SUMMIT PATHOLOGY
Offices located at Poudre Valley Hospital
1024 South Lemay Avenue
Fort Collins, CO 80524
Tel: (970) 495-8740
Fax: (970) 495-7605

ABNORMAL

SURGICAL PATHOLOGY REPORT

ADDENDED

Patient: WELLS, KIMBERLY S
Med Rec#: **3299267** PV: **177202382**
DOB: **07/12/1960** Age: **59** Sex: **F**
Physician(s):
DEPRIEST KIRK D.O. POUDRE VALLEY HOSPITAL
Attn: **AMY HAYES, MD**

Accession #: 12116119
Date Collected: **06/18/2020**
Date Received: **06/18/2020**
Date Reported: **06/19/2020**
Report Modified: **07/07/2020**

Test Requested: **PVH Surgical**

Result ID: VS20-02681

Revision (07/07/2020)
ADDENDUM:

NEO GENOMICS LABORATORIES FISH ANALYSIS REPORT RECEIVED

HER2 Breast

Results: Negative

Interpretation:
Average HER2 signals/nucleus: 3.4
Average CEN 17 signals/nucleus: 2.2
HER2/CEN 17 signal ratio: 1.5
Number of Observers: 1

Results show no evidence of HER2 amplification and a HER2/CEN17 ratio of <2.0 with an average HER2 copy number><4.0 signals per cell. This is a NEGATIVE result. Methodology: Along with fluorescence in situ hybridization (FISH) an H E stained slide was reviewed by pathologist to identify the target area containing invasive tumor. FISH analysis of 50 interphase nuclei performed within marked using dualprobe assay. Controls appropriately.>< 2.0 with an average HER2 copy number <4.0 signals per cell. This is a NEGATIVE result. Methodology: Along with fluorescence in situ hybridization (FISH) an H E stained slide was reviewed by pathologist to identify the target area containing invasive tumor. FISH analysis of 50 interphase nuclei performed within marked using dualprobe assay. Controls appropriately.>< 4.0 signals per cell. This is a NEGATIVE result.

(See report for details. Report attached) lp

Heath D Worcester, MD
Pathologist, Electronic Signature

Revision (06/24/2020)
ADDENDUM:
'VIAS' PROGNOSTIC MARKER PANEL RESULTS RECEIVED
INVASIVE CARCINOMA BREAST PROGNOSTIC MARKER PANEL

BLOCK: A1

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ESTROGEN RECEPTOR (SP1): POSITIVE, 44%, INTENSITY 2+.
PROGESTERONE RECEPTOR (1E2): NEGATIVE, LESS THAN 1% OF CELLS STAINING.
HER-2/NEU (4b5/IHC): EQUIVOCAL FOR OVER-EXPRESSION, 2+; FISH ANALYSIS PENDING.
Ki-67 (30-9): 90%, HIGH.

Comment: HER-2 DISH was unsuccessful and the specimen has been forwarded for FISH analysis.

Tissue fixation is in 10% formalin and the duration of fixation is 6-72 hours. Tissue is paraffin embedded.

The testing is performed on Bench Mark ULTRA Stainer, Ventana Medical Systems, Inc., with ultra VIEW Universal DAB detection. Positive and negative controls react satisfactorily. The immunohistochemical stains are used for clinical purposes. Interpretation is performed by Summit Pathology using the Ventana Medical Systems, Inc. iScan Coreo whole slide brightfield scanner with Virtuoso software.

Estrogen receptor (ER) and progesterone receptor (PR) require 1% or greater nuclear staining to be considered positive. Intensity of ER and PR staining is based on a scale of 0 (negative) to 3 (most intense). HER-2 positivity requires greater than 10% of tumor cells showing complete membrane staining; a score of 2+ is equivocal and will be confirmed by ISH. A score of 3+ is strong positive. Only the strong positive (3+) HER-2 shows strong concordance with clinical trial results for Herceptin. HER-2 scores of 0 and 1+ (faint, incomplete staining) are considered negative. This scoring method for HER-2/neu by IHC is per the ASCO/CAP guidelines for HER-2/neu testing.

Ki-67 is a proliferation marker. Scoring is per the recommendations of the International Ki-67 in Breast Cancer Working Group. (Dowsett et al, J. Natl Cancer Inst: 103:1-9, 2011). Category Criteria: 0-10% low, 11-19% intermediate, greater than or equal to 20% high. When Ki-67 rates fall in the intermediate range on needle core biopsy, repeat testing from excisional material should be considered. Ki-67 can also be used as a surrogate marker to assist in distinguishing between luminal A and luminal B tumor types in an ER positive tumor. (Less than 14% favors luminal A; greater than or equal to 14% favors luminal B).

