

miRInform™ Thyroid— Characterizing FNAs with Molecular Precision

miRInform™ Thyroid is a molecular test used to improve the preoperative diagnosis of thyroid cancer

Background

Palpable thyroid nodules occur in 5-7% of the adult population but, the clinical relevance of thyroid nodules rests with the need to exclude thyroid cancer which occurs in 5-15% of them¹. Fine needle aspiration (FNA) is currently the standard preoperative diagnostic procedure used to characterize thyroid nodules. Characterization is performed by a pathologist who looks at cells from the nodule under a microscope to determine if the nodule is benign or malignant. However, in 10-40% of the cases, the cytological diagnosis remains indeterminate, due to overlapping cytological features between benign and malignant nodules².

About the Panel

miRInform™ Thyroid is a panel of American Thyroid Association-recommended (recommendation level “C”) molecular markers which improves preoperative diagnostic accuracy for patients with indeterminate thyroid nodules¹. Asuragen’s Panel consists of 17 analytically validated mutations and translocations and utilizes fine needle aspirate (FNA) specimens, collected in an easy-to-use nucleic acid preservation solution (see panel on reverse side).

The miRInform™ Thyroid panel is a cutting edge molecular diagnostic assay utilizing DNA and RNA based markers. Multiple independent studies have shown that the mutations and genetic rearrangements, assayed by miRInform™ Thyroid, correlate with malignant thyroid nodules^{3, 4}. Therefore, miRInform™ Thyroid can aid physicians in diagnosis and patient management decisions.

miRInform™ Thyroid Panel

DNA Mutation Markers				RNA fusion transcripts
KRAS	BRAF	HRAS	NRAS	RET/PTC1
G12R	V600E	Q61L	Q61R	RET/PTC3
G12V		Q61R	Q61K	PAX8/PPARg
G13D		G12V	Q61L	
G12D				
G12A				
G12C				
G12S				

The mutations and translocations assayed by miRInform™ Thyroid are found in up to 80% of papillary (BRAF, RAS, RET/PTC) and 70% of follicular (RAS, PAX8/PPARg) thyroid cancers based on post-operative histological analysis⁵.

- Molecular testing supported by numerous peer-reviewed publications
- Markers that can aid in the characterization of malignancies
- Performed on a single FNA sent in a provided preservative
- Run in conjunction with your current cytopathology testing

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Independent study showing performance of mutational analysis on indeterminate FNAs

Atypia or Follicular lesions of undetermined significance (n=247)			Sensitivity 63% Specificity 99% PPV 88% NPV 94% Accuracy 94%
Mutation Positive (n=25)	Histology Malignant (n=35) 16 RAS (16 PTC,FV) 5 BRAF (4 PTC, 1 PTC,FV) 1 PAX8/PPARg (1 PTC,FV)	Histology Benign (n=212) 3 RAS (3 FA)	
Mutation Negative (n=222)	13 (11 PTC, FV, 2 PTC)	209 (166 HN, 43 FA)	
Follicular or Hürthle cell neoplasm/Suspicious for follicular neoplasm (n=214)			Sensitivity 57% Specificity 97% PPV 87% NPV 86% Accuracy 86%
Mutation Positive (n=38)	Histology Malignant (n=58) 2 BRAF (1 PTC, 1 PTC,FV) 29 RAS (21 PTC,FV, 5 PTC, 3 FTC) 2 PAX8/PPARg (2 PTC,FV)	Histology Benign (n=156) 5 RAS (5 FA)	
Mutation Negative (n=176)	25 (16 PTC,FV, 3 PTC, 6 FTC)	151 (95 HN, 56 FA)	
Suspicious for malignant cells (n=52)			Sensitivity 68% Specificity 96% PPV 95% NPV 72% Accuracy 81%
Mutation Positive (n=20)	Histology Malignant (n=28) 10 BRAF (10 PTC) 7 RAS (6 PTC,FV, 1 FTC) 1 PAX8/PPARg (1 FTC) 1 RET/PTC (1 PTC)	Histology Benign (n=24) 1 RAS (1 FA)	
Mutation Negative (n=32)	9 (7 PTC, 2 PTC,FV)	23 (17 HN, 6 FA)	

Nikiforov et al, 2011 Impact of Mutational Testing on the Diagnosis and Management of Patients with Cytologically Indeterminate Thyroid Nodules: A Prospective Analysis of 1056 FNA Samples. J Clin Endocrinol Metab 96(11):0000-0000

How to order

Acquiring the materials needed to order the miRInform™ Thyroid Panel is free and easy. Simply contact Asuragen's Clinical Laboratory and we'll send you the sample collection kit. The kit contains all the materials needed to order Asuragen's miRInform™ Thyroid panel including our proprietary nucleic acid preservative, test requisition form, shipping materials and pre-paid return postage.

- 1 Request a free sample collection kit
- 2 Perform routine FNA
- 3 Add specimen to nucleic acid preservative
- 4 Complete requisition form and ship

References

1. Cooper DS, Doherty GM, Haugen BR, et al. Revised American Thyroid Association management guidelines for patients with thyroid nodules and differentiated thyroid cancer. *Thyroid* 2009;19:1167-214.
2. Baloch, ZW, et al., Diagnostic terminology and morphologic criteria for cytological diagnosis of thyroid lesions: a synopsis of the National Cancer Institute Thyroid Fine-Needle Aspiration State of the Science Conference. *Diagn Cytopathol*, 36(6): p. 425-37.2008.
3. Nikiforov YE, Steward DL, Robinson-Smith TM, et al. Molecular testing for mutations in improving the fine-needle aspiration diagnosis of thyroid nodules. *J Clin Endocrinol Metab* 2009;94:2092-8.
4. Cantara S, Capezzone M, Marchisotta S, et al. Impact of proto-oncogene mutation detection in cytological specimens from thyroid nodules improves the diagnostic accuracy of cytology. *J Clin Endocrinol Metab* 2010;95:1365-9.
5. Kondo T, Ezzat S, and Asa SL, Pathogenetic mechanisms in thyroid follicular-cell neoplasia. *Nat Rev Cancer*, 6(4): p. 292-306.2006.