MAGLUMI T3（CLIA）

REF 130203003M Σ 100

Shenzhen New Industries Biomedical Engineering Co., Ltd
4F,Wearnes Tech Bldg,
Science&Industry Park,
Nanshan,Shenzhen, China 518057
Tel. + 86 755 26508518
Fax.+ 86 755 26508339

EC REP

Lotus Global Co., Ltd
15 Alexandra Road
London UK
NW8 0DP
Tel. + 44-20-75868010
Fax.+ 44-20-79006187

CE

FOR PROFESSIONAL USE ONLY
Store at 2...8 °C

COMPLETELY READ THE INSTRUCTIONS BEFORE PROCEEDING

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SYMBOLS USED ON LABELS

EC REP	Authorized Representative in Europe
	Manufacturer
	Attention. See Instructions For Use
CONT	Contents of kit
IVD	In vitro diagnostic medical device (In vitro diagnostic use)
LOT	Lot number
REF	Catalogue Code
	Expiry date (Use by…)
8°C 2°C	Temperature limitation (store at 2...8 °C)
Σ	Number of tests
	Keep away from sunlight
	Biological risks

1. INTENDED USE

The kit has been designed for the quantitative determination of Triiodothyronine (T3) in human serum.
The method can be used for samples over the range of 0-10ng/ml.
The test has to be performed on the Maglumi fully auto analyzer (Including Maglumi 1000, Maglumi 2000, Maglumi 2000 plus).

2. SUMMARY AND EXPLANATION OF THE TEST

In healthy subject, the thyroid secretes approx. 5-10µg triiodothyronine per day. Circulating 3,5,3'-triiodothyronine (T3) is, however, for the most part produced by peripheral deiodination so that the overall daily secretion rate of total T3 amounts to approx. 20ug. In serum, the thyroid hormones are bound to carrier proteins, and only their free fraction is physiologically active.
The clinical relevance of quantitative T3 determination in suspected thyroid disease lies mainly in the diagnosis and evaluation of hyperthyroidism. Particularly in isolated T3 hyperthyroidism, elevated T3 concentrations with concomitant normal TBG and T4 levels are observed. Following surgical resection of the thyroid gland and therapy with iodine-131, T3 concentrations may - in contrast to those of T4 – remain at an elevated level or even rise (recurrence of hyperthyroidism).
Occasional elevations of triiodothyronine levels are also found in approx. 50% of patients with autonomous adenoma associated with hyperthyroidism. Such elevations may also occur in the early stages of hyperthyroidism, in endocrine ophthalmopathy associated with latent hyperthyroidism, during treatment of hyperthyroidism (thyrostatics), in iodine deficiency with and without goitre and in Hashimoto's thyroiditis, whereby the metabolic state may be normal.

3. PRINCIPLE OF THE TEST

Competitive immunoluminometric assay:
Use an anti-T3 monoclonal antibody to label ABEI, and use a purified T3 antigen to label FITC. Sample, Calibrator, or Control, ABEI Label, FITC Label and nano magnetic microbeads coated with sheep anti-FITC are mixed thoroughly and incubated at 37℃, forming complexes; after sediment in a magnetic field, decant the supernatant, then cycle washing for 1 time. Subsequently, the starter reagents are added and a flash chemiluminescent reaction is initiated. The light signal is measured by a photomultiplier as RLU within 3 seconds and is proportional to the concentration of T3 present in controls or samples.

4. KIT COMPONENTS

4.1 Material supplies

Reagent Integral for 100 determinations	
Nano magnetic microbeads: TRIS buffer, 1.2%(W/V), 0.2%NaN_3, coated with sheep anti- FITC polyclonal antibody.	2.5ml
Calibrator low	2.5ml
Calibrator high	2.5ml
ABEI Label: anti-T3 monoclonal antibody labeled ABEI, containing BSA, 0.2% NaN_3.	6.5ml
FITC Label: purified T3 antigen labeled FITC, containing BSA, 0.2%NaN_3.	6.5ml
All reagents are provided ready-to-use.	

Accessories required but not provided

Maglumi Reaction module
Maglumi Starter kit 1+2
Maglumi Light check
Maglumi Wash /System Liquid

4.2 Preparation of the Reagent Integral

Before the sealing is removed, gentle and careful horizontal shaking of the Reagent Integral is essential (avoid foam formation!) Remove the sealing and turn the small wheel of the magnetic microbeads compartment to and fro, until the colour of the suspension has changed into brown. Place the Integral into the reagent area and let it stand there for 30 mins. During this time, the magnetic microbeads are automatically agitated and completely resuspended.
Do not interchange Nano Magnetic Microbeads from different reagents!

4.3 Storage of the Reagents Integral

- Sealed: Stored at 2-8℃ until the expiry date.
- Opened： Stable for 4 weeks. After this period, it is still possible to keep on using the Reagent Integral provided that the controls are found within the expected ranges.
- Keep upright for storage.

- Keep away from direct sunlight.

5. Origin of Calibrators.

Calibrators in the reagent kit are from Sigma.

Biological root: synthetic materials, processed by HPLC purification, detected by SDS-PAGE with a purity ≥95%. No HBsAg, anti-HCV, and anti-HIV is found.

6. Calibration

6.1 2 point recalibration

Via the measurement of calibrators, the predefined master curve is adjusted (recalibrated) to a new, instrument-specific measurement level with each calibration.

6.2 Frequency of Recalibration

- After each exchange of lot (Reagent Integral or Starter Reagents).
- Every week and/or each time a new Integral is used (recommendation).
- after each servicing of the Maglumi Fully Auto analyzer.
- If controls are beyond the expected range.

