

Comparative Overview of Molecular Tests for Indeterminate Thyroid Nodules

Test Characteristics		ThyGeNEXT® + ThyraMIR® ¹	ThyroSeq GC® ²	Afirma GSC® ³
Methodology		<ul style="list-style-type: none"> • DNA Sequencing • RNA Sequencing • microRNA Classification 	<ul style="list-style-type: none"> • DNA Sequencing • RNA Sequencing 	<ul style="list-style-type: none"> • RNA Sequencing
Published Performance (Bethesda III and IV Nodules)	Sensitivity	95%*	94%	91%
	Specificity	90%*	82%	68%
	NPV	97%*	97%	96%
	PPV	75%*	66%	47%
	Cancer Prevalence	30%	28%	24%
Test Result Categories		<ul style="list-style-type: none"> • Negative • Moderate • Positive 	<ul style="list-style-type: none"> • Negative • Positive 	<ul style="list-style-type: none"> • Negative • Suspicious
Comparative Performance (30% Cancer Prevalence)	NPV	97%*	97% ⁴	95% ⁴
	PPV	75%*	69% ⁴	55% ⁴
Sample Type Accepted		<ul style="list-style-type: none"> • 1 Dedicated Pass —or— • Cell Blocks • Diagnostic Cytology Slide (>80 follicular cells) 	<ul style="list-style-type: none"> • 1 Dedicated Pass —or— • Cell Blocks • Diagnostic Cytology Slide (>200-300 follicular cells) 	<ul style="list-style-type: none"> • 2 Dedicated Passes
Detects BRAFV600E, 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		✓	✗	✗

*Performance prevalence-adjusted to histopathologic subtypes. 3-category performance aligned to clinical decision-making.

†The Afirma Xpression Atlas can detect ALK fusions.

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1. Lupo MA, et al. *Diagn Cytopathol.* 2020;1-11. <https://doi.org/10.1002/dc.24564>. 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.