Total Rat/Mouse IGF-I ELISA RUO

AL-137

INTENDED USE

The Total Rat/Mouse IGF-I enzyme linked immunosorbent assay (ELISA) kit provides materials for the quantitative measurement of IGF-I in mouse and rat serum, plasma, and other biological fluids.

SUMMARY AND EXPLANATION

IGF-I, also known as somatomedin C, is a 7.6 kDa, 70 amino acid residue peptide, which mediates the actions of growth hormone (GH).[1] IGF-I is synthesized as a prohormone, a polypeptide consisting of A, C, B, D, and E domains.[1,2] After post-translational modification, the mature IGF-I consists of the A, C, B and D domains, and is structurally homologous to IGF-II and insulin. In vivo, IGF-I is secreted by the liver and several other tissues and is postulated to have mitogenic and metabolic actions at or near the sites of synthesis; this has been termed the paracrine role of IGF-I.[1] IGF-I also appears in the peripheral circulation where it circulates primarily in a high molecular weight tertiary complex with IGF-binding protein-3 (IGFBP-3) and acid-labile subunit (ALS).[2,3] A smaller proportion of IGF-I may circulate in association with other IGF-binding proteins.[3] It has been estimated that <5% of plasma IGF-I circulates unbound.[4] In vivo synthesis of IGF-I is stimulated by GH, and is also dependent on other factors, including adequate nutrition.[1,5] IGF-I may inhibit pituitary production of GH; however, a feedback mechanism has not been completely defined.

In humans, plasma IGF-I levels are low during fetal and neonatal life, increase gradually during childhood, peak during mid-puberty, and decline gradually through adult life.[1,5-7] Average plasma IGF-I levels are slightly higher in females at each age. Maternal plasma levels increase during pregnancy.[1] Plasma IGF-I levels are stabilized by the IGF-binding proteins and there is negligible diurnal variation.[5] Plasma IGF-I levels are low relative to age- and sex-related norms in GH deficiency[5-7], malnutrition[5,8] and in the syndrome of GH-receptor deficiency (Laron dwarfism).[9] Abnormally low levels of plasma IGF-I have been used as a diagnostic indicator of GH deficiency, although a significant proportion of GH-deficient children may have IGF-I levels in the normal range, and normal short children may have low IGF-I levels.[1,6,7] Plasma IGF-I levels may also be used to monitor the short- and long-term in vivo responses to GH treatment.[5] Abnormally elevated IGF-I levels in acromegaly (GH excess) may be used as a diagnostic tool and to monitor treatment.[1,5]

Assay of plasma IGF-I is complicated by the presence of IGF-binding proteins, which may sequester IGF-I in the reaction mixture.[1] Various methods have been devised to separate the IGF and IGF-binding proteins prior to assay. Size-exclusion gel chromatography in acid is optimal[1,10], but this procedure is not feasible for routine use. Acidification followed by ethanol precipitation of the IGFBP fraction[1,11] gives results which are like acid-chromatography. SepPak C-18 cartridges are less convenient[11] and give variable results and relatively low recovery.

The Ansh Labs Total Rat/Mouse IGF-I assay uses an acidification and neutralization method to dissociate IGF-I from all the binding proteins. IGF-I levels are quantified in the extracted samples using a highly sensitive and specific enzyme-linked immunosorbent assay. Also, the ratio of Free Mouse IGF-I to Total Mouse IGF-I can now be measured in individual subject using the Ansh Free Rat/Mouse IGF-I ELISA (AL-136) along with the Total Rat/Mouse IGF-I ELISA (AL-137).

