MAGLUMI IGF-I（CLIA）

REF 130205007M Σ 100

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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 Growth Hormone (IGF-I) in human serum.
The method can be used for samples over the range of 0-1000ng/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

Insulin-like growth factor-I (IGF-I) bioactivity is regulated by genetic and non-genetic factors like growth hormone, nutrition and insulin. The rate of development of microalbuminuria (MA), an important early marker of diabetic nephropathy, has been related not only to factors such as age at diagnosis, sex and blood pressure, but also with the activity of the growth hormone–insulin-like growth factor-I (GH–IGF-I) axis. Poor glycaemic control in type I diabetes, the most important factor for diabetic complications, is associated with elevated GH secretion and serum IGF binding protein (IGFBP)-1 levels, as well as reduced serum IGF-I levels。 In addition, derangements of the GH–IGF-I axis have been associated with hyperfiltration and MA in type I diabetes. The mechanism behind this imbalance in the GH–IGF-I axis in type 1 diabetes has been suggested to be due to relatively low portal insulin levels resulting from s.c. administration of insulin. Complete correction of the GH–IGF-I axis only seems possible with portal administration of insulin.
In the type I, II diabetes, GH / IGF-I axis is abnormal, GH increased, IGF-I reduced. In type I diabetes, liver resistant GH, leading the liver IGF-I concentrations decreased. At the same time, more IGFBP-I are generated, IGFBP-I can play a role in binding to and inhibit IGF-I. This reduction of IGF-I cause the feedback of growth hormone's decrease. Increased release of GH will lead to high blood sugar by antagonizing the function of insulin. At the same time, the reduction of IGF-I also led to j growth retardation of uvenile or young with type I diabetes. In poorly controlled type II diabetes, there will be also a high release of GH, antagonising the effect of peripheral tissues' insulin. In any kind of diabetes, IGF-I can mprove the control of blood sugar and reduce the serum GH's insulin-resistance In addition, IGF-I is important factor to adjust the function of bone cell and metabolism.

3. PRINCIPLE OF THE TEST

Sandwich immunoluminometric assay:
Use an anti-IGF-I monoclonal antibody to label ABEI, and use another monoclonal antibody to label FITC. Sample, Calibrators or Control, ABEI Label FITC Label and magnetic microbeads coated with anti-FITC are mixed thoroughly and incubated at 37℃, forming a sandwich; after sediment in a magnetic field, decant the supernatant, then cycle washing it 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 IGF-I 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	3.0ml
Calibrator high	3.0ml
ABEI Label: anti-IGF-I monoclonal antibody labeled ABEI, contains BSA, 0.2%NaN_3.	7.5ml
FITC Label: anti-IGF-I monoclonal antibody labeled FITC, contains BSA, 0.2%NaN_3.	7.5ml
HCl	8ml
NaOH	8ml
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 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: Human recombinant protein, 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.

7.1 Pretreatment of Sample

1. Draw 5ml of Venous Blood, standing still in room temperature, then centrifuged, separate the serum. (Note:plasma sample contains EDTA or liquaemin sodium as anticoagulant is nor recommended.)

2. Add HCL into the serum in the ratio of 1:10, mix thoroughly, incubates at 37 for 10 min. Then add the same volume of NaOH into the tube, mix thoroughly, after that, run test in Maglumi analyzer immediately. (NOTE: pretreatment is required for sample! But not required for calibrator)

For long time preservation, distribute the sample immediately, seal up the tube then freeze to below -20℃。Avoid repeated freezing and thawing cycles.

8. WARNING AND PRECAUTIONS FOR USERS

- Draw elbow vein blood 5ml in the tube, centrifugate at room temperature, then pipette the serum into another tube for use
- Add the HCL to the serum by the 1:10 volume ratio (NaOH : Serum = 1:10), then place it on the mixer to mix it, and incubate at 37℃ for 15 mins,
- And then add the NaOH to the serum by the 1:10 volume ratio (HCl: Serum = 1:10), then place it on the mixer to mix it
- Test on the analyzer right now
- **For example :** 500ml serum with 50ml HCl to mix, and incubate at 37 ℃ for 15 mins firstly, then add 50ml NaOH, and mix it on the mixer. Finally, test on the analyzer
- **Note :**
- The sample which is placed in the room temperature more than 8 hours couldn't be used again.
- For longer storage periods: freeze to below - 20℃, Avoid repeated freezing and thawing cycles.
- Plasma with Liquaemin Sodium or EDTA is not recommended.
- **Sample and Biorad control should be pretreated as above. The inner control and calibrator need no pretreatment**

9. 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 barcode on the Reagent Integral. For further information please refer to the Maglumi Fully Auto Operator's Manual.

100μl	Sample, calibrator or controls
+50μl	ABEI Label
+50μl	FITC Label
+20μl	Nano magnetic microbeads
10 min	Incubation
400μl each time	Cycle washing
3 s	Measurement

10. Quality Control

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

11 Results

11.1 Calculation of Results

- The analyzer automatically calculates the IGF-I 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. For further information please refer to the Maglumi fully auto Operator's Manual.

11.2 Interpretation of Results

Reference values： 60-350ng/ml

- Results may differ between laboratories due to variations in population and test method. Each laboratory should establish its own reference range.

12. Limitations of the procedure

12.1

IGF-I assay values may only be interpreted in context with the clinical picture and other diagnostic procedures. A skillful technique and strict adherence to the instructions are necessary to obtain reliable results. Bacterial contamination of samples or repeated freeze-thaw cycles may affect the test results. Assay results should be utilized in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.

12.2 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.

12.3 High-Dose Hook

No high-dose hook effect was seen for IGF-I concentrations up to 10000 ng/ml.

13. Performance Characteristics

13.1 Accuracy

Consider calibrator high of known concentration as a sample, dilute it by 1:2 ratio with diluent, 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%.

13.2 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%.

13.3 Sensitivity

The sensitivity is defined as the concentration of IGF-I 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 5 ng/ml.

13.4 Specificity

The specificity of the IGF-I assay system was assessed by measuring the apparent response of the assay to various potentially cross reactive analytes. When IGF-II=600 ng/ml, IGF-I in the test results <100 ng/ml.

13.5 Linearity

Conduct a logarithmic transform to the RLU value and concentration value of 6 standards. After a double logarithmic fitting, the absolute value of its linearity should exceed 0.9800.

14. References

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