Lab ID	Collection Date/Time
Ref Doctor	Reporting Date/Time

SIN No:S-15741/22 A

Cytogenetics

Her-2/neu (ErbB2) Gene Amplification, Fluorescence In-Situ Hybridization (FISH)

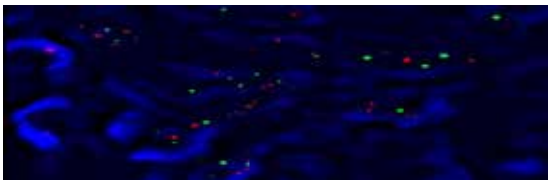
Laboratory Number : F-816-22

Specimen: Received FFPE tissue from Block No. S-15741/22 A

Source of tissue: Left breast mass biopsy

Clinical History: Invasive duct carcinoma, NST

Number of cells scored	100
Total HER2 signals	492
Total CEP17 signals	263
Average HER2 signals per cell	4.92
Average CEP17 signals per cell	2.63
HER2:CEP17 ratio	1.87



Result : HER-2/neu:CEP 17 ratio = **1.87 and a**verage HER2 signals per cell = 4.92

IHC [Her-2/neu] = 2+

Interpretation : The tumor cells are **NEGATIVE** for HER-2/neu gene amplification as per ASCO/CAP 2018 guidelines.*

***Comment:** It is uncertain whether patients with ≥4.0 and <6.0 HER2 signals/cell and HER2/CEP17 ratio <2.0 benefit from HER2 targeted therapy in the absence of protein overexpression (IHC3+).

Clinical Significance: Amplification of the Her-2/neu (ERBB2) gene occurs in ~15-20% of breast cancers and ~20% of gastric cancers. Accurate assessment of HER2 status helps in prediction of response to HER2-targeted therapy (e.g., trastuzumab, Herceptin) in individuals with breast or gastric cancer. Patients with HER2 overexpression show increased overall survival rate with HER2 targeted therapy.

Comment: As the initial HER2 test result in a core needle biopsy specimen of a primary breast cancer is negative, a new HER2 test **may** be ordered on the excision specimen, if high grade carcinoma is identified in excision specimen.

Reference: 2018 ASCO/CAP dual probe FISH reporting guidelines (Wolff et al., Arch Pathology Lab Med).

Probe description: Pathvision kit, Vysis, Abbott Molecular, Inc. This test is approved by U.S Food and Drug Administration. LSI HER-2 probe labeled in Spectrum Orange and CEP 17 probe labeled in Spectrum Green. Signals scored in total 100 nuclei after confirmation of probe performance by concurrent controls. This test was validated and its performance characteristics have been determined by Cytogenetics Laboratory, Max Hospital. Since only a portion of the tumor was tested, it is possible that this result may not represent the entire tumor population. As per ASCO/CAP guidelines, HER2 FISH test results are valid for non-decalcified paraffin embedded specimens fixed in 10% neutral buffered formalin between 6 and 72 hours. Results from specimens fixed outside these parameters should be interpreted accordingly.

Kindly correlate with clinical findings

***** End Of Report *****

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Booking Centre :1103 - Max Hospital Saket(East Block), 1, 2, Press Enclave Marg, Saket Institutional Area, Saket, New Delhi
The authenticity of the report can be verified by scanning the Q R Code on top of the page

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