7. Sample Collection, Material and Storage

- Collect samples using standard procedures.
- Sample material: serum.
- Store at 2-8℃: 24 hours.
- For longer storage periods: freeze to below - 20℃.
- Avoid repeated freezing and thawing cycles.
- Stored samples should be thoroughly mixed prior to use (Vortex mixer).
- ***Vacuum tubes**

  (a) Blank tubes are recommended type for collecting samples.

  (b) If plasma sample is needed, EDTA tube is conformed has no effect on the results RLUs.

  (c) Liquaemin Sodium tube is found to increase the sample RLU and cause test results deviation.

  (d) Please ask SNIBE for advice if special additive must be used in the sample blood.

8. Interfering Substances

No interference with test results is seen by concentrations of bilirubin ＜ 0.125mg/ml, haemoglobin＜16mg/dl or triglycerides＜12.5mg/ml.

9. WARNING AND PRECAUTIONS FOR USERS

- For use in *IN-VITRO* diagnostic procedures only.
- Do not interchange reagents from different lots. Do not use kit components beyond their labeled expiry date.
- All samples, biological reagents and materials used in the assay must be considered potentially able to transmit infectious agents. They should therefore be disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each country. Disposable materials must be incinerated; liquid waste must be decontaminated with sodium hypochlorite at a final concentration of 5% for at least half an hour. Any materials to be reused must be autoclaved using an overkill approach（USP 24,2000,p.2143）. A minimum of one hour at 121℃ is usually considered adequate, though the users must check the effectiveness of their decontamination cycle by initially validating it and routinely using biological indicators.
- The calibrators in this kit are prepared from bovine serum products. However, because no test method can offer complete assurance that HIV, Hepatitis B Virus or other infectious agents are absent, these reagents should be considered a potential biohazard and handled with the same precautions as applied to any serum or plasma specimen.

10. Test Procedure

To ensure proper test performance, strictly adhere to the operating instructions of the Maglumi Fully Auto Analyzer. Each test parameter is identified via a RFID tag on the Reagent Integral. For further information please refer to the Maglumi Fully Auto Operator's Manual.

40μl +40μl +40μl +20μl	Sample, calibrator or controls ABEI label FITC label Nano magnetic microbeads
15 min	Incubation
400μl each time	Cycle washing
3 s	Measurement

11. Quality Control

- Observe quality control guidelines for medical laboratories.
- Use suitable controls for in-house quality control.

12 Results

12.1 Calculation of Results

The analyzer automatically calculates the T3 concentration in each sample by means of a calibration curve which is generated by a 2-point calibration master curve procedure. The results are expressed in ng/ml .

Conversion factor: 1 ng/ml = 1.54 nmol/L

12.2 Interpretation of Results

- Reference values：0.69-2.15ng/ml
- Results may differ between laboratories due to variations in population and test method. Each laboratory should establish its own reference range.

13. Limitations of the procedure

13.1

Normal T3 concentrations do not necessary reflect a normal-thyroid state. Certain thyroid disorders (such as latent hypo- or hyperthyroidism, compensatory T3 over secretion in iodine deficiency, TBG oversecretion) may also be associated with euthyroid T3 levels.

Furthermore, the clinical evaluation of serum findings must take into consideration both age- or pregnancy-related differences as well as a potential influence of wxogenously administered thyroid hormones, contraceptives, steroids, salicylates, diphenylhydantoin or other drugs as well as changes of the binding capacities of serum proteins for thyroid hormones.

Serum T3 levels alone give no evidence of the presence or absence of thyroid disease. They must always be interpreted in context with the clinical picture and other diagnostic procedures.

13.2 HAMA

Patient samples containing human anti-mouse antibodies (HAMA) may give falsely elevated or decreased values. Although HAMA-neutralising agents are added, extremely high HAMA serum concentrations may occasionally influence results.

14. Performance Characteristics

14.1 Accuracy

Consider calibrator high of known concentration as a sample, dilute it by 1:2 ratio with diluents, and measure its diluted concentration for 10 times. Then calculate the recovery of measured concentration and expected concentration. The recovery should be within 90% -110%.

14.2 Precision

Intra-assay coefficient of variation was evaluated on Calibrator High repeatedly measured 10 times in the same assay, calculating their coefficient of variation, the results should ≤10%

Inter-assay coefficient of variation was evaluated on three batches of kit, repeatedly measured 10 times of Calibrator High, calculating three batches of kit for Calibrator High between the measured values of the coefficients of variation, the results should ≤15%

14.3 Sensitivity

The sensitivity is defined as the concentration of T3 equivalent to the mean RLU of 20 replicates of the zero standard plus two standard deviations corresponding to the concentration from the standard curve. The sensitivity is typically less than 0.06 ng/ml.

14.4 Specificity

The results of the T4, rT3 assay should accord with the following description

When T4=300ng/ml, the detection result of T3 is less than 0.3ng/ml.

When rT3=100ng/ml, the detection result of T3 is less than 0.5ng/ml.

14.5 Linearity

Conduct a logarithmic transform to the RLU value and concentration value of 10 standards. After a double logarithmic fitting, the absolute value of its linearity should exceed 0.9800.

15. References

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2. Dahlquist G, et al. Effect of metabolic control and duration on exercise-induced albuminuria in diabetic teenagers. Acta Pediatr Scand 1983;72:895-902
3. Hostetter TH. Diabetic nephropathy. New Engl J Med 1985;312:642-4.
4. Kroc Collaborative Study Group. Blood glucose control and the evolution of diabetic netinopathy and albuminuria. A preliminary multicenter trial. New Engl J Med 1984;311:365-72