

Wide measuring range

Item	Measuring range	Item	Measuring range
TSH	0.005-100 μIU/mL	TG	0.1-500 ng/mL
T3	0.1-10 ng/mL	Anti-TG	10-2000 IU/mL
T4	0.5-30 μg/dL	Anti-TPO	2-1000 IU/mL
FT3	0.2-50 pmol/L	CT	4-2000 pg/mL
FT4	2.5-100 pmol/L	PTH	2-3000 pg/mL

Clinical Application

- TSH

 - Assesse the statue of thyroid, help to diagnosis and treat thyriod disease.
 - Monitor thyriod function during pregnancy.
- T3

 - Reflect the statue of thyroid scretion and function.
 - Marker of early hyperthyroidism.
 - Monitor the recurrence of hyperthyroidism.
- FT3

 - Diagnosis T3 type hyperthyroidism and not affected by TBG.
- T4

 - Marker for diagnosis of hrperthroidism.
 - Diagnosis primary and secondary hyperthroidism.
 - Monitor the effect of TSH suppression treatment.
- FT4

 - Reflect the metabolic statue of thyroid and not interfered by TBG.
 - Monitor thyroid function during pregnacy.
- TRAb

 - Auxiliary diagnosis of Graves' disease.
 - Monitoring the therapy of hyperthyroidism patients and prediction of relapse.
 - Risk assessment of hyperthyroidism before and after pregnancy.
- rT3

 - A metabolite of T4, an inactive form of T3 that is incapable of the metabolic activity normally carried out by T3.
 - Distinguish ESS (Euthyroid sick syndrome) or Hypothyroidism.
- TG

 - A main tumor marker of differentiated thyroid cancer (DTC).
 - Monitoring DTC 's recurrence with high sensitivity and specificity.
 - Evaluate DTC 's recurrence or residue, combined with Anti-TG.
- CT

 - Diagnosis of medullary thyroid carcinoma (MTC).
 - Judge the curative effect of MTC surgery.
 - Follow-up examination item after MTC surgery.

References

[1] NACB: Laboratory Support for the Diagnosis and Monitoring of Thyroid Disease. 2002
[2] Guideline on Diagnosis and Management of Thyroid Disease During Pregnancy and Postpartum (2nd edition) , Chinese Journal of Perinatal Medicine, 2019
[3] Guideline for Diagnosis and Treatment of Hypothyroidism in Adults, Chinese Society of Endocrinology. 2017
[4] Guideline for Diagnosis and Treatment of Thyroid Diseases in China and Auxiliary Examination of Thyroid Diseases, Chinese Society of Endocrinology, 2007
[5] Recommendation on the Application of Laboratory Test Items in the Diagnosis and Treatment of Thyroid Diseases, Chinese Society of Endocrinology. 2012
[6] Guideline for the diagnosis and management of thyroid nodules and differentiated thyroid cancer (2nd edition). Chinese Journal of Endocrinology and Metabolism. 2023

