Afirma
GENOMIC SEQUENCING CLASSIFIER

VV20008

REPORT STATUS: Final
PAGES: 1 of 2
CLIENT ID: 97
AFIRMA REQ: R123

PATIENT REPORT

Sample Patient Report

PATIENT INFORMATION

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

COLLECTION DATE	24 Sep 2019	**FACILITY NAME**	University Hospital of Anytown		
RECEIVED DATE	26 Sep 2019	**SUBMITTING PHYSICIAN**	Jane Demo	**PHONE**	(555) 555-5555
REPORT DATE	26 Sep 2019	**TREATING PHYSICIAN/CC**	---	**PHONE**	---

CLINICAL HISTORY: Suspicious Ultrasound Characteristics: Nodule A: Hypoechoic, Solid: >95% solid

RESULTS

Nodule: A 2.2 cm, Middle Left

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Benign
(Risk of Malignancy ~4%)

MTC: Negative
Parathyroid: Negative
***BRAF*:p:V600E c. 1799T>A:** Negative
***RET/PTC1, RET/PTC3*:** Not Detected

AFIRMA XPRESSION ATLAS

N/A

RESULTS INTERPRETATION

The result of this 2.2 cm nodule A is Afirma GSC Benign, which suggests a low risk of cancer at approximately 4%. Treatment like a cytologically benign nodule may be appropriate, including clinical correlation. Afirma XA is not performed on GSC Benign nodules.[7]

GROSS DESCRIPTION

Received one vial of FNAprotect, labeled with the Requisition Form # and patient initials.

E-SIGNED ON 26 Sep 2019 12:51 PM BY:
Robert J Monroe MD, PhD, Veracyte Inc. CLIA # 05D2014120
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Test Methodology: RNA Sequencing

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TEST PERFORMANCE

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%

	MTC[3,5]	***BRAF***‡,[2,5,11]	***RET/PTC***[2,5,7,11]	**Parathyroid**[5,6]
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%

	BRAF V600E‡,[4,5]	**Afirma Xpression Atlas**[7,8] **(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: 1. Patel KN, et al. *JAMA Surg* 2018. **2.** Haugen BR, et al. *Thyroid* 2016. **3.** Randolph G, et al. ATA 2017. **4.** Angell TE, et al. ATA 2017. **5.** Hao, et al. *Frontiers in Endo* 2019. **6.** Sosa JA, et al. ATA 2017. **7.** Angell, et al. *Frontiers in Endo* 2019. **8.** Data on file. **9.** TCGA Research Network. *Cell* 2014 **10.** Yoo, et al. *PLoS Genetics* 2016 **11.** Goldner, et al. *Thyroid* 2019. **12.** Stack, et al. ATA 2019.

* 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.
** Nucleotide variant performance, excluding *BRAF* V600E, 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.
# FDA approved therapies for thyroid cancer, both specific for genomic alterations and non-specific, may be found at https://www.cancer.gov/about-cancer/treatment/drugs/thyroid and https://www.cancer.gov/about-cancer/treatment/drugs/solid-tumors. See https://clinicaltrials.gov for potentially relevant clinical trials. Afirma XA is not a companion diagnostic and is not conclusive for any therapy.

Associated Neoplasm Type abbreviations – FA, Follicular Adenoma; FTC, Follicular Thyroid Carcinoma; FVPTC, Follicular Variant of Papillary Thyroid Carcinoma; NIFTP, Noninvasive Follicular Thyroid Neoplasm with Papillary-Like Nuclear Features; PTC, Papillary Thyroid Carcinoma.

This NGS assay cannot differentiate somatic and germline variants. Further testing and/or genetic counseling may be warranted depending on the patient's clinical findings, family history and/or variant identified.

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*).

Afirma Xpression Atlas (XA) is a diagnostic service provided by Veracyte, Inc. Afirma XA 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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