SUMMIT PATHOLOGY
Office located at McKee Medical Center
2000 N. Boise Avenue
Loveland, CO 80538
TEL: (970) 820-4163
FAX: (970) 820-2509

ABNORMAL

SURGICAL PATHOLOGY REPORT

ADDENDED

Patient: MEHL, NINA ELIZABETH
Med Rec#: **907371** PV: **00100874072**
DOB: **10/21/1960** Age: **59** Sex: **F**
Physician(s):
GILL SARVJIT MD MCKEE MEDICAL CENTER

Accession #: 12109519
Date Collected: **06/05/2020**
Date Received: **06/05/2020**
Date Reported: **06/10/2020**
Report Modified: **07/13/2020**

Test Requested: **McKee Surgical**

Result ID: MS20-00911

Revision (07/13/2020)
ADDENDUM:
This case is being addended to refer the reader to the attached University of Colorado Denver Department of Pathology Molecular Correlates Laboratory reports received - LUNG CARCINOMA MUTATIONAL PANEL and MULTIPLEX FUSION ANALYSIS. Block B2 was used for these studies.

LUNG CARCINOMA MUTATIONAL PANEL did not identify any mutations.

MULTIPLEX FUSION ANALYSIS was unsuccessful. The majority of the neoplastic cells were present in block B2. Repeat testing could be attempted with block B3, if requested, however there is minimal tumor present on slide B3.

Please see full reports for details. Reports are attached. ly.

Craig L Nerby, MD
Pathologist, Electronic Signature

Revision (07/07/2020)
ADDENDUM:
This case is being addended to refer the reader to the detailed COLORADO GENETICS LABORATORY report received regarding ROS1 rearrangement and MET amplification.

Block B2 was used for this study.

Note: Please see full report for Results/Details. Report is attached. ly

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Craig L Nerby, MD
Pathologist, Electronic Signature

Revision (07/02/2020)
ADDENDUM:
This case is being addended to refer the reader to the attached University of Colorado Denver Department of Pathology Molecular Correlates Laboratory report received - ALK and PD-L1 IMMUNOHISTOCHEMISTRY. Block B2 was used for this study.

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Please see full reports for details. Reports are attached. ly.

Carrie Pizzi, MD
Pathologist, Electronic Signature

Revision (06/23/2020)
ADDENDUM:
This case is retrieved from archives on 6/23/20 in order to select a block for CMOCO lung panel at the request of Dr. Sorensen, the patient's oncologist. Slides and report are reviewed. Block B2 is selected.

Craig L Nerby, MD
Pathologist, Electronic Signature

FINAL DIAGNOSIS:

A) **LYMPH NODE, LEFT JUGULAR, BIOPSY:**
ONE LYMPH NODE, NEGATIVE FOR METASTATIC CARCINOMA (0/1).

B) **LYMPH NODES, LEFT NECK, DISSECTION :**
1. THREE OF 20 LYMPH NODES, POSITIVE FOR **METASTATIC CARCINOMA**, MORPHOLOGICALLY AND IMMUNOHISTOCHEMICALLY CONSISTENT WITH PULMONARY PRIMARY (3/20).
2. SEE COMMENT.

C) **LYMPH NODE, SUPRACLAVICULAR, BIOPSY:**
TWO LYMPH NODES, NEGATIVE FOR METASTATIC CARCINOMA (0/2).

COMMENT:

Sections of the lymph nodes in part B demonstrate a large lymph node (block B2) showing metastatic carcinoma. The neoplastic cells are evaluated with immunohistochemical stains and demonstrate features most consistent with metastatic non-small cell pulmonary carcinoma, possibly adenosquamous carcinoma. In addition, two smaller lymph nodes are also positive for metastatic carcinoma with limited metastatic foci.