PRINCIPLE OF THE TEST

The Total Rat/Mouse IGF-I is a quantitative two-step sandwich type immunoassay. In the first step Calibrators, Controls and unknown samples and biotinylated antibody solution are added to antibody coated microtiter wells and incubated. After the first incubation and washing, the wells are incubated with streptavidin horseradish peroxidase conjugate (SHRP) solution. After the second incubation and washing, the wells are incubated with substrate solution (TMB) followed by an acidic stopping solution. In principle, the mouse IGF-I antibody-biotin conjugate binds to the solid phase antibody-antigen complex which in turn binds to the streptavidin-enzyme conjugate. The antibody-antigen-biotin conjugate-SHRP complex bound to the well is detected by enzyme-substrate reaction. The degree of enzymatic turnover of the substrate is determined by dual wavelength absorbance measurement at 450 nm as primary test filter and 630 nm as reference filter. The absorbance measured is directly proportional to the concentration of Mouse IGF-I in the samples and calibrators.

MATERIALS SUPPLIED

CAL-137A - CAL-137F Total Mouse IGF-I Calibrators A thru F

Six vials, 0.5mL, labeled A-F, containing varying concentrations of Mouse IGF-I, in the range of 0 to 50 ng/mL (**Refer to Calibration Card for exact values**), in buffer with ProClin 300. Store unopened at 0 to -20°C until the expiration date. Avoid repeated freeze thaw cycles.

NOTE: The calibrators are traceable to R&D System Mouse IGF-I preparation (Catalog number 791-MG-050).

CTR-137-I & CTR-137-II Total Mouse IGF-I Controls I & II

Two vials, 0.5 mL, labeled Levels I and II containing low and high IGF-I concentrations (**Refer to Calibration Card for exact values**) in buffer with ProClin 300. Store unopened at 0 to -20°C until the expiration date. Avoid repeated freeze-thaw cycles.

PLT-136 Rat/Mouse IGF-I Ab Coated Microtitration strips

One stripholder, containing 12 strips and 96 microtitration wells with IGF-I antibody immobilized to the inside wall of each well. Store at 2-8°C until expiration date in the resealable pouch with a desiccant to protect from moisture.

SPB-121-I IGF-I Sample Buffer I

One bottle, 25 mL, containing sample buffer I with a non-mercury preservative. Store unopened at 2 to 8°C until the expiration date.

SPB-121-II IGF-I Sample Buffer II

One bottle, 25mL, containing sample buffer II with a non-mercury preservative. Store unopened at 2 to 8°C until the expiration date.

CND-136 Mouse IGF-I Conjugate Diluent

One bottle, 12 mL, containing a protein-based (BSA)-buffer with non-mercury preservative. Store at 2-8°C until the expiration date.

BCC-137 Total Mouse IGF-I Biotin Conjugate Concentrate (50X)

One vial, 0.4 mL containing biotinylated detection antibody in a protein-based buffer with a non-mercury preservative. Dilute prior to use in Total Mouse IGF-I assay. Store at 2-8°C until expiration date.

SAR-137 Total Mouse IGF-I Streptavidin-Enzyme Conjugate Ready-To-Use (RTU)

One bottle, 12 mL, containing streptavidin-HRP (horseradish peroxidase) in a protein-based buffer and a non-mercury preservative. Store undiluted at 2-8°C until expiration date.

TMB-100 TMB Chromogen Solution

One bottle, 12 mL, containing a solution of tetramethylbenzidine (TMB) in buffer with hydrogen peroxide. Store at 2-8°C until expiration date.

STP-100 Stopping Solution

One bottle, 12 mL, containing 0.2 M sulfuric acid. Store at 2 to 30°C until expiration date.

WSH-100 Wash Concentrate A

One bottle, 60 mL, containing buffered saline with a nonionic detergent. Store at 2 to 30°C until expiration date. Dilute 25-fold with deionized water prior to use.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Microtitration plate reader capable of absorbance measurement at 450 nm, 405 nm, and 630 nm.
2. Microplate shaker.
3. Microplate washer.
4. Semi-automated/manual precision pipette to deliver 5–250 µL.
5. Vortex mixer.
6. Deionized water.
7. Disposable 12 x 75 mm culture tubes.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.

