



PATIENT INFORMATION

PATIENT: John Doe	DOB: 13 Jun 1992	SEX: M	LAB ID:	MRN:
COLLECTION DATE: 10 Jan 2023	FACILITY NAME: Production Test Clinic - DemoData			
RECEIVED DATE: 11 Jan 2023	SUBMITTING PHYSICIAN: Jane Doe	PHONE: ---		
REPORT DATE: 06 Mar 2023	TREATING PHYSICIAN/CC: ---	PHONE: ---		

CLINICAL HISTORY: No clinical history provided on the Afirma test requisition form

RESULTS

Nodule: **A** Thyroid, Upper Right, 1.2 cm

AFIRMA GENOMIC SEQUENCING CLASSIFIER

Ensemble Classifier	Xpression Atlas	Other Classifiers	
Benign (Risk of Malignancy ~4%)	N/A	<b>BRAF p. V600E c. 1799T&gt;A:</b> Negative <b>RET/PTC1, RET/PTC3:</b> Not Detected	<b>MTC:</b> Negative <b>Parathyroid:</b> Negative

TERT PROMOTER REGION

TERT c.-124C>T (C228T): Test Not Performed (TNP)  
TERT c.-146C>T (C250T): Test Not Performed (TNP)

NODULE A RESULTS SUMMARY

The result of this 1.2cm Bethesda III 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<sup>7</sup>. TERT promoter region analysis is not performed on GSC Benign nodules.

GROSS DESCRIPTION

A: Received 1 vial(s) of FNAProtect



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**TEST PERFORMANCE**

Afirma GSC - Ensemble Classifier <sup>1,5</sup>	Cytopathology Diagnosis Indeterminate*
Risk of Malignancy: Afirma GSC Benign	~4%
Risk of Malignancy: Afirma GSC Suspicious	~50%
Sensitivity:	91%
Specificity:	68%
Limit of Detection <sup>1</sup> :	5%

	MTC <sup>3,5</sup>	BRAF V600E <sup>1,2,4,5,11</sup>	RET/PTC <sup>2,5,7,11</sup>	Parathyroid <sup>5,6</sup>	XA Nucleotide Variant Panel**	XA Fusion Panel***	TERT <sup>8</sup>
Sensitivity	>99%			>99%			
Specificity	>99%			>99%			
PPA		>99%			74%	82%	>99%
NPA		>99%	>99%		>99%	>99%	>99%
Confirmation Rate			>99%		>98%	>99%	>99%
Limit of Detection	20%	5%	10%	15%	5%	10%	5%

**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. 13. Whitmer D, et al. *Frontiers in Endo* 2022.

\* Indeterminate includes Atypia of Undetermined Significance / Follicular Lesion of Undetermined Significance and (suspicious for) Follicular Neoplasm / Hürthle Cell Neoplasm.  
<sup>1</sup> Analytical sensitivity studies demonstrated the test's ability to detect malignant cells in a background of benign cells.  
<sup>2</sup> BRAF classifier performance is based on a comparison to a castPCR DNA assay for the BRAF V600E mutation.  
<sup>\*\*</sup> 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.  
<sup>\*\*\*</sup> Fusion performance is based on a comparison to an RNA AmpliSeq fusion assay and TaqMan assays.  
<sup>§</sup> Confirmation rate is the proportion of positive calls that are confirmed positive by the reference method.  
<sup>¶</sup> Analytical sensitivity studies demonstrate the test's ability to detect a positive variant in a background of wild type.  
<sup>#</sup> 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 molecular testing. The Ensemble Classifier, Parathyroid Classifier, MTC Classifier, BRAF V600E Classifier, XA, DNA assay of the TERT promoter region, and their performance characteristics were determined by Veracyte. The Ensemble Classifier measures the expression profile of RNA isolated from the nodule and classifies the sample as benign or suspicious for malignancy. The Parathyroid Classifier determines if the FNA specimen is positive or negative for parathyroid tissue. The Medullary Thyroid Carcinoma (MTC) Classifier determines if the nodule is positive or negative for MTC. The BRAF V600E Classifier measures RNA isolated from the nodule and classifies the sample as positive or negative for the BRAF V600E mutation. The RET/PTC assay sequences the RET and PTC genes to detect RET/PTC1 and RET/PTC3 fusions and reports them as detected or not detected. XA evaluates 593 genes included in Afirma GSC for 905 specific variants and 235 specific fusion pairs. The DNA analysis evaluates the two TERT promoter variants, C228T and C250T.