

Patient Name	: Mrs Dummy	Sample Collected	: Jul 06, 2024, 03:50 PM.
DOB/Age/Gender	: 38 Y/Female	Report Date	: Jul 12, 2024, 04:58 PM.
Patient ID / UHID	: XXX	Barcode No	: XXX
Referred By	: Dr. XXX	Report Status	: Final Report
Sample Type	: FFPE tissue		

**HER2/neu by FISH**

<b>CLINICAL INDICATION</b>	BIRADS III Lesion in upper outer quadrant of right breast ?fibroadenoma
<b>SPECIMEN DETAILS</b>	Right breast, Block No.RCL-HP-4603-24
<b>FISH PROBE USED</b>	LSI HER-2 probe labeled in Spectrum Orange and CEP 17 probe labeled in Spectrum Green
<b>HER2NEU FISH SIGNAL PATTERN</b>	Total Number of cells scored : 20 Average CEP17 signals per cell :5.4 Average HER2 signals per cell : <b>7.3</b> HER2:CEP17 ratio : 1.35

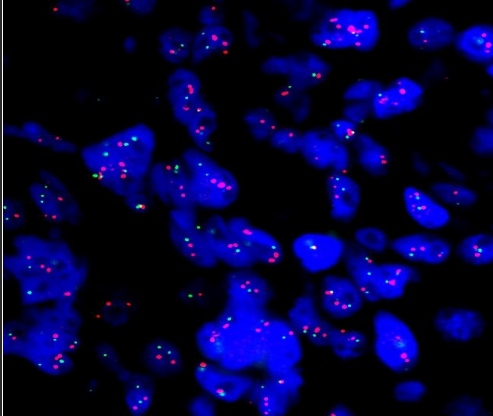


Figure: The representative image from the patient tissue depicting a positive Her2Neu FISH signal pattern.

**RESULT : Positive/Amplification of Her2/neu gene in the submitted patient block (RCL-HP-4603-24)**

**NOMENCLATURE: nuc ish 17cen(D17Z1x5.4),17q12q21(ERBB2x7.3)[20]**

**INTERPRETATION:**

**Negative:** FISH Dual Probe with HER2/CEP17 ratio of <2.0 with an average HER2 gene copy number of < 4 signals/nucleus for test systems without an internal control probe reveals are considered as Negative for Her2 gene amplification. **Positive:** The Her2/Neu FISH assay can reveal amplification of Her2 oncogene if Dual probe Her2/CEP17 ratio greater than or equal to 2.0 with an average Her2 copy number greater than or equal to 4.0 signals per cell or dual-probe Her2/CEP17 ratio greater than or equal to 2.0 with an average Her2 copy number < 4.0 signals per cell or dual-probe Her2/CEP17 < 2.0 with an average Her2 copy number greater than or equal to 6.0 signals per cell is considered to indicate amplification. **This test will not detect other abnormalities that have clinical significance. This test must be evaluated in conjunction with other clinically significant laboratory parameters.**

**H&E ASSESSMENT:-**

BLOCK SUBMITTED FOR TESTING	1
BLOCK ID	RCL-HP-4603-24
TISSUE TYPE	BREAST BIOPSY
CARCINOMA	INVASIVE
% OF TUMOR PRESENT	75%

**Dr. Ankur Jindal (Ph.D)**  
Consultant Cytogenomics

Processing Lab :- Redcliffe Lifetech Pvt. Ltd., H-55, Sector-63, Noida, Uttar Pradesh - 201301

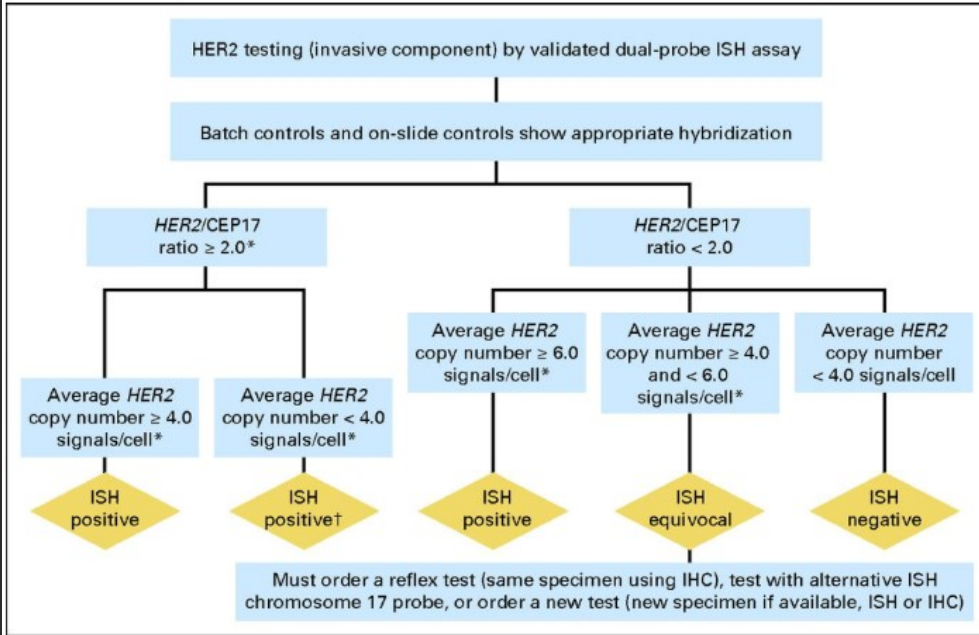
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**HER2/NEU ASSAY COMMENT:**

Slides from this samples were evaluated by an in-house pathologist and deemed adequate for Her2 FISH analysis by evaluating the invasive tumor per ASCO/CAP guidelines. controls provided the anticipated results. this case was reviewed by at least two observers. Note that improper handling and fixation could affect the results if the cold ischemic time is > 1 hour, or if the fixation time < 6 hours or > 72 hours (j.clin. oncol, 2013, 31(31) : 3997 - 4013).

Results from this test are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in patients with invasive breast carcinoma. The performance of this test has not been fully investigated for other tumors. Clinical correlation is recommended. This test is also indicated as an aid in the assessment of patients from whom Her2 targeted therapy (e.g. Herceptin; Trastuzumab) is being considered.

This test was developed and its performance characteristics have been determined by the Redcliffe Labs Private Limited, Noida. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test. Reporting is in accordance with American Society of Clinical Oncology (ASCO) / College of American Pathologist (CAP) guidelines recommendation for Human Epidermal Growth Factor Receptor 2 (Her2) testing in breast cancer.



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

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2. It is to be presumed that the tests performed pertain to the specimen/sample attributed to the Customer's name or identification. It is presumed that the verification particulars have been cleared out by the customer or his/her representation at the point of generation of said specimen / sample. It is hereby clarified that the reports furnished are restricted solely to the given specimen only.
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