The following precautions should be observed:

a) Follow good laboratory practice.

b) Use personal protective equipment. Wear lab coats and disposable gloves when handling immunoassay materials.

c) Handle and dispose of all reagents and material in compliance with applicable regulations.

WARNING: Potential Biohazardous Material

Handle all reagents and patient samples at a Biosafety Level 2, as recommended for any potentially infectious human material in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 5th Edition, 2007.[12]

WARNING: Potential Chemical Hazard

Some reagents in this kit may contain ProClin 300 and Sodium azide[13] as a preservative. ProClin 300 and Sodium azide in concentrated amounts are irritants to skin and mucous membranes.

For further information regarding hazardous substances in the kit, please refer to the MSDS, either at AnshLabs.com or by request.

SAMPLE COLLECTION

a) Serum or plasma is the recommended sample type.

b) Sample handling, processing, and storage requirements depend on the brand of blood collection tube that you use. Please reference the manufacturer's instructions for guidance. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products.

c) Samples should be stored frozen at -20°C or lower.

d) Avoid repeated freezing and thawing of samples.

e) Avoid assaying lipemic, hemolyzed or icteric samples.

f) For shipping, place specimens in leak proof containers in biohazard specimen bags with appropriate specimen identification and test requisition information in the outside pocket of the biohazard specimen bag. Follow DOT and IATA requirements when shipping specimens.

PROCEDURAL NOTES

1. A thorough understanding of this package insert is necessary for successful use of the Total Rat/Mouse IGF-I ELISA assay. It is the customer's responsibility to validate the assay for their use. Accurate results will only be obtained by using precise laboratory techniques and following the package insert.
2. A calibration curve must be included with each assay.
3. Bring all kit reagents to room temperature before use. Thoroughly mix the reagents before use by gentle inversion. Do not mix various lots of any kit components and do not use any component beyond the expiration date.
4. Use a clean disposable pipette tip for each reagent, calibrator, control, or sample. Avoid microbial contamination of reagents, contamination of the substrate solutions with the HRP conjugates. The enzyme used as the label is inactivated by oxygen, and is highly sensitive to microbial contamination, sodium azide, hypochlorous acid and aromatic chlorohydrocarbons often found in laboratory water supplies. Use deionized water.
5. Incomplete washing will adversely affect the outcome and assay precision. Care should be taken to add TMB into the wells to minimize potential assay drift due to variation in the TMB incubation time. Avoid exposure of the reagents to excessive heat or direct sunlight.

PREPARATION OF REAGENTS

1. **Wash Solution:** Dilute wash concentrate 25-fold with deionized water. The wash solution is stable for one month at room temperature when stored in a tightly sealed bottle.
2. **Microtitration Wells:** Select the number of coated wells required for the assay. The remaining unused wells should be placed in a resealable pouch with a desiccant. The pouch must be resealed to protect it from moisture.
3. **Total Mouse IGF-I Antibody-Biotin Conjugate Solution:** The Total Mouse IGF-I Antibody-Biotin Conjugate Concentrate should be diluted at a ratio of 1 part conjugate to 50 parts of Mouse IGF-I Conjugate Diluent, according to the number of wells used. If an entire plate is to be used pipet exactly 220 µL of the Concentrate into 11 mL of the buffer.

ASSAY PROCEDURE

Allow all specimens and reagents to reach room temperature and mix thoroughly by gentle inversion before use. Calibrators, controls, and unknowns should be assayed in duplicate.

1. Label the microtitration strips to be used.
2. **Sample Preparation (1:51 dilution):**
   a. In a tube, pipette 5 µL of the sample into 125 µL of **IGF-I Sample Buffer I**.
   b. Vortex and place the tubes in a tight-fitting tube rack and shake at a slow speed (300-400 rpm) at room temperature (23 ± 2°C) for 30 minutes.
   c. Add 125 µL of **IGF-I Sample Buffer II** to the sample vial, vortex, and incubate at a slow speed (300-400 rpm) at room temperature (23 ± 2°C) for 10 minutes. The sample is now ready to be assayed.

