SPRING STREET LABORATORIES
NEW YORK

PATHOLOGY REPORT

Patient: Mott, Elizabeth
DOB: 08/29/1960
Age/Sex: 57/F

MRN: 34298347
Acct: 23409384

Attending Provider: John H Wilson MD

Date Collected: 04/12/2018

Pathology Specimen S18-349833

ADDENDUM #2: FISH Results

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ADDITIONAL TESTING: Fluorescence In-Situ Hybridization (FISH) for HER2 (ERBB2) gene amplification:

A: Left breast 12 o'clock, 1 cm from nipple, needle core biopsy

Invasive ductal carcinoma:

POSITIVE for HER2 gene amplification by FISH ratio criteria Monosomy of CEP-17 present (see comment below)

COMMENT: The invasive carcinoma is POSITIVE for HER2 amplification, with an overall HER2/CEP17 ratio of 2.1. Approximately 30% of the analyzed cells have monosomy for the CEP17 signal, which is contributing to the elevated ratio. However, there are increased copies of the HER2 gene with an average of 4.0 HER2 copies/cell (range: 1-10 copies per cell) with 15% of the cells greater than or equal to 6.

FLUORESCENCE IN-SITU HYBRIDIZATION (FISH) STUDIES:
Source: Block A1
Population: Cells of interest

Procedure	Score	Result
HER2 FISH	**4**	
CEP-17	**1.9**	
# of Nuclei scored	**200**	
FISH estimated Ratio	**2.1**	**See comment**

Interpretation: Invasive ductal carcinoma, POSITIVE for HER2 gene amplification. Monosomy of CEP-17 present. See comment.
Interpreted by: Peter Lidstrom, MD PhD

Comment: A manual count was performed by two separate technologists.

According to the CAP/ASCO 2013 Recommendations, amplification is defined as a HER2/CEP17 signal ratio ≥ 2.0 and/or single-prove average HER2 copy number ≥ 6.0 signals/cell (JCO 31:3997-4013, 2013). Signal ratios < 2.0 and/or single-probe average HER2 copy number < 4.0 is considered negative. Dual-probe HER2/CEP17 ratio < 2.0 with an average HER2 copy number ≥ 4.0 and < 6.0 signals/cell is considered to be an "equivocal" result, and should be tested with an alternative assay and/or a new specimen, if available. The results of this test are meant to be used as an adjunct to other prognostic indicators.

Methodology: Fluorescence in situ hybridization (FISH) for HER-2/neu gene amplification (using PathVysion probes and manual scoring).

This test was modified from the FDA-approved protocol and its performance characteristics determined by Spring Street Laboratories, New York, NY 10013. This test is for clinical purposes. It should not be regarded as investigational or for research. This laboratory is regulated under the 1988 CLIA amendments as qualified to perform high complexity clinical testing.

Addendum #2 performed by Peter Lidstrom, MD PhD. Electronically signed 04/26/2018 11:23.