Insulin-Like Growth Factor-1 (IGF-1) Test System
Product Code: 13325-300

1.0 INTENDED USE

For Laboratory Professional Use
For In Vitro Diagnostics
For Manual or Open System Automation Use

The Insulin-Like Growth Factor-1 (IGF-1) AccuBind® ELISA Test System is intended for the quantitative determination of IGF-1 concentration in human serum or plasma by a colorimetric microplate enzyme immunoassay. Results are to be used in conjunction with other clinical and laboratory findings as an aid in the diagnosis and monitoring of growth disorders such as growth hormone deficiency (GHD), Laron Syndrome and acromegaly.

2.0 SUMMARY AND EXPLANATION OF THE TEST

Insulin-Like Growth Factor-1 (IGF-1) is a small polypeptide composed of 70 amino acids with a molar mass of about 7649 Da. 99% of IGF-1 is bound to six binding proteins, of which IGFBP-3 is the most abundant. Additionally, 80% of IGF-1 is bound in a ternary complex with IGFBP-3 and acid labile subunit (ALS).[2] Though the majority of IGF-1 is secreted by the liver to act as an endocrine hormone, it is also secreted by many other tissues. IGF-1 has structural similarity to insulin and weakly binds to insulin receptors, leading to its naming convention.[1]

There have been some studies demonstrating the significance of IGF-1 in insulin resistance and diabetes, but its primary role is in regulating growth.[1, 3-4] IGF-1 is required by mammals to utilize growth hormone (GH). Deficiencies in IGF-1 lead to stunted development and growth such as in Laron Syndrome.[1] Excess IGF-1 is indicated in other growth disorders such as acromegaly. Monitoring of IGF-1 is essential to control symptoms and associated morbidities such as insulin resistance, glucose intolerance, and cardiovascular disease.[5]

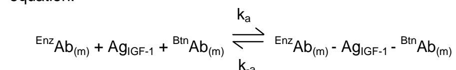
IGF-1 (also known as somatomedin-c) has become the preferred first step in diagnosis of growth hormone deficiency (GHD) since circulating IGF-1 levels do not vary as much as GH due to factors such as exercise and fasting.[6-7] In children, IGF-1 values near the age specific mean or in the upper half of the normal range make GHD unlikely and no further testing is required. Low IGF-1 concentrations suggest the presence of GHD and can be confirmed with a GH-stimulation test, especially if combined with clinical manifestations of GHD.

In adults, GHD can be observed with normal levels of IGF-1. However, when adults have extremely low levels of IGF-1 (< 2 SD) exhibiting symptoms of GHD or similar disorders, they can be considered as GHD without the need for GH-stimulation test.[9-10]

3.0 PRINCIPLE

Immunoenzymometric assay (TYPE 3):
The essential reagents required for an immunoenzymometric assay include high affinity and specificity antibodies (enzyme conjugated and immobilized), with different and distinct epitope recognition, **in excess,** and native antigen. In this procedure, the immobilization takes place during the assay at the surface of a microplate well through the interaction of streptavidin coated on the well and exogenously added biotinylated monoclonal anti-IGF-1 antibody.

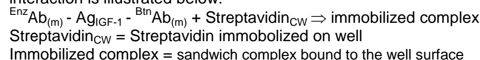
Upon mixing monoclonal biotinylated antibody, the enzyme-labeled antibody and a serum containing the native antigen, reaction results between the native antigen and the antibodies, without competition or steric hindrance, to form a soluble sandwich complex. The interaction is illustrated by the following equation:



$$^{Enz}Ab_{(m)} + Ag_{IGF-1} + {}^{Btn}Ab_{(m)} \underset{k_{-a}}{\overset{k_a}{\rightleftharpoons}} {}^{Enz}Ab_{(m)} - Ag_{IGF-1} - {}^{Btn}Ab_{(m)}$$

$^{Btn}Ab_{(m)}$ = Biotinylated Monoclonal Antibody (Excess Quantity)
Ag_{IGF-1} = Native Antigen (Variable Quantity)
$^{Enz}Ab_{(m)}$ = Enzyme -Monoclonal Antibody (Excess Quantity)
$^{Enz}Ab_{(m)} - Ag_{IGF-1} - {}^{Btn}Ab_{(m)}$= Antigen-Antibodies Sandwich Complex
k_a = Rate Constant of Association
k_{-a} = Rate Constant of Dissociation

Simultaneously, the complex is deposited to the well through the high affinity reaction of streptavidin and biotinylated antibody. This interaction is illustrated below:



$^{Enz}Ab_{(m)} - Ag_{IGF-1} - {}^{Btn}Ab_{(m)} + Streptavidin_{CW} \Rightarrow$ immobilized complex
$Streptavidin_{CW}$ = Streptavidin immobolized on well
Immobilized complex = sandwich complex bound to the well surface

After equilibrium is attained, the antibody-bound fraction is separated from unbound antigen by decantation or aspiration. The enzyme activity in the antibody-bound fraction is directly proportional to the native antigen concentration. By utilizing several different serum references of known antigen values, a dose response curve can be generated from which the antigen concentration of an unknown can be ascertained.