   NOTE: *Samples should be run within 30 minutes after extraction (step 2c).*
3. Pipette **25 µL** of the **Calibrator, Controls and Unknowns** from step **2c** to the appropriate wells.
4. Add **100 µL** of the **Antibody-Biotin Conjugate** to each well using a repeater pipette. (Prepare the Total Mouse IGF-I Antibody-Biotin Conjugate Solution by diluting the Total Mouse IGF-I Biotin Conjugate Concentrate in Mouse IGF-I Conjugate Diluent as described under the Preparation of the Reagents section of this package insert.)
5. Incubate the plate, shaking at a fast speed (**600-800 rpm**) on an orbital microplate shaker, for **60 minutes** at room temperature (23 ± 2°C).
6. Aspirate and wash each strip **5 times** with Wash Solution **(350 µL/per well)** using an automatic microplate washer.
7. Add **100 µL** of the **Total Mouse IGF-I Streptavidin-Enzyme Conjugate-RTU** to each well using a repeater pipette.
8. Incubate the plate, shaking at a fast speed (**600-800 rpm**) on an orbital microplate shaker, for **30 minutes** at room temperature (23 ± 2°C).
9. Aspirate and wash each strip **5 times** with the Wash Solution **(350 µL/per well)** using an automatic microplate washer.
10. Add **100 µL** of the **TMB chromogen solution** to each well using a repeater pipette. Avoid exposure to direct sunlight.
11. Incubate the wells, shaking at **600–800 rpm** on an orbital microplate shaker, for **8-12 min** at room temperature (23 ± 2°C).
    ***NOTE**: Visually monitor the color development to optimize the incubation time.*
12. Add **100 µL** of the **Stopping solution** to each well using a repeater pipette. Read the absorbance of the solution in the wells within **20 minutes**, using a microplate reader set to **450 nm**.
    ***NOTE**: Zero calibrator should be programmed as "**Blank**" while reading the optical density. If instrument has a wavelength correction, set the instrument to dual wavelength measurement at **450 nm** with background wavelength correction at **630 nm**.*

RESULTS

***NOTE:** The results in this package insert were calculated by plotting the **log optical density (OD) data on the y-axis and log IGF-I concentration on X-axis** using a cubic regression curve-fit. Alternatively, log vs. log quadratic regression curve-fit can be used. Other data reduction methods may give slightly different results.*

1. Calculate the mean optical density (OD) for each calibrator, Control, or Unknown.
2. Plot the log of the mean OD readings for each of the Calibrators along the y-axis versus log of the IGF-I concentrations in ng/mL along the x-axis, using a cubic regression curve-fit.
3. Determine the IGF-I concentrations of the Controls and unknowns from the calibration curve by matching their mean OD readings with the corresponding IGF-I concentrations.
4. Any sample reading lower than the analytical sensitivity should be used as measured concentration.
5. **Multiply the measured concentrations in ng/mL by the dilution factor (51 folds, step 2).**

LIMITATIONS

The reagents supplied in this kit are optimized to measure rat/mouse IGF-I levels in serum. If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial. For assays employing antibodies, the possibility exists for interference by heterophilic antibodies in the samples.[14]

QUALITY CONTROL

- Each laboratory should establish mean values and acceptable ranges to assure proper performance.
- Mouse IGF-I ELISA controls or other commercial controls should fall within established confidence limits.
- The confidence limits for Mouse IGF-I controls are printed on the Calibration card.
- A full calibration curve, low and high-level controls, should be included in each assay.
- TMB should be colorless. Development of any color may indicate reagent contamination or instability.

