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Thyroid Cancer Gene Mutation Detection Kit (Next Generation Sequencing)

BACKGROUND

The last three decades have witnessed steady, worldwide increases in the incidence of TC . Rates vary widely from country to country, with the highest figures (per 100 000 person-years) reported in Lithuania (15.5), Italy (13.5), Austria (12.4), Croatia (11.4) and Luxembourg (11.1). Estimated TC-related mortality rates, by contrast, are low (0.7 and 0.5 cases per 100 000 person-years for women and men, respectively) with considerably less regional and temporal variation[2].Thyroid carcinoma occurs two to three times more often in women than in men. Thyroid carcinoma is currently the seventh most common malignancy diagnosed in women.

FNA SAMPLE ASSISTED DIAGNOSIS

Definite diagnosis is the premise of tumor treatment. Ultrasound and ultrasound-guided US-FNA are the first choice for the screening of benign and malignant thyroid nodules. However, FNA cytology can also produce about 20% - 30% uncertain results [1].。 The 2023 BETHESDA SYSTEM FOR REPORTING THYROID CYTOPATHOLOGY（TBSRTC） recommend gene testing for Bethesda type III、 IV or V nodules with uncertain US-FNA cytological diagnosis, which can assist in the diagnosis of benign and malignant nodules , the classification of thyroid cancer subtypes, and guide the follow-up treatment [2].

TABLE 2. THE 2023 BETHESDA SYSTEM FOR REPORTING THYROID CYTOPATHOLOGY: IMPLIED RISK OF MALIGNANCY WITH EXPECTED RANGES BASED ON FOLLOW-UP OF SURGICALLY RESECTED NODULES WITH RECOMMENDED CLINICAL MANAGEMENT

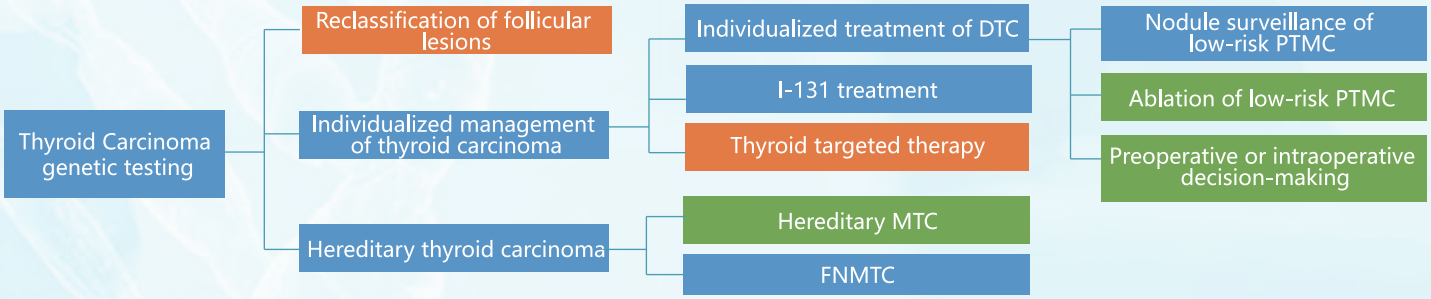
Diagnostic category	*ROM*[a] *Mean % (range)*	*Usual management*[b]
Nondiagnostic	**13** (5–20)[c]	Repeat FNA[d] with ultrasound guidance
Benign	**4** (2–7)[e]	Clinical and ultrasound follow-up
Atypia of undetermined significance[f]	**22** (13–30)	Repeat FNA,[d] molecular testing, diagnostic lobectomy, or surveillance
Follicular neoplasm[g]	**30** (23–34)	Molecular testing,[h] diagnostic lobectomy
Suspicious for malignancy	**74** (67–83)	Molecular testing,[h] lobectomy or near-total thyroidectomy[i]
Malignant	**97** (97–100)	Lobectomy or near-total thyroidectomy[i]

The 2023 BETHESDA SYSTEM FOR REPORTING THYROID CYTOPATHOLOGY

[1] NCCN Thyroid Carcinoma 2023 V3
[2] Thyroid. 2023 Sep;33(9):1039-1044.

OTHER DIAGNOSIS AND TREATMENT TIPS

In addition, thyroid cancer gene detection can provide prompt information for the formulation of surgical plan, the use of targeted drugs, the diagnosis and treatment of hereditary thyroid cancer. Both FDA and NMPA have approved a variety of targeted drugs for the treatment of unresectable, recurrent and refractory Differentiated Thyroid Carcinoma (DTC), Medullary Thyroid Carcinoma (MTC) and undifferentiated Thyroid Carcinoma. Companion diagnosis of drugs includes RET fusion and mutation detection, BRAF V600E detection and NTRK fusion detection.



Note: papillary thyroid microcarcinoma (PTMC), familial non medullary thyroid carcinoma (FNMTC)

DETECTED GENES

The test kit is based on high-throughput sequencing, covering all common genes related to thyroid tumor typing, prognosis, medication and genetics recommended in NCCN guidelines, CSCO guidelines and expert consensus.

Mutation Type	Detection Gene					
Mutation	BRAF	RET	KRAS	NRAS	HRAS	TERT-P
	TP53	PIK3CA	AKT1	CTNNB1	EIF1AX	TSHR
	GNAS	ZNF148	SPOP	PTEN		
Fusion	209 fusion forms of 87 genes including RET, NTRK1/2/3, PAX8, PPARγ, ALK, BRAF, RAF1, MET, THADA, etc.					

PRODUCT INFORMATION

Product Name	Core Technology	Pack Size	Instruments Validated	Sample Type
Thyroid Cancer Gene Mutation Detection Kit	RingCap®	16 Tests/Kit 32 Tests/Kit	Ion torrent Illumina MGISEQ	Tumor tissue,FNA (For germline detection, peripheral blood is required)

DETECTION SIGNIFICANCE

- Molecular diagnostics may be useful to allow reclassification of follicular lesions as either more or less likely to be benign or malignant based on the genetic profile.
- DTC patients who are going to undergo surgery, radioactive iodine therapy or ablation therapy should be tested to determine the risk of tumor recurrence and formulate individualized treatment plans.
- For patients with advanced thyroid carcinoma who are selected for targeted therapy, target genes should be detected to guide the selection of targeted drugs.
- Patients with hereditary MTC and their family members should be tested to provide guidance information for diagnosis, treatment and prevention.

FEATURES & ADVANTAGES

Ease of Use: Based on the independent patent technology RingCap®, Library preparation in 2 steps.

Fast Results: The library preparation takes only 3.5 hours.

Comprehensive Coverage: Detects mutations in 16 genes and up to 209 fusion forms in 87 genes for individualized management of thyroid carcinoma .

High Sensitivity: It can detect gene mutations as low as 1% in 5ng FNA samples or 25ng tissue samples, and gene fusions as low as 200 copies/ul in RNA samples.

DETECTION PROCESS

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