Patient Name:	**Doe, Jane**	**Physician:**	**John Doe, MD**	**Accession #:**	**M14-00063**
Sex:	Female	**Specialty Group:**	Facility Name	**Collected:**	7/18/2016
DOB:	9/1/1964 (51)	**Phone / Fax:**	999-999-9999 / 999-999-9999	**Received:**	7/19/2016
Reference #:	M14-00063	**CC:**		**Reported:**	8/19/2016

Molecular Pathology Report

Clinical History

Invasive ductal carcinoma, intermediate grade

DIAGNOSIS

A. **BREAST, LEFT:**

1. **Positive for HER2 gene amplification by FISH; please see comment**
2. **Positive for HER2 protein expression by immunohistochemistry; please see comment**

Summary Notes / Comments :

While HER2 breast cancer testing guidelines released by the ASCO-CAP task force (1) describe a new equivocal category, which includes a range of HER2/Chromosome 17 centromere ratio of 1.8-2.2, the 2013 revised ASCO-CAP guidelines now consider HER2 ratio score equal or above 2.0 as positive (2). Additional scoring changes were also introduced and approved by the revision task force, including absolute average HER2 gene count of over 6 (as positive), and mandatory correlation with histologic and hormone receptor status findings. Our interpretation, therefore, is in line with these recommendations, and go beyond them, as other, unmentioned important parameters were not included in the published guidelines (2). As part of our HER2 quality assurance program launched in 2000 (3), parallel IHC testing (performed at either the referring institution or at our laboratory) is recorded and data collected for QA/QC purposes.

References:
1. Wolff A, et al. American Society of Clinical Oncology/College of American Pathologists Guidelines Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. Arch Pathol Lab Med 2007;131:18-43.
2. Wolff A, et al. American Society of Clinical Oncology/College of American Pathologists Guidelines Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. Arch Pathol Lab Med 2013 (online ahead of print).
3. Yaziji H. et al. HER2 Testing in Breast Cancer Using Parallel Tissue-Based Methods. JAMA 2004 291:1972-2004.

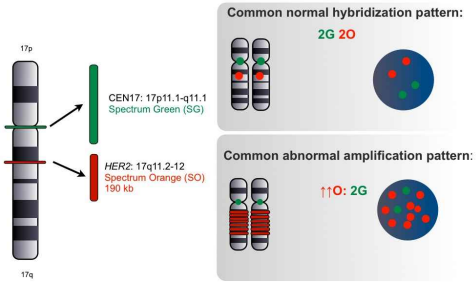
Table of Immunohistochemistry Results

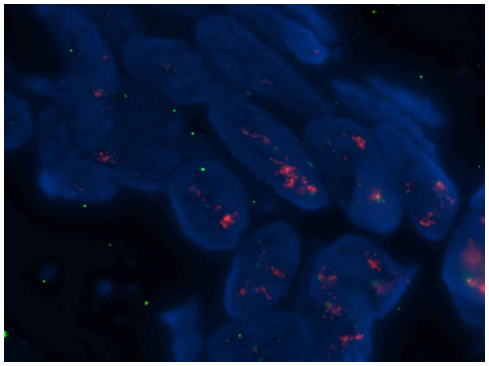
Block	Antibody Name(Clone)	Result(s)	% Positive Cells
M14-00063	HER2 (SP3)	Positive (3+)	100 %

Table of Fluorescence In Situ Hybridization Results

Block	Target DNA	Probe	Av. Copy #	Ratio	Result(s)
M14-00063	HER2	SpectrumOrange	17.0	8.5	Positive
M14-00063	Chromosome 17 Centromere	SpectrumGreen	2.0		

Images





Positive for HER2 gene amplification by FISH

HER2 ASCO/CAP 2013 Guidelines QR Code

Procedure

Smears, liquid cell preparations, or deparaffinized sections were prepared for hybridization, along with appropriate controls. Cells were hybridized with the fluorescently-labeled probes (see accompanying information in image/table). For fusion or breakapart assays, probes recognize target DNA

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Molecular Pathology Report

Procedure

sequences or in the common breakpoints on the gene of interest, respectively. For signal enumeration assays, the probes recognize target DNA sequence related to the specific locus/centromere/chromosome segment. 30-200 target nuclei were analyzed (the number of evaluated cells vary depending on sample cellularity). For fusion assays, nuclei with fusion signals (F) are considered positive (positive cutoff varies depending on validation parameters for each assay). For breakapart assays, nuclei with split signals are considered positive. For signal enumeration assays, abnormal results depend on the copy number of probe. For non-FDA approved (and IVD) assays), the individual probes were validated at Vitro Molecular Laboratories as an Analyte Specific Reagents (ASR).

Gross Description

A. Received from John Doe, MD (Miami, FL) are 4 unstained slides labeled M14-00063 with accompanying report and requisition sheet. Specimen was submitted for HER2 by IHC and FISH.

Electronic Signature **Hadi Yaziji, M.D.**

CPT Code(s): 88377 (1), 88360 (1)

***** END OF REPORT *****