



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

PATIENT REPORT

PATIENT INFORMATION

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

COLLECTION DATE 11 Mar 2018 University Hospital of Anytown **FACILITY NAME**

12 Mar 2018 Jane Demo **PHONE** (555) 555-5555 **RECEIVED DATE** SUBMITTING PHYSICIAN

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	ISTHMUS
Α	Indeterminate	Benign (ROM 4%¹)	Negative	N/A	MIDDLE
					RIGHT LEFT

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			
AFIRMA GSC RESULT MALIGNANCY CLASSIFIERS RESULTS	Benign Negative: BRAF p. V600E c. 1799T Not Detected: RET/PTC1, RET/PTC			
MALIGNANCY CLASSIFIERS	Negative: BRAF p. V600E c. 1799T Not Detected: RET/PTC1, RET/PTC			

RESULTS INTERPRETATION

Cytopathology Diagnosis Afirma GSC ^{1,5} Indeterminate*		Malignancy Classifiers			
Indeterminate*		MTC ^{3,8}	BRAF#2,4,8	RET/PTC ^{2,8}	Parathyroid 6,8
4%	Sensitivity/Specificity	>99% / >99%			>99% / >99%
~50%	PPA/NPA		>99% / >99%		
91%	Confirmation Rate/NPA			>99% / >99%	
68%	Risk of Malignancy	>99%	>95%	>95%	
5%	Limit of Detection [†]	20%	5%	10%	15%
	Indeterminate* 4% ~50% 91% 68%	Indeterminate* 4% Sensitivity/Specificity ^50% PPA/NPA 91% Confirmation Rate/NPA 68% Risk of Malignancy	Indeterminate* 4% Sensitivity/Specificity ^50% PPA/NPA 91% Confirmation Rate/NPA Risk of Malignancy >99% >99%	Indeterminate*	Indeterminate* MTC3.8 BRAF±24.8 RET/PTC2.8 4% Sensitivity/Specificity >99% / >99% >99% / >99% "50% PPA/NPA >99% / >99% >99% / >99% 91% Confirmation Rate/NPA >99% / >99% >99% / >99% 68% Risk of Malignancy >99% / >99% >95% >95%

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).

E-SIGNED ON 23 Apr 2018 06:53 AM BY:

Robert J Monroe MD, PhD, Veracyte Inc. CLIA # 05D2014120 6000 Shoreline Ct, Suite 100, South San Francisco, CA 94080

CYTOPATHOLOGY E-SIGNED ON 12 Mar 2018 11:22 AM BY:

Tom Traweek, MD, Thyroid Cytopathology Partners, CLIA # 45D2037953 12357-A Riata Trace Parkway, Bldg. 5, Suite 100, Austin, TX 78727 Professional component provided by the above TCP pathologist

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6000 Shoreline Court, Suite 100 South San Francisco, CA 94080

888.9AFIRMA (888.923.4762) 650.243.6350 (International)

F 650.243.6388 E support@veracyte.com





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

ISTHMUS **XPRESSION MALIGNANCY NODULE** CYTOPATHOLOGY **AFIRMA GSC CLASSIFIERS ATLAS** UPPER MIDDLE Indeterminate Negative Not Detected LOWER RIGHT LEF1

See Xpression Atlas results overview page for additional information

RESULTS DETAILS NODULE A SIZE: 1.1 cm **LOCATION:** Upper Right Indeterminate - Follicular Lesion of Undetermined Significance (FLUS - Bethesda Category III) CYTOPATHOLOGY DIAGNOSIS These features are best classified as atypia of undetermined significance. DIAGNOSTIC COMMENTS 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 **Negative**: *BRAF* p. V600E c. 1799T>A, MTC **Not Detected**: *RET/PTC1*, *RET/PTC3* **MALIGNANCY CLASSIFIERS RESULTS** MTC and BRAF malignancy classifier results were negative and RET/PTC1 and RET/PTC3 were not detected. These **MALIGNANCY CLASSIFIERS** results do not change the risk of malignancy (ROM) of the Afirma GSC Suspcious result. **COMMENTS GROSS DESCRIPTION** Received one vial of CytoLyt and one vial of FNAprotect, each labeled with the Requisition Form # and patient

RESULTS INTERPRETATION

Afirma GSC ^{1,5}	Cytopathology Diagnosis Indeterminate [§]		Ma MTC ^{3,8}	lignancy Classi BRAF ^{‡2,4,8}	fiers RET/PTC ^{2,8}	Parathyroid ^{6,8}
Risk of Malignancy: Afirma GSC Benign	4%	Sensitivity/Specifi			KLI/FIC "	>99% / >99%
Risk of Malignancy: Afirma GSC Suspicious	~50%	PPA/NPA	city - 33707 - 3370	>99% / >99%		, 33,07 - 33,0
Sensitivity:	91%	Confirmation Rate	/NPA		>99% / >99%	
Specificity:	68%	Risk of Malignanc	y >99%	>95%	>95%	
Limit of Detection [†] :	5%	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

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[‡] BRAF classifier performance is based on a comparison to a castPCR DNA assay for the BRAF V600E mutation.

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E-SIGNED ON 24 Apr 2018 08:50 AM BY:

Robert J Monroe MD, PhD, Veracyte Inc. CLIA # 05D2014120 6000 Shoreline Ct, Suite 100, South San Francisco, CA 94080

CYTOPATHOLOGY E-SIGNED ON 12 Mar 2018 11:43 AM BY:

Cherry Starling, MD, Thyroid Cytopathology Partners, CLIA # 45D2037953 12357-A Riata Trace Parkway, Bldg. 5, Suite 100, Austin, TX 78727 Professional component provided by the above TCP pathologist

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6000 Shoreline Court, Suite 100 South San Francisco, CA 94080 T 888.9AFIRMA (888.923.4762) T 650.243.6350 (International) 650.243.6388 support@veracyte.com