REPRESENTATIVE CALIBRATION CURVE DATA

Well Number	Calibrators	Mean Absorbance	Conc (ng/mL)	Conc. (x51), ng/mL
A1, A2	A	0.033 (**Blank**)	0	0
B1, B2	B	0.072	2.0	102.0
C1, C2	C	0.182	4.0	204.0
D1, D2	D	0.430	8.0	408.0
E1, E2	E	1.204	20.0	1020.0
F1, F2	F	2.859	50.0	2550.0

***CAUTION:** The above data must not be employed in lieu of data obtained by the user in the laboratory. (Note: Calibrator concentration is multiplied by 51 to account for sample dilution.)*

ANALYTICAL CHARACTERISTICS

All concentrations listed are in ng/mL.

Analytical Sensitivity

The analytical sensitivity in the Total Rat/Mouse IGF-I assay, as calculated by the interpolation of mean plus two standard deviations of 15 replicates of calibrator A (0 ng/mL) and calibrator B (2.0 ng/mL), is 0.24 [12.2 (51X)] **ng/mL**.

Imprecision

Reproducibility of the Total Rat/Mouse IGF-I assay was determined in a study using two controls and one serum pool. The study included a total of 6 assays, 3 replicates of each per assay (n=18). Representative data were calculated based on EP10A-3 guidelines and are presented in the following table.

Sample	Mean Conc. (ng/mL)	SD (ng/mL)	%CV
1	2.0	0.121	5.93
2	4.0	0.23	5.7
3	7.8	0.45	5.78

Linearity of Dilution

Calibrator F containing various mouse IGF-I levels was diluted serially in Calibrator A. Samples should be diluted in low mouse IGF-I containing serum and extract as per the protocol. The % recovery is presented in the following table.

Sample ID	Dilution factor (1 in X)	Expected Value in ng/mL	Observed Value in ng/mL	% Recovery	Average % Recovery
CAL-F	NEAT VALUE	50.00			107%
	2	25.00	25.733	103%	
	4	12.50	13.369	107%	
	8	6.25	7.009	112%	

Analytical Specificity

Cross-reactivity to other closely related analytes is represented in the table below.

Sample No.	Cross-reactant	Concentration (ng/mL)	% Cross-reactivity
1	Mouse IGFBP-2	50	ND
2	Mouse IGFBP-3	50	ND
3	Mouse IGFBP-4	50	ND
4	Mouse IGFBP-5	50	ND
5	Mouse IGF-II	50	ND
6	Rat IGF-II	50	ND

Species Immunoreactivity

The monoclonal antibody pair used in the assay detects **bovine, equine, canine, rabbit, goat, squirrel, porcine, rat, and monkey** as represented in table below.

Sample#	Species	Type	Dilution Factor	O.D.	Observed Conc. (ng/mL)	Calculated Conc. (ng/mL)
1	Rabbit	Serum	51	0.379	3.484	177.684
2	Rabbit	Serum	51	0.438	3.947	201.297
3	Rabbit	Serum	51	0.669	5.732	292.332
4	Goat	Serum	51	0.307	2.909	148.359
5	Goat	Serum	51	0.388	3.555	181.305
6	Goat	Serum	51	0.553	4.839	246.789
7	Bovine	Serum	51	0.74	6.277	320.127
8	Bovine	Serum	51	0.217	2.162	110.262
9	Bovine	Serum	51	0.391	3.578	182.478
10	Canine	Serum	51	0.113	1.194	60.894
11	Canine	Serum	51	0.262	2.541	129.591
12	Canine	Serum	51	0.357	3.309	168.759
13	Equine	Serum	51	0.206	2.067	105.417
14	Equine	Serum	51	0.389	3.562	181.662
15	Equine	Serum	51	0.28	2.689	137.139
16	Feline	Serum	51	0.082	0.837	42.687
17	Feline	Serum	51	0.106	1.119	57.069
18	Ovine	Serum	51	-0.009	ND	ND
19	Ovine	Serum	51	0.002	ND	ND
20	Porcine	Serum	51	0.295	2.811	143.361
21	Porcine	Serum	51	3.3	26.346	1343.646
22	Porcine	Serum	51	2.088	16.771	855.321
23	Mouse	Serum	51	2.263	18.151	925.701
24	Mouse	Serum	51	0.688	5.878	299.778
25	Rat	Serum	51	1.039	8.578	437.478
26	Rat	Serum	51	0.192	1.945	99.195
27	Squirrel Monkey	Serum	51	0.217	2.162	110.262
28	Squirrel Monkey	Serum	51	0.176	1.802	91.902
29	Vervet Monkey	Serum	51	0.218	2.17	110.67

