



Laboratory Investigation Report

Patient NameCentreAge/GenderOP/IP No/UHIDMaxID/Lab IDCollection Date/TimeRef DoctorReporting Date/Time

Cytogenetics



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

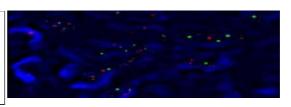
Laboratory Number: F-816-22

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 average 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 ***

Dr. Nitin Dayal, M.D. Principal Consultant & Head, Haematopathology

Dr Atul Thatai, Ph.D Director Molecular and Cyto Genomics Dr. Tanvi Gupta
MD D.N.B PDF Cytogenetics
Consultant Cytogenomics

Test Performed at :910 - Max Hospital - Saket M S S H, Press Enclave Road, Mandir Marg, Saket, New Delhi, Delhi 110017
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

Page 1 of 1



Max Lab Limited (A Wholly Owned Subsidiary of Max Healthcare Institute Ltd

Max Super Speciality Hospital, Saket (West Block), 1, Press Enclave Road, Saket, New Delhi - 110 017, Phone: +91-11-6611 5050 (CIN No.: U85100DL2021PLC381826)

📞 Helpline No. 7982 100 200 🏻 📾 www.maxlab.co.in 🚾 feedback@maxlab.co.in

Conditions of Reporting: 1. The tests are carried out in the lab with the presumption that the specimen belongs to the patient name as identified in the bill/test request form. 2. The test results relate specifically to the sample received in the lab and are presumed to have been generated and transported per specific instructions given by the physicians/laboratory. 3. The reported results are for the information and interpretation by the referring doctor only. 4. Some tests are referred to other laboratories to provide a wider test menu to the customer. 5. Max Healthcare shall in no event be liable for accidental damages loss, or destruction of specimen which is not attributable to any direct and mala fide act or omission of Max Healthcare for deficiency of services, or other errors and omissions shall be limited to fee paid by the patient for the relevant laboratory services.