Craig L Nerby, MD
Pathologist, Electronic Signature

The case has been reviewed with the following pathologist(s) who concur with the interpretation: Meghan Riley, MD, Christopher

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ADDENDED

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DOB: **10/21/1960** Age: **59** Sex: **F**
Physician(s):
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Accession #: 12109519
Date Collected: **06/05/2020**
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Report Modified: **07/13/2020**

Bee, MD

Clinical History: left neck mass
Clinical Diagnosis: Left neck mass

GROSS DESCRIPTION:

A) Received fresh, which has been verified to belong to patient: MEHL, NINA ELIZABETH and labeled "A left jugular lymph node" is a 2.0 x 1.3 x 1.3 cm red-tan, rubbery lymph node. Sectioning reveals red- tan cut surfaces. Touch preps are performed, and the specimen is submitted entirely for frozen section evaluation. The frozen section remnant is submitted entirely in blocks A1.

B) Received fresh, which has been verified to belong to patient: MEHL, NINA ELIZABETH and labeled "B left neck dissection" is a 10.5 x 10.3 x 2.4 cm unoriented aggregate of yellow-tan, fatty soft tissue. No attached skeletal muscle is grossly identified. The specimen contains a suture which is located on 1 lymph node designated per the requisition as lymph node for biopsy (frozen). The lymph node at the sutured area is 1.4 by 1.2 x 0.9, the cut surfaces are tan-pink, touch preps are performed, and the specimen was submitted entirely for frozen section evaluation. Further sectioning through the soft tissue reveals a 1.5 x 1.2 x 1.0 cm firm, pink-tan lymph node which is located within the center of the specimen. The cut surfaces of the lymph node are tan-white an gritty. An H&E touch prep is performed. Sectioning through the attached fat reveals an additional 27 possible lymph nodes ranging in size from 0.2-1.1 cm. The lymph nodes are submitted entirely as follows:
Cassette Summary:
B1: FSB1, lymph node indicated by surgeon
B2: Largest lymph node (lymph node touch prep was performed on)
B3: 4 intact lymph nodes
B4: 5 intact lymph nodes
B5: 1 lymph node, sectioned
B6: 1 lymph node, sectioned
B7: 2 differentially inked and bisected lymph nodes
B8: 3 intact lymph nodes
B9: 2 intact lymph nodes
B10: 2 intact lymph nodes
B11: 3 intact lymph nodes
B12: 4 intact lymph nodes

C) Received in a formalin filled bottle/container, which has been verified to belong to patient: MEHL, NINA ELIZABETH and labeled "C additional supraclavicular lymph node" is a 2.3 x 1.8 x 0.6 cm aggregate of yellow-tan, fatty soft tissues. The soft tissues focally contain cautery artifact. Sectioning reveals a 1.0 cm in greatest dimension pink-tan lymph node, the cut surfaces are pink-tan. The tissue is submitted entirely as follows:
Cassette Summary:
C1: Lymph node, sectioned
C2: Disected fat

INTRAOPERATIVE CONSULT DIAGNOSIS:

A) Frozen: FSA) lymph node with no carcinoma identified.

6/5/20 at 1328.

[performed by Carrie Pizzi, MD]

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ABNORMAL

SURGICAL PATHOLOGY REPORT

ADDENDED

Patient: MEHL, NINA ELIZABETH
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DOB: **10/21/1960** Age: **59** Sex: **F**
Physician(s):
GILL SARVJIT MD MCKEE MEDICAL CENTER

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B) Frozen: FSB1) Lymph node with no carcinoma.

6/5/20 at 1408.

TPB2) Lymph node positive for malignant cells.

6/5/20 at 1416. [performed by Carrie Pizzi, MD]

MICROSCOPIC DESCRIPTION:

A) One intraoperative Diff-Quik-stained touch preparation, one intraoperative H&E-stained touch preparation, two H&E-stained slides from one frozen section block, and one H&E-stained slide from one paraffin block examined. Sections demonstrate an enlarged lymph node with intact architecture comprised of numerous primary and secondary follicles. There is also maintenance of the mantle zone around the germinal centers, an intact paracortex, and patent sinuses. No sheets of or aggregates of large atypical cells are seen. Metastatic disease is not identified. A panel of properly-controlled immunohistochemical stains is performed to further characterize the nodal architecture and components. The results are as follows: CD3, CD5, and CD43 highlight paracortical T-cells as well as scattered follicular helper T-cells within the germinal centers. CD20 and PAX-5 highlight B-cells within the primary follicles, germinal centers, and mantle zones. Germinal center B-cells are also positive for CD10 and BCL-6 and are appropriately negative for BCL-2. BCL-2 is positive in the paracortical, primary follicular, and mantle zone lymphocytes. CD23 highlights the retained follicular dendritic meshwork within the follicles and cyclin D1 shows no aberrant staining. Ki-67 shows a normal proliferation pattern with higher expression within the germinal centers.

NOTE: The immunoperoxidase tests utilized in this examination were developed and their performance characteristics determined by the laboratory at Summit Pathology. 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. This test is 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.

B) One intraoperative Diff-Quik-stained touch preparation, two intraoperative H&E-stained touch preparations, two H&E-stained slides from one frozen section block, 12 H&E-stained slides and 10 immunohistochemical stains (CK7, CK20, TTF-1, CDX-2, GATA-3, p40, p63, napsin A, CK5/6, and p16 with appropriate controls) from 12 paraffin embedded blocks examined. The immunohistochemical stains are performed to evaluate the metastatic tumor cells and show the following:
CK7- positive.
CK20 - patchy positive.
TTF-1 - positive.
CDX-2 - negative.
GATA-3 - negative.
p40 - negative.
p63 - focally positive.
Napsin A - positive.
CK5/6 - positive.
p16 - negative.

The immunohistochemical stains support the above diagnosis.

C) Two H&E slides from two paraffin blocks examined.

Preliminary results discussed with Elaina at Dr. Gill's office on 6/9/20.

NOTE: The immunoperoxidase tests utilized in this examination were developed and their performance characteristics determined by the laboratory at Summit Pathology. 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. This test is 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.

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ABNORMAL

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ADDENDED

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Med Rec#: **907371** PV: **00100874072**
DOB: **10/21/1960** Age: **59** Sex: **F**
Physician(s):
GILL SARVJIT MD MCKEE MEDICAL CENTER

Accession #: 12109519
Date Collected: **06/05/2020**
Date Received: **06/05/2020**
Date Reported: **06/10/2020**
Report Modified: **07/13/2020**

CPT Code(s): 88341 x19, G9424, 88331 x2, 88363, 88305 x2, 88342 x2, 88307

Specimen grossed and processed at: Summit Pathology 5802 Wright Dr., Loveland, CO, 80538
Specimen interpreted at: McKee Medical Center 2000 Boise Ave, Loveland, CO 80538

Colorado Genetics Laboratory

12705 East Montview Blvd., Suite 400
Aurora, Colorado 80045
Office 303-724-5701
Toll Free 888-659-4932
Fax 303-724-5795

Molecular Cytogenetics (FISH) Report

PATIENT: MEHL, NINA E.
BIRTHDATE: 10/21/1960
PATIENT ID: 907371
PHYSICIAN: Dr. Matthew Sorensen
FACILITY: McKee Medical Center
SPECIMEN: Paraffin Embedded Left Neck Lymph Node

ACCESSION NO.: 20FS-2109
COLLECTION DATE: 06/05/2020
RECEIPT DATE: 06/26/2020
ACCESSION DATE: 06/26/2020
LAB ID:
CASE ID:
SPECIMEN ID: MS20-00911-B2

PROCEDURE:
Fluorescence In Situ Hybridization

CLINICAL INDICATION:
Three of 20 lymph nodes, positive for metastatic carcinoma, morphologically and immunohistochemically consistent with pulmonary primary, initial study

PROBE:	RESULTS:	PERCENT:	TOTAL CELLS:	NORMAL CUTOFFS:
5'ROS1 (6q22.1) / 3'ROS1 (6q22.1)	Negative for a ROS1 rearrangement	100.0	100	
MET(7q31)/ 7cen	Negative for MET amplification (Ratio MET:7cen=1.1)	N/A	102	N/A

INTERPRETATION:

Interphase Molecular Cytogenetic (FISH) Studies:
ROS1
A dual color break apart translocation probe for interphase cells was performed on formalin fixed, paraffin embedded tissue that was pretreated with Proteinase K, and hybridized with Vysis (Abbott Laboratories) ROS1 (6q22.1) probe. ROS1 assay is considered positive if 15% or more of the cells demonstrate a rearrangement pattern; negative if <15% show a rearrangement pattern.