ND: Not Detectable

Interference

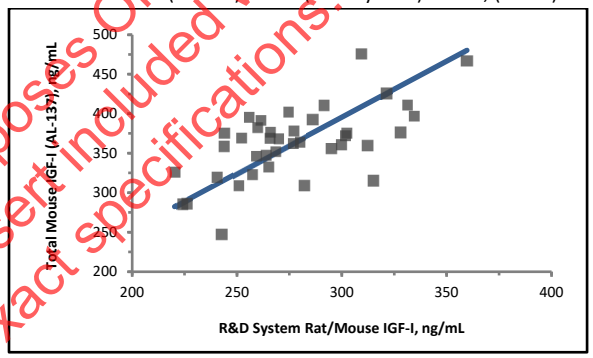
When hemoglobin, biotin, intralipids, and bilirubin were added at greater than two folds of their physiological concentrations to control sample, average mouse IGF-I concentrations were within ± 15% of the control as represented in the following table.

Interferent	Interferent Dose	Sample IGF-I (ng/mL)	Dosed Sample IGF-I (ng/mL)	% Difference
Hemoglobin	1 mg/mL	66.61	66.1	-0.8
	1 mg/mL	62.58	61.74	-1.3
Biotin	1200 ng/mL	69.26	70.79	2.2
	600 ng/mL	79.02	76.58	-3.1
Biotin	1200 ng/mL	68.19	64.74	-5.0
	600 ng/mL	71.25	77.06	8.2
Intralipids	20 mg/mL	84.48	78.77	-6.8
	10 mg/mL	84.02	83.59	-0.5
Intralipids	20 mg/mL	78.29	78.51	0.3
	10 mg/mL	81.19	75.07	-7.5
Bilirubin	0.66 mg/mL	84.74	81.42	-3.9
	0.2 mg/mL	85.65	82.39	-3.8
Bilirubin	0.66 mg/mL	79.51	87.92	10.6
	0.2 mg/mL	84.28	81.42	-3.4

Method Comparison

Total Rat/Mouse IGF-I has been compared to commercially available Rat/Mouse IGF-I (R&D System) kit using 39 mouse samples. Passing Bablok analysis of the results yield the following Regression:

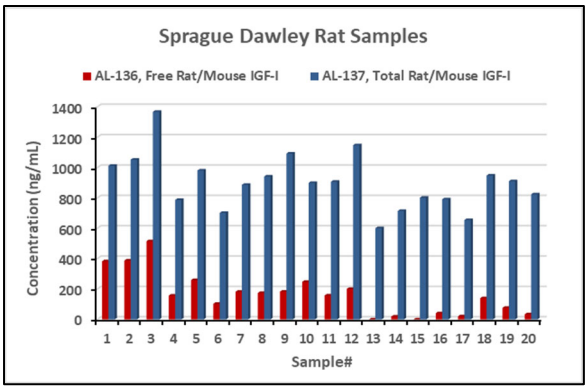
Total Mouse IGF-I (AL-137) = 1.42 (R&D System) -30.47; (r^2=0.8)



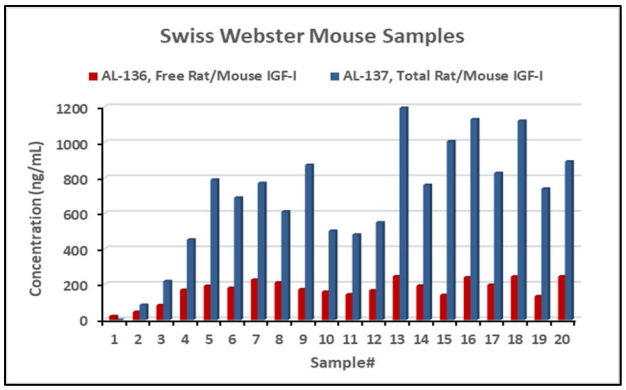
Total to Free IGF-I Concentration

20 Sprague Dawley rat samples and 20 Swiss Webster mouse samples were assayed in Ansh Labs Free Rat/Mouse IGF-I ELISA (AL-136) and Total Rat/Mouse IGF-I ELISA (AL-137).

