



MAGLUMI® IGF-I (CLIA)

INTENDED USE

The kit is an *in vitro* chemiluminescence immunoassay for the quantitative determination of Insulin-like-growth factor 1 (IGF-I) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the assessment of individuals with suspected or confirmed growth disorders.

SUMMARY

Insulin-like-growth factor 1 (IGF-I), a 70 amino-acid peptide hormone, belongs to the insulin family^{1,2}. Serum IGF-I is mainly derived from the liver under the control of GH and circulates bound to the IGF binding proteins (IGFBPs)³. The majority of bound IGF-I circulates in a ternary complex composed of IGF-I, IGFBP-3 and a protein known as the acid labile subunit (ALS)⁴. IGF-I availability is tightly regulated by the so-called insulin like growth factor binding proteins (IGFBPs), which may act by increasing IGF-I half-life. IGF-I acts to provide an inhibitory feedback signal on GH secretion in the hypothalamus by stimulating somatostatin production in the pituitary⁵. IGF-I is a circulating growth factor with hepatic release dependent on nutritional status. Somatomedin-C, or IGF-I, is a circulating protein that appears to be released by the liver and whose production may reflect hepatic anabolic-catabolic balance⁶. The insulin-like growth factors (IGFs) play a major role in regulating cell growth and differentiation. IGF-I is a major mediator of the growth-promoting effects of growth hormone; therefore, circulating IGF-I levels are often used to assess the status of the growth hormone axis⁴. IGF-I levels does not undergo short-term fluctuations in the manner that GH does making it the preferred IGF-I biomarker for the diagnosis of growth related disorders². GH and IGF-I measurements are widely used in the diagnosis of disorders of GH secretion, evaluation of children with short stature from multiple causes, management of disorders that lead to nutritional insufficiency or catabolism, and monitoring both GH and IGF-I replacement therapy⁷. Growth hormone deficiency (GHD) is a rare but important cause of short stature in childhood with a prevalence of 1 in 4000³. Serum IGF-I assays have been found to monitor the response to GH treatment in adults⁸. IGF-I has also been found very important in establishing the diagnosis of acromegaly and gigantism, and in monitoring the response to treatment of acromegaly and gigantism^{6,9}. Laron syndrome (GH insensitivity syndrome) is a hereditary dwarfism resulting from a variety of GHR mutations¹⁰. Affected patients are characterized by short stature, truncal obesity, low serum IGF-I, and elevated serum GH and GH resistance, and growth can be partially restored by IGF-I treatment¹⁰. IGF-I deficiency has been shown to be associated with deregulated lipid metabolism, cardiovascular disease, diabetes, and an altered metabolic profile of diabetic patients⁵. IGF-I overexpression resulted in significant hypoglycemia, hypoinsulinemia¹¹. In addition to these applications in GH-related disorders, IGF-I levels have been associated with risk for certain malignancies. IGF-I levels in patients with malignant diseases is also important to improve prognosis⁹. Upregulation of IGF-I and downregulation of IGFBP-3 and IGFBP-7 may be potential diagnostic biomarkers for *non-small-cell lung cancer* (NSCLC)¹².

TEST PRINCIPLE

Sandwich chemiluminescence immunoassay.

The sample and Displacing Reagent are mixed thoroughly and incubated, buffer and magnetic microbeads coated with IGF-I monoclonal antibody are then added and incubated, performing a wash cycle after a precipitation in a magnetic field. ABEI labeled with another IGF-I antibody are then added and incubated, reacting to form sandwich complexes. After precipitation in a magnetic field, the supernatant is decanted and then a wash cycle is performed. Subsequently, the Starter 1+2 are added to initiate a chemiluminescent reaction. The light signal is measured by a photomultiplier as relative light units (RLUs), which is proportional to the concentration of IGF-I present in the sample.

