Afirma
THYROID FNA ANALYSIS

VV20991

REPORT STATUS: Final
PAGES: 1 of 1
CLIENT ID: 97
AFIRMA REQ: R123

PATIENT REPORT

PATIENT INFORMATION

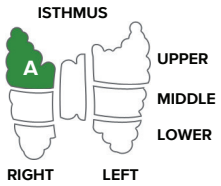
PATIENT: Jane Doe | **DOB:** 01 Jan 1977 | **GENDER:** F | **LAB ID:** L123 | **MRN:** M123

COLLECTION DATE	11 Mar 2018	**FACILITY NAME**	University Hospital of Anytown		
RECEIVED DATE	12 Mar 2018	**SUBMITTING PHYSICIAN**	Jane Demo	**PHONE**	(555) 555-5555
REPORT DATE	23 Apr 2018	**TREATING PHYSICIAN/CC**	---	**PHONE**	---

CLINICAL HISTORY: No Clinical History Provided

RESULTS SUMMARY

NODULE	CYTOPATHOLOGY	AFIRMA GSC	MALIGNANCY CLASSIFIERS	XPRESSION ATLAS
A	Indeterminate	Benign (ROM 4%[1])	Negative	N/A



RESULTS DETAILS

NODULE A	**SIZE:** 1.5 cm **LOCATION:** Upper 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	**Benign**
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 Benign 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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REPORT STATUS: Final
PAGES: 1 of 2
CLIENT ID: 99
AFIRMA REQ: R123

PATIENT REPORT

PATIENT INFORMATION

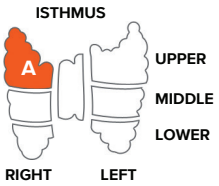
PATIENT: John Doe | **DOB:** 01 Jan 1973 | **GENDER:** M | **LAB ID:** L123 | **MRN:** M123

COLLECTION DATE	11 Mar 2018	**FACILITY NAME**	Production Test Clinic		
RECEIVED DATE	12 Mar 2018	**SUBMITTING PHYSICIAN**	Rob Monroe	**PHONE**	---
REPORT DATE	24 Apr 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	Not Detected



See Xpression Atlas results overview page for additional information

RESULTS DETAILS

NODULE A	**SIZE:** 1.1 cm **LOCATION:** Upper Right
CYTOPATHOLOGY DIAGNOSIS	**Indeterminate - Follicular Lesion of Undetermined Significance** (FLUS - Bethesda Category III)
DIAGNOSTIC COMMENTS	These features are best classified as atypia of undetermined significance.
MICROSCOPIC DESCRIPTION	The cytologic and cell block preparations are sparsely cellular and show a few clusters of follicular cells in crowded or microfollicular groups and some 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.

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