Afirma
THYROID FNA ANALYSIS

VV21251

REPORT STATUS: Final
PAGES: 1 of 2
CLIENT ID: 97
AFIRMA REQ: R1234

PATIENT REPORT

PATIENT INFORMATION

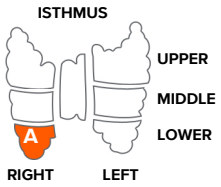
PATIENT: John Doe | **DOB:** 01 Jan 1973 | **GENDER:** M | **LAB ID:** L123 | **MRN:** M123

COLLECTION DATE	23 Apr 2018	**FACILITY NAME**	University Hospital of Anytown		
RECEIVED DATE	04 May 2018	**SUBMITTING PHYSICIAN**	Jane Demo	**PHONE**	(555) 555-5555
REPORT DATE	04 May 2018	**TREATING PHYSICIAN/CC**	---	**PHONE**	---

CLINICAL HISTORY: History of Cancer: No, Family History of Thyroid Cancer: No, History of I(131)radiation or external radiation therapy: No

RESULTS SUMMARY

NODULE	CYTOPATHOLOGY	AFIRMA GSC	MALIGNANCY CLASSIFIERS	XPRESSION ATLAS
A	Indeterminate	Suspicious (ROM ~50%[1])	Negative	*NRAS*:p.Q61R c. 182A>G *TSHR*:p.M453T c. 1358T>C



See Xpression Atlas results overview page for additional information

RESULTS DETAILS

NODULE A	**SIZE:** 1.45 cm **LOCATION:** Lower Right
CYTOPATHOLOGY DIAGNOSIS	**Indeterminate - Atypia of Undetermined Significance** (AUS - Bethesda Category III)
DIAGNOSTIC COMMENTS	These features are best categorized as follicular lesion of undetermined significance (Bethesda Category III).
MICROSCOPIC DESCRIPTION	The cytologic and cell block preparations are sparsely cellular and contain only microfollicles and scant colloid.
AFIRMA GSC RESULT	**Suspicious**
MALIGNANCY CLASSIFIERS RESULTS	**Negative**: *BRAF* p. V600E c. 1799T>A, MTC **Not Detected**: *RET/PTC1*, *RET/PTC3*
MALIGNANCY CLASSIFIERS COMMENTS	MTC and *BRAF* malignancy classifier results were negative and *RET/PTC1* and *RET/PTC3* were not detected. These results do not change the risk of malignancy (ROM) of the Afirma GSC Suspcious result.
GROSS DESCRIPTION	Received one vial of CytoLyt and one vial of FNAprotect, each labeled with the Requisition Form # and patient initials.

RESULTS INTERPRETATION

Afirma GSC[1,5]	**Cytopathology Diagnosis Indeterminate**[§]
Risk of Malignancy: **Afirma GSC Benign**	4%
Risk of Malignancy: **Afirma GSC Suspicious**	~50%
Sensitivity:	91%
Specificity:	68%
Limit of Detection[†]:	5%

	Malignancy Classifiers			
	MTC[3,8]	***BRAF***[‡2,4,8]	***RET/PTC***[2,8]	**Parathyroid**[6,8]
Sensitivity/Specificity	>99% / >99%			>99% / >99%
PPA/NPA		>99% / >99%		
Confirmation Rate/NPA			>99% / >99%	
Risk of Malignancy	>99%	>95%	>95%	
Limit of Detection[†]	20%	5%	10%	15%

References: 1. Patel KN, et al. WCTC 2017. 2. Haugen BR, et al. *Thyroid* 2016. 3. Randolph G, et al. ATA 2017 4. Angell TE, et al. ATA 2017. 5. Hu Z, et al. ATA 2017. 6. Sosa JA, et al. ATA 2017. 8. Data on file.