REAGENTS

Kit Contents

Component	Description	100 tests/kit	50 tests/kit	30 tests/kit
Magnetic Microbeads	Magnetic microbeads coated with IGF-I monoclonal antibody (~2.67 µg/mL) in PBS buffer, NaNa ₃ (<0.1%).	2.5 mL	1.5 mL	1.0 mL
Calibrator Low	A low concentration of IGF-I antigen in PBS buffer, NaNa ₃ (<0.1%).	1.0 mL	1.0 mL	1.0 mL
Calibrator High	A high concentration of IGF-I antigen in PBS buffer, NaNa ₃ (<0.1%).	1.0 mL	1.0 mL	1.0 mL
Displacing Reagent	Acetic acid (2.98%).	6.5 mL	3.5 mL	2.3 mL
Buffer	Tris-HCl buffer, NaNa ₃ (<0.1%).	12.5 mL	7.0 mL	4.8 mL
ABEI Label	ABEI labeled with IGF-I monoclonal antibody (~0.833 µg/mL) in MES buffer, NaNa ₃ (<0.1%).	12.5 mL	7.0 mL	4.8 mL
Control 1	A low concentration of IGF-I antigen (100 ng/mL) in PBS buffer, NaNa ₃ (<0.1%).	1.0 mL	1.0 mL	1.0 mL
Control 2	A high concentration of IGF-I antigen (500 ng/mL) in PBS buffer, NaNa ₃ (<0.1%).	1.0 mL	1.0 mL	1.0 mL

All reagents are provided ready-to-use.

Warnings and Precautions

- For *in vitro* diagnostic use.
- For professional use only.
- Exercise the normal precautions required for handling all laboratory reagents.
- Personal protective measures should be taken to prevent any part of the human body from contacting samples, reagents, and controls, and should comply with local operating requirements for the assay.
- A skillful technique and strict adherence to the package insert are necessary to obtain reliable results.
- Do not use kit beyond the expiration date indicated on the label.
- Do not interchange reagent components from different reagents or lots.
- Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).
- All waste associated with biological samples, biological reagents and disposable materials used for the assay should be considered potentially infectious and should be disposed of in accordance with local guidelines.
- This product contains sodium azide. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Immediately after disposal, flush with a large volume of water to prevent azide build-up. For additional information, see Safety Data Sheets available for professional user on request.

Note: If any serious incident has occurred in relation to the device, please report to Shenzhen New Industries Biomedical Engineering Co., Ltd. (Snibe) or our authorized representative and the competent authority of the Member State in which you are established.

Reagent Handling

- To avoid contamination, wear clean gloves when operating with a reagent kit and sample. When handling reagent kit, replace the gloves that have been in contact with samples, since introduction of samples will result in unreliable results.
- Do not use kit in malfunction conditions; e.g., the kit leaking at the sealing film or elsewhere, obviously turbid or precipitation is found in reagents (except for Magnetic Microbeads) or control value is out of the specified range repeatedly. When kit in malfunction conditions, please contact Snibe or our authorized distributor.
- To avoid evaporation of the liquid in the opened reagent kits in refrigerator, it is recommended that the opened reagent kits to be sealed with reagent seals contained within the packaging. The reagent seals are single use, and if more seals are needed, please contact Snibe or our authorized distributor.

- Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.
- Use always the same analyzer for an opened reagent integral.
- For magnetic microbeads mixing instructions, refer to the Preparation of the Reagent section of this package insert.
- For further information about the reagent handling during system operation, please refer to Analyzer Operating Instructions.

Storage and Stability

- Do not freeze the integral reagents.
- Store the reagent kit upright to ensure complete availability of the magnetic microbeads.
- Protect from direct sunlight.

Stability of the Reagents	
Unopened at 2-8°C	until the stated expiration date
Opened at 2-8°C	6 weeks
On-board	4 weeks

Stability of Controls	
Unopened at 2-8°C	until the stated expiration date



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130255007M: 100 tests/kit

130655007M: 50 tests/kit

130755007M: 30 tests/kit

Opened at 10-30°C	6 hours
Opened at 2-8°C	6 weeks
Frozen at -20°C	3 months
Frozen and thawed cycles	no more than 3 times

SPECIMEN COLLECTION AND PREPARATION

Specimen Types

Only the specimens listed below were tested and found acceptable.

Specimen Types	Collection Tubes
Serum	Tubes without additive/accessory, or tubes containing clot activator or clot activator with gel.
Plasma	Na-heparin or Li-heparin

- The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. Follow tube manufacturers' instructions carefully when using collection tubes.

