ThyGeNEXT® + ThyraMIR®v2

THYROID ONCOGENE PANEL | THYROID miRNA RISK CLASSIFIER

Comparative Overview of Clinical Validation Studies

Test Characteristics		ThyGeNEXT® + ThyraMIR®v2[1]	ThyroSeq GC®[2]	Afirma GSC®[3]
Methodology		• DNA Sequencing • RNA Sequencing • microRNA Classification	• DNA Sequencing • RNA Sequencing	• RNA Sequencing
Published Performance (Bethesda III and IV Nodules)	Sensitivity	98%* Negative/Moderate Thresholds	94%	91%
	Specificity	98%* Positive Threshold	82%	68%
	NPV	99%* Negative Samples	97%	96%
	PPV	96%* Positive Samples	66%	47%
	Cancer Prevalence	30%*	28%	24%
Comparative Performance (30% Cancer Prevalence)	NPV	99%* Negative Samples	97%[4]	95%[4]
	PPV	96%* Positive Samples	69%[4]	55%[4]
Test Result Categories		• Negative • Moderate • Positive	• Negative • Positive	• Negative • Suspicious
Sample Type Accepted		•1 Dedicated Pass —or— •Diagnostic Cytology Slide (at least 80 follicular cells) •Cell Blocks	•1 Dedicated Pass —or— •Diagnostic Cytology Slide (>200-300 follicular cells) •Cell Blocks	•2 Dedicated Passes
Detects *BRAF* V600E, *RET/PTC*		✓	✓	✓
Test Can Detect MTC		✓	✓	✓
Detects *TERT* Promoter Mutations		✓	✓	✕
Detects *ALK* Mutations		✓	✓	✕†
Fixed Cytology Smears Acceptable for Testing		✓	✓	✕
High Quality Digital Slide Image Captured and Stored		✓	✕	✕
Sample Can Be Stored and Shipped **Without** Refrigeration		✓	✕	✕
Compact Shipping Kit to Minimize Office Storage Needs		✓	✕	✕

Patient management decisions are based on the independent medical judgment of the physician and molecular test results should be taken into consideration in conjunction with all relevant imaging, clinical findings, patient and family history, as well as patient preference.

*3-Category performance aligned to clinical decision-making in Bethesda III and IV nodules and based upon positive and negative thresholds. Binary test performance metrics are 99% NPV and 75% PPV.[1,5]

†The Afirma Xpression Atlas can detect *ALK* fusions.

ThyroSeq® and Afirma® are trademarks of UPMC and Veracyte, Inc., respectively.

References: 1. Finkelstein SD, Sistrunk JW, Malchoff CD, et al. A retrospective evaluation of the diagnostic performance of an interdependent pairwise microRNA expression analysis with a mutation panel in indeterminate thyroid nodules [published online ahead of print, August 9, 2022]. *Thyroid*. doi:10.1089/thy.2022.0124. **2.** Steward DL, et al. *JAMA Oncol*. 2019;5(2):204-212. **3.** Patel KN, et al. *JAMA Surg*. 2018;153(9):817-824. **4.** Data on File. **5.** Lupo MA, et al. *Diagn Cytopathol*. 2020;1-11. https://doi.org/10.1002/dc.24564.

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