

Comparative Overview of Clinical Validation Studies

Test Characteristics		ThyGeNEXT [®] + ThyraMIR [®] v2 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	98%* Negative/Moderate Thresholds	94%	91%
	Specificity	98%* Positive Threshold	82%	68%
	NPV	99% ^{1,4*} Negative Threshold	97%	96%
	PPV	94% ^{1,4*} Positive Threshold	66%	47%
	Cancer Prevalence	30%*	28%	24%
Comparative Performance (30% Cancer Prevalence)	NPV	99% ^{1,4*} Negative Threshold	97% ^{2,4}	95% ^{3,4}
	PPV	94% ^{1,4*} Positive Threshold	69% ^{2,4}	55% ^{3,4}
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
Sample Type Accepted		<ul style="list-style-type: none"> 1 Dedicated Pass —or— Diagnostic Cytology Slide (at least 80 follicular cells) Cell Blocks 	<ul style="list-style-type: none"> 1 Dedicated Pass —or— Diagnostic Cytology Slide (>200-300 follicular cells) Cell Blocks 	<ul style="list-style-type: none"> 2 Dedicated Passes
Detects <i>BRAF</i> V600E, <i>RET</i> / <i>PTC</i>		✓	✓	✓
Test Can Detect MTC		✓	✓	✓
Detects <i>TERT</i> Promoter Mutations		✓	✓	✓ [‡]
Detects <i>ALK</i> 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.^{1,4,5}

¹The Finkelstein, et al. study was designed to provide a deeper analysis of microRNA expression, and therefore evaluated all study samples. When aligned to commercial specimen handling and reporting, the NPV and PPV are 99% and 94%, respectively (Bethesda III and IV nodules).^{1,4}

[‡]The *TERT* promoter mutation is not part of the Afirma GSC or Xpression Atlas panels and is ordered separately. The Xpression Atlas can detect *ALK* fusions.

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

References: 1. Finkelstein SD, et al. *Thyroid*. 2022;32(11):1362-1371. 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. Interpace Diagnostics. 5. Lupo MA, et al. *Diagn Cytopathol*. 2020;1-11. <https://doi.org/10.1002/dc.24564>.