These tests were developed and their performance characteristics validated by Summit Pathology. This laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical testing. Summit Pathology meets or exceeds all of the ASCO/CAP guidelines for estrogen receptor, progesterone receptor, and HER-2/NEU testing.The most recent ASCO/CAP guidelines are utilized for these assessments: (Arch Pathol Lab Med. 2018;142:1364–1382; doi: 10.5858/arpa.2018-0902-SA, Her2) and Arch Pathol Lab Med. 2020;144(5):545-563, ER/PR.

Jeremiah Andersen, MD
Pathologist, Electronic Signature

FINAL DIAGNOSIS:

LYMPH NODE, LEFT AXILLARY, CT-GUIDED CORE BIOPSY:

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Med Rec#: **3299267** PV: **177202382**
DOB: **07/12/1960** Age: **59** Sex: **F**
Physician(s):
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Attn: **AMY HAYES, MD**

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METASTATIC CARCINOMA, FAVOR MAMMARY PRIMARY (SEE COMMENT)

COMMENT:

Clinical and radiologic correlation is necessary. The breast prognostic panel will be reported in an addendum.

Heath D Worcester, MD
Pathologist, Electronic Signature

The case has been reviewed with the following pathologist(s) who concur with the interpretation: Michael Walts, MD

Clinical History: Left axillary LN.

GROSS DESCRIPTION:

Received in a formalin filled bottle/container, which has been verified to belong to patient: WELLS, KIMBERLY S and labeled "LT axillary LN core" is a 1.0 x 0.4 x 0.2 cm aggregate of multiple gray-white needle core biopsies and fragments, filtered and entirely submitted in blocks A1-A2, with A2 for conserve.

Out of Body: 0930 on 6/18/20
In formalin: 0930 on 6/18/20
Out of formalin: 1822 on 6/18/20

MICROSCOPIC DESCRIPTION:

2 blocks, 1 slide examined each block.
Also examined are immunoperoxidase-stained sections for CK5/6, CK7, CK20, TTF-1, GATA3, CDX-2, and p40 which show tumor positivity with CK5/6, CK7 and GATA3 supporting a breast origin. The remaining stains are negative(Positive and negative controls appropriate).

(Note: The immunoperoxidase tests utilized in this examination were developed and their performance characteristics determined by the laboratory at Summit Pathology. They have 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. These tests are used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.)

CPT Code(s): 88361 x4, 88341 x6, 88305, 88342

Specimen grossed and processed at: Summit Pathology 5802 Wright Dr., Loveland, CO, 80538
Specimen interpreted at: Poudre Valley Hosp 1024 S Lemay, Fort Collins, CO 80524

NEO GENOMICS

866.776.5907, option 3

FISH Analysis
HER2 Breast

Client 1707
UC Health Poudre Valley Hospital

1024 South Lemay Ave
Attention: Christopher Bee, M
Fort Collins, CO 80524
Phone: (970) 495-8729
Fax: (970) 495-7629

FX 4

Patient Name: **Wells**, **Kimberly S**
Patient DOB / Sex: **07/12/1960 / F**
Specimen Type: **Paraffin Tissue**
Body Site: **LEFT AXILLARY**
Specimen ID: **VS20-02681/VS20-02681-A1**
MRN: **3299267**
Reason for Referral: **SEE ATTACHED**

Ordering Physician(s): **Jeremiah Andersen, MD**
Treating Physician(s): **Kirk Depriest, M.D.**
Accession / CaseNo: **2800137 / FSG20-058079**
Collection Date: **06/18/2020**
Received Date: **06/27/2020 03:12:00 PM PDT**
Report Date: **07/06/2020 03:32:37 PM EST**

Results: Negative

Interpretation:
Average HER2 signals/nucleus: 3.4
Average CEN 17 signals/nucleus: 2.2
HER2/CEN 17 signal ratio: 1.5
Number of Observers: 1

Results show no evidence of HER2 amplification and a HER2/CEN17 ratio of <2.0 with an average HER2 copy number <4.0 signals per cell. This is a NEGATIVE result.

Methodology: Along with fluorescence in situ hybridization (FISH), an H&E stained slide was reviewed by a pathologist to identify the target area containing invasive tumor. FISH analysis of 50 interphase nuclei was performed within the marked target area using a dual-probe FISH assay. Controls performed appropriately.

Reference: Wolff AC, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer; American Society of Clinical Oncology/ College of American Pathologists Clinical Practice Guideline Focused Update. Arch Pathol Lab Med. 2018;142(11):1364-1382.