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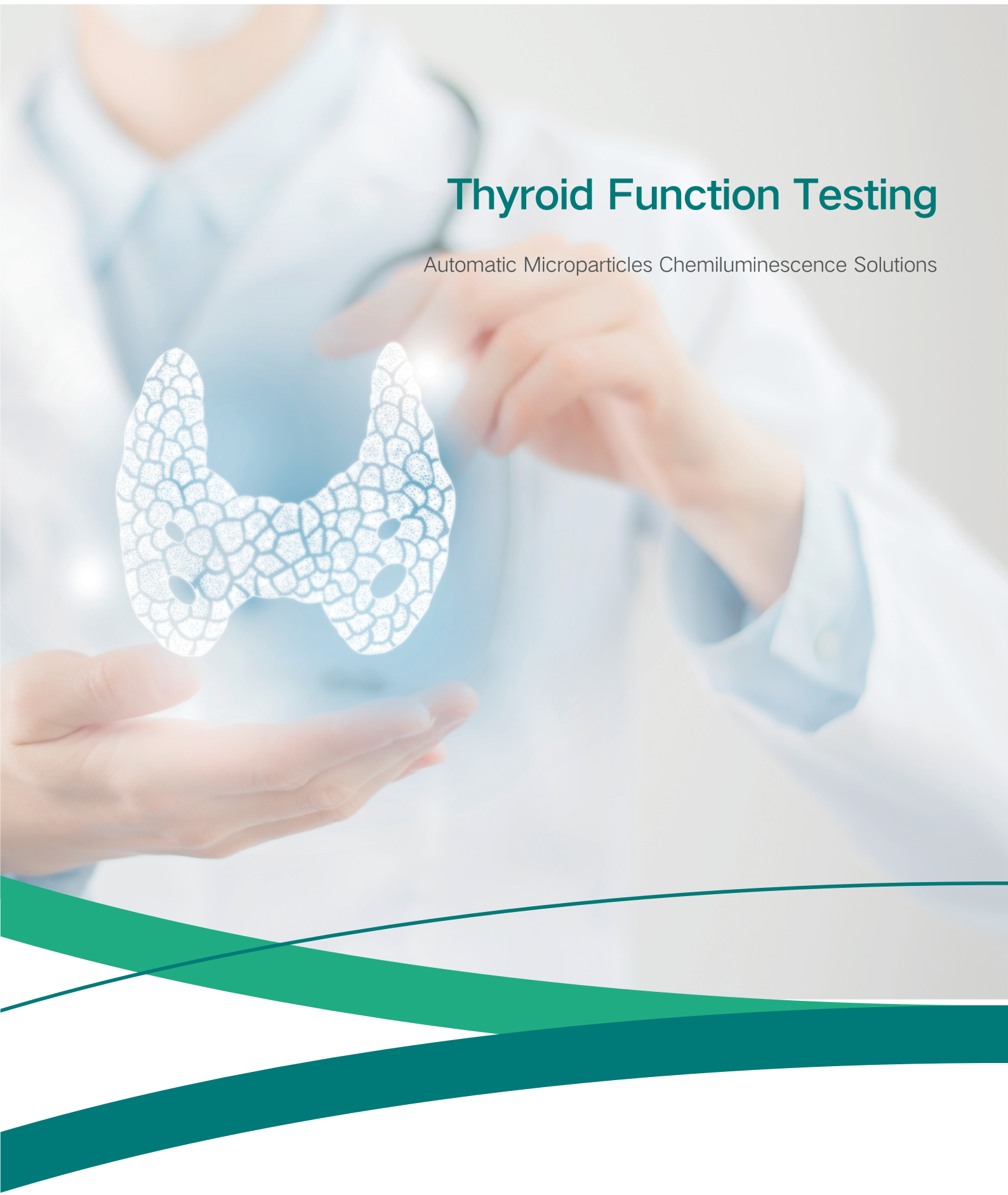
offers more than 600 in vitro diagnostic products including CLIA (microplate based CLIA and magnetic particle based CLIA), ELISA, POCT (Point of Care Test), Microbiology and Biochemistry. As an ISO9001 and EN ISO13485 manufacturer, Autobio supplies high quality products through its well established sales network and is renowned as a reliable partner. For details please visit en.autobio.com.cn. Autobio Diagnostics Co., Ltd. | NO.87 Jingbei Yi Rd | National Eco&Tech Zone | Zheng zhou City | China 450016.

You can find us on:
Facebook: @AutobioGlobal
Youtube Channel: Autobio Diagnostics
Email: info@autobio-diagnostics.com
WhatsApp: +8618595767835
Tel: +86 371 6200 7036



Thyroid Function Testing

Automatic Microparticles Chemiluminescence Solutions



Advantages

- Third generation TSH meet the clinical identification and diagnostic of the disease.
- Excellent correlation with stream brand and the product performance is equivalent.
- Product traceability leading to reliable result for laboratory.
- Complete product menu meet avariety of clinical testing needs.