There was no evidence for a ROS1 rearrangement with this technique. This negative finding, when taken in isolation, suggests that this tumor is unlikely to be responsive to ROS1 inhibitors. Clinical correlation is recommended.

MET
Method:
MET Fluorescence In Situ hybridization was performed by manual slide processing technique on neutral formalin fixed paraffin embedded tissue that was pretreated with Proteinase K, and hybridized with the MET DNA Probe set (Vysis MET SpectrumOrange and Vysis 7 centromere SpectrumGreen from Abbott Molecular). Results obtained by manual microscope analysis are as follows:

MET gene (7q31.2) mean copy per cell: 2.4
7cen (7p11.1-q11.1) mean copy per cell: 2.2
MET/7cen ratio: 1.1
Number of cells scored: 102
Number of readers: 2

Negative for amplification of MET (MET to 7cen ratio < 1.8). This negative finding, when taken in isolation, suggests that this tumor is unlikely to be responsive to MET inhibitors. Clinical correlation is recommended.

FISH ISCN:

nuc ish(ROS1x1-4)[100],(D7Z1x1-4,METx1-6)[102]

Reviewed by:

FINAL Electronically signed by: Mary M. Haag, Ph.D., FACMG - Co-Director, Cytogenetics Laboratory 7/7/2020

Additional testing may have been performed to verify or clarify clinical validity of results.

This test was developed and its performance characteristics determined by Colorado Genetics Laboratory. The FDA does not require this test to go through premarket FDA review. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing.

Department of Pathology
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

Colorado Molecular Correlates Laboratory
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12705 E. Montview Blvd.
Aurora, CO 80045
Tel: 303.724.4754
Fax: 303.724.3096

Molecular Pathology Report

Patient Name:	**MEHL, NINA E.**	Accession #:	**M20-1712**
Med. Rec. #:	1821354	Collected:	6/5/2020
DOB/Age/Gender:	10/21/1960 (Age: 59) / F	Received:	6/26/2020
Client:	UCH MetroD	Reported:	6/30/2020
Location:			
Physicians:	MATTHEW D SORENSEN MD		

Specimen(s) Information

Specimen Identifier & Block: MS20-00911 – B2
Specimen Type: Lymph nodes, left neck dissection
Originating Institution: Summit Pathology – McKee Medical Center (Loveland, CO)
Tissue Processing: Formalin fixed, paraffin embedded
Specimen Assessment: Tumor cells present, adequate for evaluation

Date of Original Collection: 06/05/2020
Date of Laboratory Receipt: 06/25/2020

Results

ALK IMMUNOHISTOCHEMISTRY

Immunohistochemical evaluation for ALK protein expression was performed using ALK D5F3 antibody (Ventana Medical Systems) according to manufacturer instructions. Controls performed appropriately.

ALK IHC: NEGATIVE for ALK expression (SEE INTERPRETATION)

INTERPRETATION

There is no evidence of ALK expression in tumor cells in this case. These findings indicate a very low probability of underlying *ALK* rearrangement in this sample. Correlation with clinical and additional molecular findings is recommended.

PD-L1 IMMUNOHISTOCHEMISTRY

Immunohistochemical testing was performed to generate a tumor proportion score (TPS) indicating the percentage of tumor cells positive for PD-L1 expression in this tumor.