The % average concentration of Free IGF-I to Total IGF-I in Sprague Dawley rat samples was calculated to be 18% as represented in figure below.



The % average concentration of Free IGF-I to Total IGF-I in Swiss Webster mouse samples was calculated to be 28% as represented in figure below.



REFERENCES

1. Daughaday E, Rotwein P: Insulin like growth factors I and II. Peptide, messenger ribonucleic acid and gene structures, serum and tissue concentrations. Endocrine Rev 10:68-91, 1989.
2. Baxter RC, Martin JL, Beniac VA: High molecular weight insulin-like growth factor binding protein complex. J Biol Chem 264:11843-11848, 1989.
3. Rechler M: Insulin-like growth factor binding proteins. Vit Horm 47:1-114, 1993.
4. Zapf J, Hauri C, Waldvogel M, Froesch ER: Acute metabolic effects and half-lives of intravenously administered insulin-like growth factors I and II in normal and hypophysectomized rats. J Clin Invest 77:1768-1775, 1986.
5. Lee PDK, Rosenfeld RG: Clinical utility of insulin-like growth factor assays. Pediatrician 14:154-161, 1987.
6. Rosenfeld RG, Wilson DM, Lee PDK, Hintz RL: Insulin-like growth factors I and II in evaluation of growth retardation. J Pediatr 109:428-433, 1986.
7. Lee PDK, Wilson DM, Rountree L, Hintz RL, Rosenfeld RG: Efficacy of insulin-like growth factor I levels in predicting the response to provocative growth hormone testing. Pediatr Res 27:45-51, 1990.
8. Soliman AT, Hassan AEHI, Aref MK, Hintz RL, Rosenfeld RG, Rogol AD: Serum insulin-like growth factors I and II concentrations and growth hormone and insulin responses to arginine infusion in children with protein-calorie malnutrition before and after nutritional rehabilitation. Pediatr Res 20:1122-1130, 1986.
9. Guevara-Aguirre J, Rosenbloom AL, Fielder PJ, Diamond FB Jr, Rosenfeld RG: Growth hormone receptor deficiency in Ecuador: Clinical and biochemical phenotype in two populations. J Clin Endocrinol Metab 76:417-423, 1993.
10. Powell DR, Rosenfeld RG, Baker BK, Liu F, Hintz RL: Serum somatomedin levels in adults with chronic renal failure: the importance of measuring insulin-like growth factor I (IGF-I) and IGF-II in acid-chromatographed uremic serum. J Clin Endocrinol Metab 63:1186-1192, 1986.
11. Underwood LE, Murphy MG: Radioimmunoassay of the somatomedins. IN Patrono C (ed): Radioimmunoassay in Basic and Clinical Pharmacology (Handbook of Experimental Pharmacology vol 82) Springer-Verlag, Heidelberg, 1987, pp 561-574.
12. HHS Publication, 5th ed., 2007. Biosafety in Microbiological and Biomedical Laboratories. Available http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5
13. DHHS (NIOSH) Publication No. 78–127, August 1976. Current Intelligence Bulletin 13 - Explosive Azide Hazard. Available http:// www.cdc.gov/niosh.
14. Kricka L. Interferences in immunoassays – still a threat. Clin Chem 2000; 46: 1037–1038.

FOR RESEARCH USE ONLY

Not for use in diagnostic procedures.

Manufactured by:
Ansh Labs
445 Medical Center Blvd.