MEDGENOME | Prima Cancer Genetics

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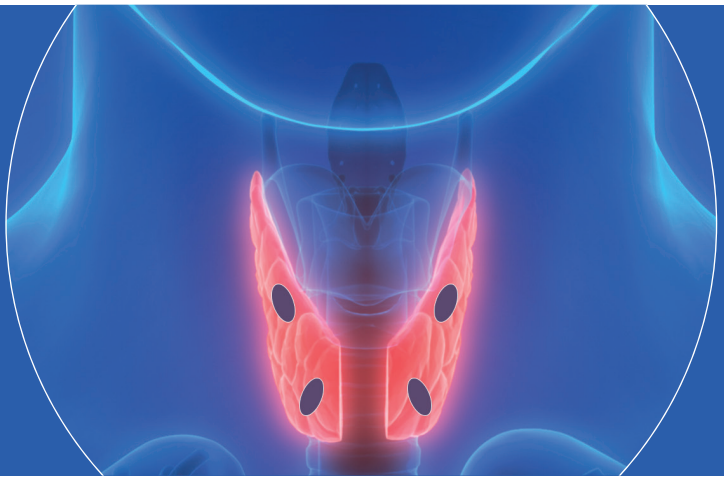
ThyroTrack

Thyroid Nodule Prognostication Test by NGS

Next generation sequencing based test to detect genomic biomarkers in thyroid nodules performed on FNAC fluid for nodule prognostication and on FFPE Tissue Block for clinical management.



ThyroTrack helps to comprehensively understand thyroid nodule genetics for diagnostic accuracy & better clinical decisions. This assay screens variable genetic alterations in thyroid cancer-related genes as per ATA (2015) & NCCN (2022) guidelines.

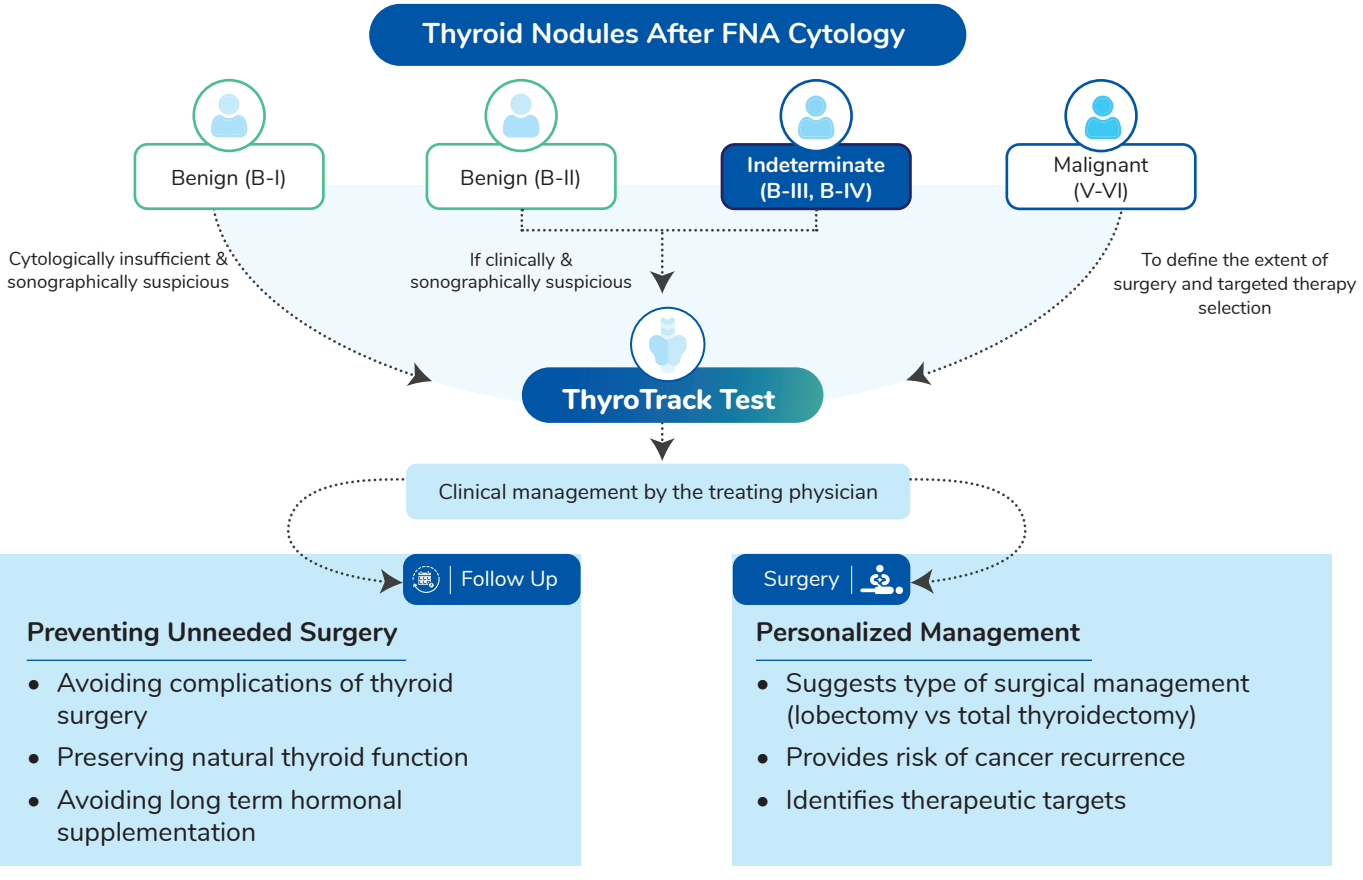
46 genes (SNVs and InDels)