PD-L1 IHC: HIGH POSITIVE for PD-L1 expression (SEE INTERPRETATION)

PD-L1 TPS: >90%

INTERPRETATION

The predictive implications of PD-L1 immunohistochemical staining depends on the clinical setting. For consideration of therapy using pembrolizumab in non–small cell lung cancer (NSCLC), the treatment history and driver mutation status must be considered (1). Pembrolizumab is indicated for the first-line treatment of patients with metastatic NSCLC whose tumors have high PD-L1 expression [tumor proportion score (TPS) ≥50% of tumor cells at any intensity], with no *EGFR*, *ALK* or *ROS1* genomic tumor aberrations. Pembrolizumab is indicated for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1% of tumor cells at any intensity), with disease progression on or after platinum-containing chemotherapy. Patients with *EGFR*, *ALK* or *ROS1* genomic tumor aberrations should have disease progression on FDA-approved therapy targeting these aberrations prior to receiving pembrolizumab. The implications of PD-L1 expression in this setting is unclear. While a recent publication indicated improved overall survival in previously treated *EGFR* positive tumors with progression after first-line targeted agents and second-line platinum containing chemotherapy demonstrating PDL1 expression (TPS ≥1% of tumor cells at any intensity) (2), additional data is required to establish testing guidelines (1). Guidelines for utilization of PD-L1 IHC results for determination of immunotherapy in other tumor types are also under development.

Materials Received

See case M20-1686.

Methods and Assay Limitation

The Ventana ALK (D5F3) CDX assay is a qualitative test to detect ALK expression as a surrogate measure of ALK rearrangement in formalin-fixed paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue specimens to aid in identifying those patients eligible for treatment with XALKORI® (crizotinib). The test is for prescription use only. This laboratory is certified under the Clinical Laboratory Improvement Act Amendment of 1988 (CLIA) as qualified to perform high complexity testing. The result has been verified by a pathologist. The Ventana ALK (D5F3) CDX assay has been approved by the U.S. Food and Drug Administration (FDA).

Antibody clone SP263 (Ventana, Inc) was utilized for immunohistochemical testing on the Ventana Medical Systems (Roche Diagnostics) Benchmark Ultra platform with DAB/peroxidase detection with appropriate controls, using reagents and instrumentation per package insert. Results are based on assessment of the proportion of tumor cells that display at least partial membranous positivity of any intensity and are reported as negative (<1%), low positive (1 to <50%) and high positive (≥50%).

1. Hanna N, et. al., J Clin Oncol 2017 (PMID: 28806116); 2. Herbst RS, et. al., Lancet 2016 (PMID: 26712084)

The performance characteristics of the PD-L1 procedure using the Ventana SP263 antibody with a DAB/peroxidase detection system has been validated by the University of Colorado, Department of Pathology on specimens previously stained with the Dako 22C3 clone. This assay has been validated for use on formalin fixed tissue or cell block material. This test has not been cleared or approved by the United States Food and Drug Administration (FDA). FDA review is not required for the performance of this test.

Final Diagnosis Reviewed and Interpreted By
Dara L. Aisner, M.D., Ph.D.
Electronically Signed, 6/30/2020

Other Case Numbers

M20-1686, M20-1710

"I Certify that (1) all services on this form were rendered and are hereby approved for Billing, (2) the medical record has been documented for these services, and (3) the rendering of the services and the documentation in the medical record are in accordance with CU Medicine guidelines."

END OF REPORT

Department of Pathology
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

Colorado Molecular Correlates Laboratory
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Aurora, CO 80045
Tel: 303.724.4754
Fax: 303.724.3096

Molecular Pathology Report

Patient Name:	**MEHL, NINA E.**	Accession #:	**M20-1686**
Med. Rec. #:	1821354	Collected:	6/5/2020
DOB/Age/Gender:	10/21/1960 (Age: 59) / F	Received:	6/25/2020
Client:	Summit - UCHealth	Reported:	7/8/2020
Location:			
Physicians:	MATTHEW D SORENSEN MD	Copy To:	Summit Pathology - McKee Medical Center