Specimen Conditions

- Do not use grossly hemolyzed/hyperlipidaemia specimens and specimens with obvious microbial contamination.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some serum specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the serum specimen is centrifuged before a complete clotting, the presence of fibrin may cause erroneous results.
- Samples must be free of fibrin and other particulate matter.
- To prevent cross contamination, use of disposable pipettes or pipette tips are recommended.

Preparation for Analysis

- Inspect all specimens for foam. Remove foam with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.
- Frozen specimens must be completely thawed before mixing. Mix thawed specimens thoroughly by low speed vortexing or by gently inverting. Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous. If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Specimens should be free of fibrin, red blood cells, or other particulate matter. Such specimens may give reliable results and must be centrifuged prior to testing. Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.
- The sample volume required for a single determination of this assay is 10 µL.

Specimen Storage

Specimens removed from the separator, red blood cells or clot may be stored up to 24 hours at 10-30°C or 48 hours at 2-8°C, or 6 months frozen at -20°C. Frozen specimens subjected to up to 2 freeze/thaw cycles have been evaluated.

Specimen Shipping

- Package and label specimens in compliance with applicable local regulations covering the transport of clinical specimens and infectious substances.
- Do not exceed the storage limitations listed above.

Specimen Dilution

- Samples, with IGF-I concentrations above the analytical measuring interval, can be diluted with Diluent manual dilution procedure. The recommended dilution ratio is 1:2. The concentration of the diluted sample must be >1000 ng/mL.
- For manual dilution, multiply the result by the dilution factor.
- Please choose applicable diluents or ask Snibe for advice before manual dilution.

PROCEDURE

Materials Provided

IGF-I (CLIA) assay, control barcode labels.

Materials Required (But Not Provided)

- General laboratory equipment.
- Fully-auto chemiluminescence immunoassay analyzer Maglumi 600, Maglumi 800, Maglumi 1000, Maglumi 2000, Maglumi 2000 Plus, Maglumi 4000, Maglumi 4000 Plus, MAGLUMI X8, MAGLUMI X3, MAGLUMI X6 or Integrated System Biolumi 8000, Biolumi CX8.
- Additional accessories of test required for the above analyzers include Reaction Module, Starter 1+2, Wash Concentrate, Light Check, Tip, and Reaction Cup. Specific accessories and accessories' specification for each model refer to corresponding Analyzer Operating Instructions.
- Please use accessories specified by Snibe to ensure the reliability of the test results.

Assay Procedure

Preparation of the Reagent

- Take the reagent kit out of the box and visually inspect the integral vials for leaking at the sealing film or elsewhere. If there is no leakage, please tear off the sealing film carefully.
- Open the reagent area door; hold the reagent handle to get the RFID label close to the RFID reader (for about 2s); the buzzer will beep; one beep sound indicates successful sensing.
- Keeping the reagent straight insert to the bottom along the blank reagent track.
- Observe whether the reagent information is displayed successfully in the software interface, otherwise repeat the above two steps.
- Resuspension of the magnetic microbeads takes place automatically when the kit is loaded successfully, ensuring the magnetic microbeads are totally resuspended homogenous prior to use.

Assay Calibration

- Select the assay to be calibrated and execute calibration operation in reagent area interface. For specific information on ordering calibrations, refer to the calibration section of Analyzer Operating Instructions.
- Execute recalibration according to the calibration interval required in this package insert.

Quality Control

- When new lot used, check or edit the quality control information.
- Scan the control barcode, choose corresponding quality control information and execute testing. For specific information on ordering quality controls, refer to the quality control section of the Analyzer Operating Instructions.

Sample Testing

- After successfully loading the sample, select the sample in interface and edit the assay for the sample to be tested and execute testing. For specific information on ordering patient specimens, refer to the sample ordering section of the Analyzer Operating Instructions.

To ensure proper test performance, strictly adhere to Analyzer Operating Instructions.

Calibration

Traceability: This method has been standardized against the WHO 1st International Standard 02/254.

Test of assay specific calibrators allows the detected relative light unit (RLU) values to adjust the master curve.

Recalibration is recommended as follows:

- Whenever a new lot of Reagent or Starter 1+2 is used.
- Every 28 days.
- The analyzer has been serviced.
- Control values lie outside the specified range.