Complete menu

IVDR	TSH (3 rd Generation)	IVDR	TG (Thyroglobulin)
IVDR	T3	IVDR	Anti-TG
IVDR	T4	IVDR	Anti-TPO
IVDR	FT3	IVDR	PTH
IVDR	FT4	IVDR	CT (Calcitonin)
IVDR	rT3	IVDR	TRAb



Traceability

Item	Traceability level	Calibrators traceability to
TSH	Reference Material	WHO 3 rd IRP 81/565
T4	Reference Measurement Procedure	Reference Method:ID-LC/MS/MS Primary Standard:IRMM-468 The T4/T3 reference measurement procedure run by the Autbio Reference Laboratory has been approved by CNAS
T3	Reference Measurement Procedure	Reference Method:ID-LC/MS/MS Primary Standard:IRMM-469 The T4/T3 reference measurement procedure run by the Autbio Reference Laboratory has been approved by CNAS
FT3	Enterprise Standard	Enterprise primary calibrator
FT4	Enterprise Standard	Enterprise primary calibrator
Anti-TG	Reference Material	WHO IRP 65/093
Anti-TPO	Reference Material	NIBSC MRC 66/387
TG	Reference Material	BCR-457
PTH	Reference Material	NIBSC 95/646
rT3	Reference Material	Internal Reference Method:ID-LC/MS/MS
TRAb	Reference Material	WHO 2 nd IRP 08/204

- Autbio has two reference laboratories accredited by CNAS
- Autbio Reference Laboratory is a stakeholder member of the Joint Committee on Traceability in Laboratory Medicine (JCTLM)
- For 9 consecutive years, Autbio has participated in RELA-IFCC comparisons with excellent results
- For 5 consecutive years, Autbio has participated in National Central for Clinical Laboratories' reference measurement ability comparison with qualified score



Excellent Performance of Clinical Evaluation

A total of 300 clinical samples were included in this experiment, and each sample was detected on four immunoassay platforms, namely A (platform E), B (platform X), C (platform D) and Autbio (A2000 plus).

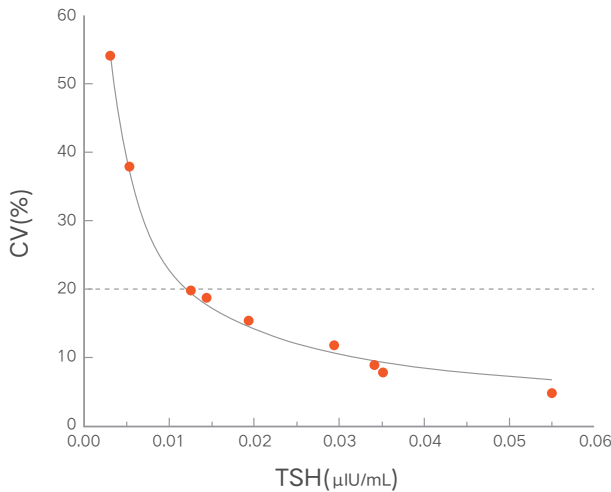
With A manufacturer as the reference result, the correlation and coincidence rate between the other three platforms and the reference results were analyzed.

	Parameter	TSH	FT4	FT3	T4	T3
Correlation (R)	Autbio VS A	0.997	0.984	0.983	0.916	0.983
	B VS A	0.997	0.983	0.992	0.932	0.963
	C VS A	0.992	0.970	0.978	0.853	0.949
Coincidence rate	Autbio VS A	97.67%	92.33%	97.00%	94.33%	95.67%
	B VS A	90.67%	91.00%	97.33%	88.14%	86.90%
	C VS A	89.51%	69.12%	81.69%	78.23%	88.70%

The data showed that the correlation and coincidence rate between the results of Autbio platform and the results of reference platform were very high.

The 3rd generation TSH

The functional sensitivity of TSH of Autbio meets the third generation functional sensitivity (≤ 0.02 mIU/L) required by the guidelines from NACB⁽¹⁾.



Stability

The results of IQC are stable and inter-run CV are less than 6%;
Both QC and samples have a high degree of lot-to-lot constancy with a small bias(<6.25%).