Specimen(s) Information

Specimen Identifier & Block: MS20-00911 – B2
Specimen Type: Lymph nodes, left neck dissection
Originating Institution: Summit Pathology – McKee Medical Center (Loveland, CO)
Tissue Processing: Formalin fixed, paraffin embedded
Specimen Assessment: Tumor cells present, adequate for evaluation
Date of Original Collection: 06/05/2020
Date of Laboratory Receipt: 06/25/2020

Results

LUNG CARCINOMA MUTATIONAL PANEL by Targeted Next-Generation Sequencing		
Gene	**Predicted Protein Changes (if applicable)**	**Nucleotide Change (if applicable)**
1. *EGFR*	No mutation detected	
2. *KRAS*	No mutation detected	
3. *BRAF*	No mutation detected	
4. *ERBB2 (HER2)*	No mutation detected	

**Other variants, not included as part of the ordered panel, were preliminarily identified in *NOTCH1*. Additional characterization and interpretation of these findings can be provided upon clinical request.

INTERPRETATION

No significant mutations were identified in *EGFR*, *KRAS*, *BRAF*, or *ERBB2* (HER2) in this sample. Tumor enrichment methodology was reviewed to ensure appropriate levels of tumor testing in this specimen, based on the analytic sensitivity of the assay. Please refer to the Assay Limitations section.

Materials Received

Received from Summit Pathology, 5802 Wright Drive, Loveland, CO 80538 is one paraffin embedded block labeled “MS20-00911 – B2” (06/05/2020). Accompanying the block is a pathology report containing the number “MS20-00911” and identifying the patient as Nina Elizabeth Mehl.

Methods and Assay Limitation

Preanalytical Processing: H&E-stained paraffin sections were examined by a board-certified anatomic pathologist for testing suitability. Tumor cells were isolated by microscope assisted microdissection followed by tumor cell lysis and DNA extraction.

Lung Cancer Sequencing Panel

Library preparation for multiple gene targets was carried out using the Archer VariantPlex Solid Tumor sequencing panel (ArcherDx, Inc.). Within this 54 gene preparation, regions of *EGFR*, *KRAS*, *BRAF* and *ERBB2 (*HER2*)* are evaluated as part of the selected panel. [Reference Sequences: *EGFR*: NM_005228.4; *BRAF*: NM_004333.4; *ERBB2*: NM_004448.2 *KRAS*: NM_004895.3] Specific regions of analysis for these 4 genes can be provided upon request. A bioinformatic analysis algorithm developed by the assay manufacturer was applied to map targeted regions and identify variants and assay artifacts. Variants not anticipated to result in changes to amino acid sequence (most intronic variants, synonymous variants) are not reported with the exception of clinically relevant splice site alterations which are reported. In addition to the 4 reported gene targets, an additional 50 genes are part of the technical assay preparation, and can be additionally analyzed upon request (additional charges may apply). Additional genes which may be available for analysis include selected regions of: *AKT1, ALK, APC, ATM, AURKA, CDH1, CDK4, CDKN2A, CTNNB1, DDR2, ERBB3, ERBB4, ESR1, FBXW7, FGFR1, FGFR2, FGFR3, FOXL2, GNA11, GNAQ, GNAS, H3F3A,*

HNF1A, HRAS, IDH1, IDH2, KDR, KIT, MAP2K1, MET, MLH1, NOTCH1, NRAS, PDGFRA, PIK3CA, PIK3R1, PTEN, PTPN11, RB1, RET, RHOA, ROS1, SMAD4, SMARCB1, SMO, SRC, STK11, TERT, TP53, VHL.

Assay Limitations: This assay does not detect all types of mutations. For example, chromosomal translocations, gene fusions, and copy number alterations are not detected. Insertions larger than 21 base pairs and deletions larger than 30 base pairs may not be detected. At 100x minimum read depth (based on de-duplicated reads), the analytic sensitivity for mutations in the genes listed above is 10% variant allele frequency. Unless otherwise specified, all reported regions met the minimum criteria of 100x coverage. Although microdissection is employed, mutations present at a level below the analytic sensitivity may not be detected by this assay. This assay is not designed for the detection of germline alterations.