Includes *BRAF, RAS* and *PI3K* Pathway genes

23 genes (Fusions)

Includes known and unknown fusions in *RET, NTRK, ALK* and other genes

- ✓ **Can be used pre-surgery on FNA sample and post-surgery on FFPE tissue block**
- ✓ **Determines accurate diagnosis and informed surgery decisions in thyroid nodules with benign/indeterminate FNA cytology**
- ✓ **Provides informed clinical management and treatment options for malignant thyroid nodules**



Preventing Unneeded Surgery

- Avoiding complications of thyroid surgery
- Preserving natural thyroid function
- Avoiding long term hormonal supplementation

Personalized Management

- Suggests type of surgical management (lobectomy vs total thyroidectomy)
- Provides risk of cancer recurrence
- Identifies therapeutic targets

Who can be tested?

- Thyroid FNA with indeterminate cytology (Bethesda categories III and IV)
- Malignant thyroid cytology (Bethesda category V and VI), when results of the NGS are expected to affect the decision for extent of oncological surgery/treatment
- Benign thyroid cytology (Bethesda category II), when strong suspicion of malignancy exists on clinical grounds such as presence of a highly suspicious sonographic pattern
- Bethesda category I nodules which are cytologically insufficient and suspicious on sonographic findings
- When the diagnosis of thyroid cancer is established cytologically or histologically and molecular profiling will affect decision regarding radioactive iodine therapy, intensity of follow up, or for selection of targeted therapies in patients with advanced cancer

Assay specification

Test Code | Test Name	MGM2538 | ThyroTrack
TAT	14 Working Days
Sample Requirements*	**FNAC Fluid in RNAlater; Tissue in RNAlater ; FFPE tissue block**
FFPE Block Requirement*	Cross-sectional tumor area of 25mm^2 containing at least 40 µm of tumor
Tumor Purity Minimum	20%
Limit of Detection	5% VAF* for SNV and InDels >10 spanning reads for fusions
Panel Inclusion	46 genes analysed for SNVs and InDels 23 genes analysed for fusions (All partners can be identified)
Depth of Sequencing	Average >250X
Analytical Sensitivity	98%
Analytical Specificity	>99.9%

*VAF Variant allele frequency | RNA Later solution will be provided by MedGenome

Gene list

SNVs and InDels									
AKT1	*CTNNB1*	*EZH1*	*IDH1*	*MET*	*NTRK3*	*PPARG*	*RNF213*	*TERT*	*VHL*
ALK	*DICER1*	*FARSB*	*IDH2*	*NF2*	*PI3K*	*PTEN*	*ROS1*	*TG*	
APC	*EIF1AX*	*FGFR2*	*KDM6A*	*NRAS*	*PICALM*	*PTH*	*SLC5A5*	*TP53*	
BRAF	*EP300*	*GNAS*	*KRAS*	*NTRK1*	*PIK3CA*	*RAF1*	*STK11*	*TSC2*	
CHEK2	*ERBB4*	*HRAS*	*MEN1*	*NTRK2*	*PIK3R2*	*RET*	*SYN2*	*TSHR*	

Fusions							
ALK	*EML4*	*FGFR2*	*NTRK1*	*PAX8*	*RAF1*	*ROS1*	*THADA*
BRAF	*ERBB4*	*KIF5B*	*NTRK2*	*PICALM*	*RET*	*SS18*	*UACA*
CLIP1	*FARSB*	*MET*	*NTRK3*	*PPARG*	*RNF213*	*SYN2*	

Clinical Evidences

Positive testing for *BRAF*, *RET/PTC* or *PAX8/PPARγ* was specific for a malignant outcome in 100% of cases, whereas *RAS* mutations had an 84% risk of cancer and a 16% chance of benign follicular adenoma [PMID: 24811481].

462 thyroid nodules with AUS/FLUS cytology were assessed using mutation profiling;

31 were positive on mutational analysis (6.7%). 98 of the cases (21%) had a definitive diagnosis by either surgical (n=96) or non-surgical (n=2) methods [PMID: 26356635].

In the largest prospective study of nodules with indeterminate cytology (n=653); detection of mutations was reported to convey an 88% risk of cancer among nodules with surgical follow-up;

63% of cancers on final histopathology were identified with a positive mutation preoperatively and 94% of nodules that were negative on mutation analysis had a benign final histopathology [PMID: 21880806].

Talk to the Experts

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