Reference Ranges:
HER2 Breast: Based on 2018 CAP/ASCO guidelines, a case is considered POSITIVE when the HER2/CEN17 ratio is >/=2.0 with >/= 4.0 signals/cell [Group 1] and NEGATIVE when the HER2 to CEN17 ratio is <2.0 and <4.0 HER2 signals/cell [Group 5]. If HER2/CEP17 ratio >/= 2.0 with average HER2 <4.0 [Group 2], or HER2/CEN17 ratio <2.0 with >/=6.0 signals/cell [Group 3], or HER2/CEN17 <2.0 with >/=4.0 and <6.0 signals/cell [Group 4] a definitive diagnosis will be rendered on additional work-up using the HER2 IHC staining with a concomitant workup.

[Groups 2 and 4] If the IHC result is 3+, the case is considered HER2 POSITIVE. If the IHC result is 0 or 1+, the case is considered HER2 NEGATIVE. If the IHC is 2+ the FISH is recounted for an additional 20 cells in the area of invasive cancer with IHC 2+ staining. If reviewing the additional count remains within the bounds of Group 2 or Group 4, then the case is considered NEGATIVE. If the review results in a different ISH category a total of 50 additional cells will be recounted and the result is adjudicated to that final category.

[Group 3] If the IHC result is 3+, the case is considered HER2 POSITIVE. If the IHC result is 0 or 1+, the case is considered HER2 NEGATIVE. If the IHC is 2+ the FISH is recounted for an additional 20 cells in the area of invasive cancer with IHC 2+ staining. If reviewing the additional count remains within the bounds of Group 3, then the case is considered POSITIVE. If the review results in a different ISH category a total of 50 additional cells will be recounted and the result is adjudicated to that final category.

Probe Set Detail:
HER2 Breast: nuc ish(CEN17x2.2,HER2x3.4)[50]

Comments:

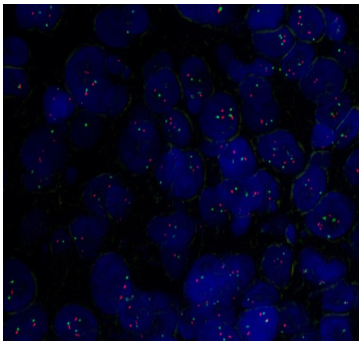
The 2018 ASCO/CAP guidelines state that if the initial HER2 test result in a core needle biopsy specimen of a primary breast cancer is negative, then a new HER2 test may be ordered on the excision specimen if one of the following is observed: (1) tumor is grade 3, (2) amount of invasive tumor in the core biopsy specimen is small, (3) resection specimen contains high-grade carcinoma that is morphologically distinct from that in the core, (4) core biopsy result is equivocal for HER2 after testing by both ISH and IHC, (5) there is doubt about the handling of the core biopsy specimen (long ischemic time, short time in fixative, different fixative), or the test is suspected by the pathologist to be negative on the basis of testing error.

Specimens for HER2 breast and gastroesophageal prognostic testing should be submitted following 2018/2016 ASCO/CAP guidelines: Incisional and excisional biopsy samples should have a cold ischemia time of no longer than 1 hour and be fixed in 10% neutral buffered formalin at least 6 hours to no more than 72 hours HER2. The fixative, fixation time and/or cold ischemic time were not provided.

The results of this assay have been determined within the limitations described and should not be used interchangeably with resulting values from other methods or kits. These results are intended to be used as an adjunct to other concurrent testing in patient care management. Therefore, the presence or absence of a malignant disease cannot be determined based solely on these results. Clinical correlation is advised.

Invasive Tumor Nuclei Scored: 50

Probe set	Scoring method	CPT Code	# of Units
HER2 Breast	Computer Assisted Technology	88374	1



FSG20-058079.Wells_Kimberly.HER2 Breast~A.231.JPG

Electronic Signature

Paul Kirshman, M.D., Pathologist

All controls were within expected ranges.
The Technical Component Processing, Analysis and Professional Component of this test was completed at NeoGenomics California, 31 Columbia, Aliso Viejo, CA / 92656 / 866-776-5907 / CLIA #05D1021650 / Medical Director(s): Sally Agersborg, M.D.
The HER2 Breast Cancer FISH Test uses a two probe cocktail comprising a HER2 (ERBB2 at 17q12) probe in red and a centromere 17 (D17Z1) probe in green. This test was developed and its performance characteristics determined by the performing laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. This laboratory is regulated under CLIA '88 as qualified to perform high complexity testing.
Interphase FISH does not include examination of the entire chromosomal complement.
Images that may be included within this report are representative of the patient but not all testing in its entirety and should not be used to render a result.
The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.