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

NON-GYN CYTOPATHOLOGY REPORT

ADDENDED

Patient: JONAS, FRANK J
Med Rec#: **2457267** PV: **177442697**
DOB: **12/03/1946** Age: **73** Sex: **M**
Physician(s):
DEPRIEST KIRK D.O. POUDRE VALLEY HOSPITAL

Accession #: 12115832
Date Collected: **06/17/2020**
Date Received: **06/17/2020**
Date Reported: **06/19/2020**
Report Modified: **07/30/2020**

Test Requested: **PVH Non-Gyn Cytology**
Result ID: VC20-00409

Revision (07/30/2020)

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 - LUNG CARCINOMA MUTATIONAL PANEL. Block B1 was used for this study.

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

Heath D Worcester, MD
Pathologist, Electronic Signature

Revision (07/02/2020)

ADDENDUM:
PD-L1 (SP263) IHC Results:
HIGH EXPRESSION: >50%
-Tumor proportion score: 60% staining

Stain performed on block B1

Interpretive information:

PD-L1 SP263 Ventana Assay performed by immunohistochemistry. Routinely processed formalin-fixed, paraffin-embedded tissues are suitable for use with this primary antibody when used with OptiView DAB IHC detection kit and BenchMark Ultra IHC/ISH instrument. PD-L1 protein expression is determined by using tumor proportion score, which is the presence of viable tumor cells showing partial or complete membrane staining at any intensity above baseline. This assay is indicated as an aid in identifying treatment. Positive and negative controls react satisfactorily. Dr. Bee reviewed the PD-L1 stain and concurs with the above interpretation.

Billing codes associated with this revision: 88360

Michael Walts, MD
Pathologist, Electronic Signature

FINAL DIAGNOSIS:

A) LYMPH NODE, SUBCARINAL, ENDOBRONCHIAL ULTRASOUND-GUIDED FNA:
1. ADEQUATE FOR EVALUATION
2. MALIGNANT; COMPATIBLE WITH NON-SMALL CELL CARCINOMA

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B) LYMPH NODE, RIGHT HILAR, ENDOBRONCHIAL ULTRASOUND-GUIDED FNA:
1. ADEQUATE FOR EVALUATION
2. MALIGNANT; COMPATIBLE WITH NON-SMALL CELL CARCINOMA

C) RIGHT LUNG, UPPER LOBE, FINE NEEDLE ASPIRATION:
1. ADEQUATE FOR EVALUATION
2. MALIGNANT; COMPATIBLE WITH NON-SMALL CELL CARCINOMA

D) RIGHT LUNG, UPPER LOBE, BRUSHING CYTOLOGY:
1. ADEQUATE FOR EVALUATION
2. MALIGNANT; COMPATIBLE WITH NON-SMALL CELL CARCINOMA

E) RIGHT LUNG, UPPER LOBE, BRONCHO-ALVEOLAR LAVAGE CYTOLOGY WITH CELL BLOCK:
1. ADEQUATE FOR EVALUATION
2. MALIGNANT; COMPATIBLE WITH NON-SMALL CELL CARCINOMA

COMMENT:

The specimens show similar features of a non-small cell carcinoma. The immunophenotype is non-specific and organ specific markers are negative. No glandular or squamous differentiation is seen. These findings represent a poorly-differentiated carcinoma and cannot be further characterized in these samples. Dr. Walts concurs.

Heath D Worcester, MD
Pathologist, Electronic Signature

The case has been reviewed with the following pathologists who concur with the interpretation: Michael Walts, MD

Clinical History: Cough, possible lung cancer.

GROSS DESCRIPTION:

A) **SUBCARINAL:** Received in CytoLyt, labeled with the patient's name and "1 subcarinal needle", are 25 mL of colorless, hazy fluid. Routine ThinPrep is performed. Sample is dilute.

Received in Formalin, labeled with the patients name and "A subcarinal LN needle", are 30 mL of red, hazy fluid. One cell block is prepared using buffered 10% formalin.

Also received labeled with the patient's name, are 2 Diff-Quik stained slides and 2 fixed slides.

B) **RT HILAR:** Received in CytoLyt, labeled with the patient's name and "2 R hilar", are 28 mL of pink, hazy fluid. Routine ThinPrep is performed.

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Physician(s):
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Received in Formalin, labeled with the patients name and "B right hilar LN", are 25 mL of pale red, hazy fluid. One cell block is prepared using buffered 10% formalin.

Also received labeled with the patient's name, are 2 Diff-Quik stained slides and 2 fixed slides.