Quality Control

Controls are recommended for the determination of quality control requirements for this assay and should be run in singlicate to monitor the assay performance. Refer to published guidelines for general quality control recommendations, for example Clinical and Laboratory Standards Institute (CLSI) Guideline C24 or other published guidelines¹³.

Quality control is recommended once per day of use, or in accordance with local regulations or accreditation requirements and your laboratory's quality control procedures, quality control could be performed by running the IGF-I assay:

- Whenever the kit is calibrated.
- Whenever a new lot of Starter 1+2 or Wash Concentrate is used.

Controls are only applicable with MAGLUMI and Biolumi systems and only used matching with the same top seven LOT numbers of corresponding reagents. For each target value and range refer to the label.

The performance of other controls should be evaluated for compatibility with this assay before they are used. Appropriate value ranges should be established for all quality control materials used.

Control values must lie within the specified range, whenever one of the controls lies outside the specified range, calibration should be repeated and controls retested. If control values lie repeatedly outside the predefined ranges after successful calibration, patient results must not be reported and take the following actions:

- Verify that the materials are not expired.
- Verify that required maintenance was performed.
- Verify that the assay was performed according to the package insert.
- If necessary, contact Snibe or our authorized distributors for assistance.

If the controls in kit are not enough for use, please order IGF-I (CLIA) Controls (REF: 160201460MT) from Snibe or our authorized distributors for more.

■ RESULTS

Calculation

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 Analyzer Operating Instructions.

Conversion factors: ng/mL × 1 = µg/L; ng/mL × 0.131 = nmol/L.

Interpretation of Results

The expected range for the IGF-I assay was obtained by testing 9738 apparently healthy individuals in China, gave the following expected value:

Age (years)	Men (N=4842)			Women (N=4896)		
	2.5 th percentile (ng/mL)	50 th percentile (ng/mL)	97.5 th percentile (ng/mL)	2.5 th percentile (ng/mL)	50 th percentile (ng/mL)	97.5 th percentile (ng/mL)
1	11.4	44.1	102	18.2	56.2	110
2	13.6	50.7	110	24.8	67.7	135
3	17.6	59.3	123	32.4	75.5	164
4	24.9	72.4	142	41.5	90.4	196
5	34.0	84.3	165	51.6	105	229
6	43.8	97.6	195	62.1	121	265
7	53.5	106	229	73.4	131	281
8	62.8	121	253	83.3	151	318
9	71.5	138	289	95.5	176	354
10	79.7	160	325	108	205	423
11	87.3	190	384	121	239	438
12	107	235	450	136	283	468
13	114	265	481	147	300	482
14	122	298	494	153	319	485
15	127	320	502	155	324	493
16	132	332	505	159	317	471
17	137	333	484	163	299	463
18	140	324	463	159	277	453
19	125	305	437	152	255	432
20	129	285	406	147	238	414
21-25	126	224	334	127	196	354
26-30	117	168	258	119	175	288
31-35	106	161	236	101	159	248
36-40	98.4	147	225	92.3	146	222
41-45	86.2	135	214	81.4	132	220
46-50	79.3	127	207	73.8	121	214
51-55	69.1	121	200	67.4	114	209
56-60	60.5	116	195	62.1	111	197
61-65	55.6	114	191	55.2	110	181
66-70	54.4	111	187	53.1	101	172
71-75	49.6	103	186	50.3	93.2	168
76-80	47.8	96.6	185	51.9	91.5	170

Results may differ between laboratories due to variations in population and test method. It is recommended that each laboratory establish its own reference interval.

■ LIMITATIONS

- Results should be used in conjunction with patient's medical history, clinical examination and other findings.
- If the IGF-I results are inconsistent with clinical evidence, additional testing is needed to confirm the result.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or animal serum products can be prone to this interference and anomalous values may be observed¹⁴.
- Bacterial contamination of the specimens may affect the test results.
- Patients with malignancies may exhibit IGF-I values within the normal range. Thus, IGF-I determination is more suitable for therapeutic monitoring and follow-up as well as for a comparison with histological results. IGF-I serum levels may only be interpreted in context with the clinical symptom and other diagnostic procedures. The IGF-I assay should not be used as the only criterion for cancer screening.

■ SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

Precision

Precision was determined using the assay, samples and controls in a protocol (EP05-A3) of the CLSI (Clinical and Laboratory Standards Institute): duplicates at two independent runs per day for 5 days at three different sites using three lots of reagent kits (n = 180). The following results were obtained:

Sample	Mean (ng/mL) (n=180)	Within-Run		Between-Run		Reproducibility	
		SD (ng/mL)	%CV	SD (ng/mL)	%CV	SD (ng/mL)	%CV
Serum Pool 1	50.307	1.522	3.03	0.863	1.72	2.507	4.98
Serum Pool 2	96.510	2.091	2.17	1.432	1.48	3.369	3.49
Serum Pool 3	495.957	7.117	1.44	4.086	0.82	12.003	2.42
Plasma Pool 1	48.731	1.353	2.78	1.109	2.28	2.066	4.24
Plasma Pool 2	101.332	2.717	2.68	1.264	1.25	4.491	4.43
Plasma Pool 3	503.486	7.750	1.54	1.746	0.35	13.516	2.68
Control 1	97.747	2.607	2.67	1.467	1.50	3.816	3.90
Control 2	497.957	7.700	1.55	3.257	0.65	14.543	2.92

Linear Range

15.0-2000 ng/mL (defined by the Limit of Quantitation and the maximum of the master curve).

Reportable Interval

5.00-4000 ng/mL (defined by the Limit of Detection and the maximum of the master curve×Recommended Dilution Ratio).

Analytical Sensitivity

Limit of Blank (LoB) ≈2.50 ng/mL.

Limit of Detection (LoD) ≈5.00 ng/mL.

Limit of Quantitation (LoQ) ≈15.0 ng/mL.

Analytical Specificity

Interference

Interference was determined using the assay, three samples containing different concentrations of analyte were spiked with potential endogenous and exogenous interferents in a protocol (EP7-A2) of the CLSI. The measurement deviation of the interference substance is within ±10%. The following results were obtained:

Interference	No interference up to	Interference	No interference up to
Hemoglobin	1000 mg/dL	IgM	10 mg/mL
Intralipid	3000 mg/dL	IgA	5 mg/mL
Bilirubin	66 mg/dL	Heparin sodium salt	80 IU/mL
HAMA	40 ng/mL	Heparin lithium salt	80 IU/mL
ANA	398 AU/mL	Biotin	0.5 mg/dL
Rheumatoid factor	1200 IU/mL	Human Growth Hormone	3.0 mg/L
Human albumin	7 g/dL	Octreotide	1.5 mg/L
IgG	3.3 g/dL	Growth Hormone Antagonist	80 mg/L

Cross-Reactivity

Cross-reactivity was determined using the assay, three samples containing different concentrations of analyte were spiked with potential cross-reactant in a protocol (EP7-A2) of the CLSI. The measurement deviation of the interference substance is within ±10%. The following results were obtained:

Cross-reactant	No interference up to	Cross-reactant	No interference up to
IGFBP-1	5000 ng/mL	IGF-II	6000 ng/mL
IGFBP-2	5000 ng/mL	Insulin	1000 mIU/mL
IGFBP-3	20000 ng/mL	Proinsulin	155000 ng/mL
IGFBP-4	5000 ng/mL	LH	77505 mIU/mL
IGFBP-5	5000 ng/mL	TSH	350 mIU/mL
IGFBP-6	5000 ng/mL		

High-Dose Hook

No high-dose hook effect was seen for IGF-I concentrations up to 50000 ng/mL.

Method Comparison

A comparison of the IGF-I assay with a commercially available immunoassay, gave the following correlations (ng/mL):

Number of samples measured: 185

Passing-Bablok: y=0.9889x+0.2592, r=0.974.

The clinical specimen concentrations were between 15.10 and 1990 ng/mL.

■ REFERENCES

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■ SYMBOLS EXPLANATIONS

	Consult instructions for use		Manufacturer
	Temperature limit (Store at 2-8°C)		Use-by date
	Contains sufficient for<n> tests		Keep away from sunlight
	This way up		Authorized representative in the European Community
	In vitro diagnostic medical device		Kit component
	Catalogue number		Batch code
	CE marking with notified body ID number		

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