§ Indeterminate includes Atypia of Undetermined Significance / Follicular Lesion of Undetermined Significance and (suspicious for) Follicular Neoplasm / Hürthle Cell Neoplasm.
† Analytical sensitivity studies demonstrated the test's ability to detect malignant cells in a background of benign cells.
‡ *BRAF* classifier performance is based on a comparison to a castPCR DNA assay for the *BRAF* V600E mutation.

Afirma Thyroid FNA Analysis is a diagnostic service provided by Veracyte, Inc. for the assessment of thyroid nodules that includes cytopathology and gene expression testing. Afirma GSC, *BRAF*, MTC and *RET/PTC* tests and their performance characteristics were determined by Veracyte. MTC is an RNA classifier that identifies the presence of medullary thyroid carcinoma (MTC); *BRAF* is a *BRAF* p. V600E, c. 1799T>A RNA classifier; *RET/PTC* is a gene expression marker of somatic rearrangements of the *RET* protooncogene (*RET/PTC1* and *RET/PTC3*).

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AFIRMA XPRESSION ATLAS RESULTS OVERVIEW

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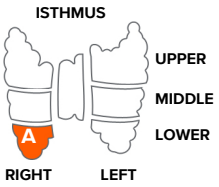
CLINICAL HISTORY: History of Cancer: No, Family History of Thyroid Cancer: No, History of I(131)radiation or external radiation therapy: No

RESULTS SUMMARY

NODULE	INSUFFICIENT PUBLISHED EVIDENCE	ASSOCIATED WITH BOTH BENIGN AND MALIGNANT NODULES	HIGHLY ASSOCIATED WITH MALIGNANT NODULES
A	*TSHR*:p.M453T c. 1358T>C	*NRAS*:p.Q61R c. 182A>G	---



Protein sequence is inferred from the nucleotide positions interrogated by the Afirma Xpression Atlas

RESULTS DETAILS

NODULE A | **SIZE:** 1.45 cm | **LOCATION:** Lower Right

XPRESSION ATLAS RESULT
Variants: *NRAS*:p.Q61R c. 182A>G, *TSHR*:p.M453T c. 1358T>C
Fusions: Not Detected

DIAGNOSTIC COMMENTS
The *NRAS*:p.Q61R c. 182A>G variant has been identified in both benign and malignant nodules. Clinical correlation is recommended.
Insufficient published evidence exists to calculate a risk of malignancy (ROM) for the *TSHR*:p.M453T c. 1358T>C variant. Clinical correlation is recommended.
Insufficient evidence exists for the ROM in the presence of multiple nucleotide variants and/or fusions.
Negative for common variants including HRAS, KRAS, PAX8/PPARG.

RESULTS INTERPRETATION

	BRAF V600E §,2,4,8	Xpression Atlas[7] (Afirma GSC suspicious, suspicious for malignancy, or malignant cytopathology) Nucleotide Variant Panel**	Fusion Panel***
NPA	>99%	>99%	>99%
PPA	>99%	74%	82%
Confirmation Rate†	>98%	>98%	>99%
Limit of Detection‡	5%	5%	10%

References: 2. Haugen BR, et al. *Thyroid* 2016. 4. Angell TE, et al. ATA 2017. 7. Sadow PM, et al. AACE 2018. 8. Data on file.

§ BRAF classifier performance is based on a comparison to a castPCR DNA assay for the BRAF V600E mutation.
** Nucleotide variant performance is based on a comparison to a DNA AmpliSeq assay that measures variants using a 5% variant allele frequency threshold.
*** Fusion performance is based on a comparison to an RNA AmpliSeq fusion assay and TaqMan assays.
† Confirmation rate is the proportion of positive calls that are confirmed positive by the reference method.
‡ Analytical sensitivity studies demonstrate the test's ability to detect a positive variant in a background of wild type.

Afirma Xpression Atlas is a diagnostic service provided by Veracyte, Inc. The Xpression Atlas sequences 511 genes to measure the presence or absence of 761 nucleotide variants and 130 fusion pairs. The performance characteristics were determined by Veracyte. Genomic coordinates or full list of genes and variants available upon request.

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