4.0 REAGENTS

Materials Provided:

A. IGF-1 Calibrators – 1.0 ml/ vial (dried) – Icons A-F
Six (6) vials containing dried serum references for IGF-1 at concentrations of 0 (**A**), 25 (**B**), 100 **(C),** 250 (**D**), 600 (**E**), and 1200 (**F**) in ng/ml. A preservative has been added. Store at 2-8°C. ***Reconstitute each vial with 1.0ml of distilled or deionized water.*** The reconstituted calibrators are stable for 60 days at 2-8 °C. To store for a longer period, aliquot the reconstituted calibrators into cryo vials and store at -20 °C. ***DO NOT FREEZE/ THAW MORE THAN ONCE.***
Note: The calibrators are traceable to the 1st WHO International Standard for IGF-1 NIBSC code 02/254.

B. IGF-1 Controls – 1.0 ml/vial (dried) – Icons M-N
Two (2) vials containing dried serum control samples for IGF-1 at various concentrations (indicated on label and COA). A preservative has been added. Store at 2-8°C. ***Reconstitute each vial with 1.0ml of distilled or deionized water.*** The reconstituted controls are stable for 60 days at 2-8 °C. To store for a longer period, aliquot the reconstituted controls into cryo vials and store at -20 °C. ***DO NOT FREEZE/ THAW MORE THAN ONCE.***

C. IGF-1 Enzyme Reagent – 13.0 ml/vial – Icon E
One (1) vial containing biotin-labeled and horseradish peroxidase (HRP) labeled mouse monoclonal antibodies to IGF-1 in a protein-stabilizing matrix with dye. Store at 2-8°C.

D. Streptavidin Coated Plate – 96 wells –Icon ⇓
One 96-well microplate coated with streptavidin and packaged in an aluminum bag with a drying agent. Store at 2-8°C.

E. Wash Solution Concentrate – 20.0 ml/vial - Icon
One (1) vial containing a surfactant in buffered saline. A preservative has been added. Store at 2-8°C.

F. Substrate Reagent – 13.0 ml/vial – Icon S
One (1) vial containing tetramethylbenzidine (TMB) and hydrogen peroxide (H_2O_2) in buffer. Store at 2-8°C.

G. Stop Solution – 8.0 ml/vial – Icon STOP
One (1) vial containing strong acid (0.5M H_2SO_4). Store at 2-8°C.

H. IGF-1 Releasing Agent – 13.0 ml/vial – Icon
One (1) vial containing protein-stabilizing matrix with pH indicator at pH 2.0. Store at 2-8°C.

I. IGF-1 Neutralizing Buffer – 13.0 ml/ vial – Icon NZ
One (1) vial containing protein-stabilizing matrix that increases the pH of sample extraction. Store at 2-8°C.

J. Product Insert

Note 1: Do not use reagents beyond the kit expiration date.
Note 2: Avoid extended exposure to heat and light. **Opened reagents are stable for sixty (60) days when stored at 2-8°C. Closed Kit and component stability are identified on the label.**
Note 3: Above reagents are for a single 96-well microplate.

4.1 Required But Not Provided:

1. Pipette capable of delivering 0.010 ml (10 µl), 0.025 ml (25 µl), and 0.100 ml (100 µl) with precision better than 1.5%.
2. Dispenser(s) for repetitive deliveries of 0.050 ml (50 µl), 0.100 ml (100 µl) and 0.350 ml (350 µl) volumes with precision better than 1.5%.
3. Glass test tubes for control and patient sample preparation.
4. Microplate washer or a squeeze bottle (optional).
5. Microplate Reader with 450nm and 620nm wavelength absorbance capability.
6. Absorbent Paper for blotting the microplate wells.
7. Plastic wrap or microplate covers for incubation steps.
8. Vacuum aspirator (optional) for wash steps.
9. Timer.
10. Quality control materials.

5.0 PRECAUTIONS

For In Vitro Diagnostic Use
Not for Internal or External Use in Humans or Animals

All products that contain human serum have been found to be non-reactive for Hepatitis B Surface Antigen, HIV 1&2 and HCV Antibodies by FDA required tests. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS Publication No. (CDC) 88-8395.

Safe Disposal of kit components must be according to local regulatory and statutory requirements.

6.0 SPECIMEN COLLECTION AND PREPARATION

The specimens should be serum or plasma in type and taken with the usual precautions in the collection of venipuncture samples. For accurate comparison to establish normal values, a fasting morning serum sample should be obtained. The blood should be collected in venipuncture tubes (with or without gel separators). Allow the blood to clot for serum samples. Centrifuge the specimen to separate the serum or plasma from the cells.

In patients receiving therapy with high biotin doses (i.e. >5mg/day), no sample should be taken until at least 8 hours after the last biotin administration, preferably overnight to ensure fasting sample.

Samples may be refrigerated at 2-8°C for a maximum period of two (2) days. If the specimen(s) cannot be assayed within this time, the sample(s) may be stored at temperatures of -20°C for up to 30 days. Avoid use of contaminated devices. Avoid repetitive freezing and thawing. Due to dilution in the procedure, at least 10 µl of the specimen is required. This is enough for duplicate testing.