The above tests were developed in and the performance characteristics determined by the Colorado University Molecular Correlates Laboratory in the Department of Pathology, University of Colorado Denver. The procedures and reagents used in immunohistochemical and molecular diagnostic tests have been validated by evaluation of normal control patients and positive controls. This testing has not been cleared by the United States Food and Drug Administration (FDA). However, the FDA has determined that such clearance or approval is not required for clinical implementation. Test results have been shown to be clinically useful. The University of Colorado Department of Pathology is accredited by the College of American Pathologists (CAP) and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) to perform high complexity clinical laboratory testing.

Final Diagnosis Reviewed and Interpreted By
Dara L. Aisner, M.D., Ph.D.
Electronically Signed, 7/8/2020

Other Case Numbers
M20-1710, M20-1712
ILI: 07012020MCS VAR

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END OF REPORT

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Molecular Pathology Report

Patient Name:	**MEHL, NINA E.**	Accession #:	**M20-1710**
Med. Rec. #:	1821354	Collected:	6/5/2020
DOB/Age/Gender:	10/21/1960 (Age: 59) / F	Received:	6/25/2020
Client:	UCH MetroD	Reported:	7/9/2020
Location:			
Physicians:	MATTHEW D SORENSEN MD		

Specimen(s) Information

Specimen Identifier & Block: MS20-00911 – B2
Specimen Type: Lymph nodes, left neck dissection
Originating Institution: Summit Pathology – McKee Medical Center (Loveland, CO)
Tissue Processing: Formalin fixed, paraffin embedded
Specimen Assessment: Tumor cells present, adequate for evaluation

Date of Original Collection: 06/05/2020
Date of Laboratory Receipt: 06/25/2020

Results

MULTIPLEX FUSION ANALYSIS by Targeted Next-Generation Sequencing

Suboptimal specimen, uninformative (see INTERPRETATION)

INTERPRETATION

Extracted nucleic acids from this specimen were evaluated for fusions and potentially oncogenic transcripts, however the nucleic acid quality did not meet minimum quality specifications. Thus this assay should be interpreted as uninformative.

Materials Received

See case M20-1686.

Methods and Assay Limitation

Preanalytical processing: H&E stained paraffin sections were examined by a board-certified anatomic pathologist for testing suitability. Previously microdissected nucleic acids were utilized for next generation sequencing.

Fusion Analysis by Targeted Next-Generation Sequencing

Anchored Multiplex PCR based enrichment and library preparation, examining RNA from selected regions of targeted genes, was carried out using the FusionPlex Solid Tumor sequencing panel (ArcherDx, Inc.). Bioinformatics analysis was carried out using version-controlled Archer Analysis (4.1.1.7). Targeted, validated gene regions include *ALK*, *ROS1* and *MET*, although other evaluated genes may be reported on a case-by-case basis in the above section indicating findings of uncertain significance.

Assay Limitations

This assay is performed on RNA extracted from tissues, and therefore negative findings may not always be informative. Although quality metrics are evaluated to best inform the confidence in negative findings, and when suboptimal they are reported as such, caution should be utilized in the interpretation of negative findings. This assay does not detect point mutations, copy number changes (including amplifications), insertions/deletions and is focused on detection of gene fusion events and alternate transcripts which are potentially oncogenic. Specification of analytic sensitivity for a RNA-based assay is generally considered to be uninformative, as expression levels that cannot be assessed in visual assessments of tumor cell content can influence the sensitivity of detection. Although tumor enrichment is performed, alterations below the threshold of this assay may not be detected. This is a targeted assay, therefore regions outside the areas of specific investigation are not assessed.

Final Diagnosis Reviewed and Interpreted By
Dara L. Aisner, M.D., Ph.D.
Electronically Signed, 7/9/2020

Other Case Numbers
M20-1686, M20-1712
ILI: 07012020KRN FUS

"I Certify that (1) all services on this form were rendered and are hereby approved for Billing, (2) the medical record has been documented for these services, and (3) the rendering of the services and the documentation in the medical record are in accordance with CU Medicine guidelines."

END OF REPORT