C) **RUL NEEDLE:** Received in CytoLyt, labeled with the patient's name and "3 RUL", are 8 mL of red, opaque fluid. Routine ThinPrep is performed.

Received in Formalin, labeled with the patients name and "C RUL", are 27 mL of red, opaque fluid. One cell block is prepared using buffered 10% formalin.

Also received labeled with the patient's name, are 2 Diff-Quik stained slides and 2 fixed slides.

D) **RUL BRUSH:** Received in CytoLyt with 1 brush labeled with the patient's name and "4 RUL brush", are 25 mL of pink, hazy fluid. Routine ThinPrep performed. Sample inadequate for cell block.

E) **RUL BAL:** Received unfixed, labeled with the patient's name and "RUL BAL", are 10 mL of bright red, opaque fluid. Routine ThinPrep is performed. One cell block is prepared using buffered 10% formalin.

INTRAOPERATIVE CONSULT DIAGNOSIS:

A) FNA Adequacy: Atypical cells and lymphoid tissues, favor lesional. (1355) [performed by Jeremiah Andersen, MD]

B) FNA Adequacy: Lymphoid cells present with fewer atypical cells than A. (1359) [performed by Jeremiah Andersen, MD]

C) FNA Adequacy: Lesional cells present, request more for cell block. (1410)
6/17/20 [performed by Jeremiah Andersen, MD]

MICROSCOPIC DESCRIPTION:

A) 1 Thin prep, 4 direct smears and 1 cell block examined.

B) 1 Thin prep, 4 direct smears and 1 cell block examined.
Also examined are immunoperoxidase-stained sections for CK5/6, CK7, CK20, TTF-1, NapsinA, p40, CDX-2, and GATA3 which show tumor positiivty for CK7 only, while 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.)

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C) 1 Thin prep, 4 direct smears and 1 cell block examined.

D) One ThinPrep slide examined.

E) One ThinPrep slide and one cell block slide examined.

CPT Code(s): 88341 x7, 88360, 88172 x3, G9418, 88173 x3, 88112 x2, 88305 x4, G9785, 88342

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

Department of Pathology
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

Colorado Molecular Correlates Laboratory
BioScience 2, Suite 400
12705 E. Montview Blvd.
Aurora, CO 80045
Tel: 303.724.4754
Fax: 303.724.3096

Molecular Pathology Report

Patient Name:	**Jonas, Frank J.**	Accession #:	**M20-1759**
Med. Rec. #:	2457267	Collected:	6/17/2020
DOB/Age/Gender:	12/3/1946 (Age: 73) / M	Received:	7/6/2020
Client:	Summit - UCHealth	Reported:	7/27/2020
Location:			
Physicians:	MATTHEW D SORENSEN MD		

Specimen(s) Information

Specimen Identifier & Block: VC20-00409 – DQ CP2
Specimen Type: Right lung, upper lobe, fine needle aspiration
Originating Institution: Summit Pathology – Poudre Valley Hospital (Aurora, CO)
Tissue Processing: Diff-Quik stained slide
Specimen Assessment: Tumor cells present, adequate for evaluation

Date of Original Collection: 06/17/2020
Date of Laboratory Receipt: 07/06/2020

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 *CDKN2A, ERBB4,* and *TP53*. 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.

Select portions of the following genes or gene regions produced reduced coverage, which may reduce detection of variants in these regions: *KRAS* exon 3. Supplemental testing of an alternate sample to further exclude mutations could be considered if available and clinically indicated.

Materials Received

Received from Summit Pathology, 5802 Wright Drive, Loveland, CO 80538 is one paraffin embedded block labeled “VC20-00409 – B1” (06/17/2020). Accompanying the block is a pathology report containing the number “VC20-00409” and identifying the patient as Frank J. Jonas.

Received on 07/14/2020 from Summit Pathology, 5802 Wright Drive, Loveland, CO 80538 are six stained slides labeled “VC20-409 - AP1, AP2 (Subcarinal Diff Quick) BP1, BP2, (RT Hilar Diff Quick) CP1, CP2 (RUL Needle Diff Quick)” and two paraffin embedded blocks labeled “VC20-00409 – A1, C1” (06/17/2020). Accompanying the block is a pathology report containing the number “VC20-00409” and identifying the patient as Frank J. Jonas.

Methods and Assay Limitation

Preanalytical Processing: Diff-Quik stained smear slides 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
Nicholas S. Willard, M.D.
Electronically Signed, 7/27/2020

Other Case Numbers
M20-1860, M20-1946
ILI: 07012020KTH VAR

"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