7.0 QUALITY CONTROL

Each laboratory should assay controls at levels in the low, normal and high range for monitoring assay performance. These controls should be treated as unknowns and values determined in every test procedure performed. Quality control charts should be maintained to follow the performance of the supplied reagents. Pertinent statistical methods should be employed to ascertain trends. The individual laboratory should set acceptable assay performance limits. In addition, maximum absorbance should be consistent with past experience. Significant deviation from established performance can indicate unnoticed change in experimental conditions or degradation of kit reagents. Fresh reagents should be used to determine the reason for the variations.

8.0 REAGENT PREPARATION

1. **Wash Buffer**
Dilute contents of wash solution to 1000ml with distilled or deionized water in a suitable storage container. Diluted buffer can be stored at room temperature (2-30°C) for up to 60 days.
2. **SAMPLE EXTRACTION (*See Notes 3 and 4)***
Obtain enough test tubes for preparation of all patient samples and control samples and label accordingly ***(Calibrators A-F and Controls M and N do not require extraction)***. Pipette 0.010 ml (10 µl) of each patient and external control sample to the bottom of each test tube. Dispense 0.10 ml (100 µl) of IGF-1 Releasing Agent into all tubes and vortex *(see note 3)*. Let the reaction proceed for 30 minutes (min). At end of the 30 min, dispense 0.100 ml (100 µl) of the IGF-1 Neutralizing Buffer to each tube (the color will change from yellow to magenta). Vortex each tube immediately after addition *(see note 3).* The extracted samples must be used within 15 minutes of neutralization.

Note 1: Do not use the substrate if it looks blue.
Note 2: Do not use reagents that are contaminated or have bacteria growth.
Note 3: Use of multiple (3) touch vortex is recommended.
Note 4: It is extremely important to accurately dispense the correct volume with a calibrated pipette and by adding near the bottom of the tubes at an angle while touching the side of the tubes. Glass tubes are highly recommended to ensure there is no adhesion to the tubes leading to incorrect volumes.

9.0 TEST PROCEDURE

Before proceeding with the assay, bring all reagents, calibrators and controls to room temperature (20 - 27°C).
*****Test Procedure should be performed by a skilled individual or trained professional*****

1. Prepare all samples according to the "Sample Extraction" procedure in section "8.0 Reagent Preparation". ***Calibrators A-F and Controls M and N do not require extraction.***
2. Format the microplates' wells for each calibrator, control and patient specimen to be assayed in duplicate. **Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8°C.**
3. Pipette 0.025 ml (25 µL) of the appropriate calibrator, kit control, or extracted specimen into the assigned well.
4. Add 0.100 ml (100 µl) of IGF-1 Enzyme Reagent to all wells
5. Mix the microplate gently for 20-30 seconds.
6. Cover and incubate for 30 minutes at room temperature.
7. Discard the contents of the microplate by decantation or aspiration. If decanting, blot the plate dry with absorbent paper.
8. Add 0.350 ml (350 µl) of wash buffer (see Reagent Preparation Section), decant (tap and blot) or aspirate. Repeat two (2) additional times for a total of three (3) washes. **An automatic or manual plate washer can be used. Follow the manufacturer's instruction for proper usage. If a squeeze bottle is employed, fill each well by depressing the container (avoiding air bubbles) to dispense the wash. Decant the wash and repeat two (2) additional times.**
9. Add 0.100 ml (100 µl) of substrate reagent to all wells. **Always add reagents in the same order to minimize reaction time differences between wells.**

DO NOT SHAKE THE PLATE AFTER SUBSTRATE ADDITION

10. Incubate at room temperature for fifteen (15) minutes.
11. Add 0.050 ml (50 µl) of stop solution to each well and gently mix for 15-20 seconds. **Always add reagents in the same order to minimize reaction time differences between wells.**
12. Read the absorbance in each well at 450nm (using a reference wavelength of 620-630nm. **The results should be read within fifteen (15) minutes of adding the stop solution.**

Note: If a sample is suspected of concentrations higher than 1200 ng/ml, the sample may be retested with 1:10 dilution after the usual extraction procedure. Use equal volumes IGF-1 Releasing Agent and IGF-1 Neutralization Buffer as the diluent.

10.0 CALCULATION OF RESULTS

A dose response curve is used to ascertain the concentration of IGF-1 in unknown specimens.

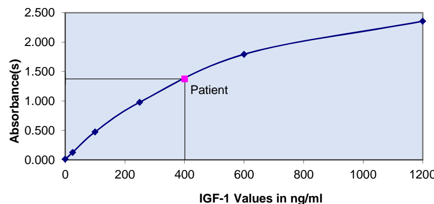
1. Record the absorbance obtained from the printout of the microplate reader as outlined in Example 1.
2. Plot the absorbance for each duplicate calibrator versus the corresponding IGF-1 concentration in ng/ml on linear graph paper (do not average the duplicates of the calibrators before plotting).
3. Connect the points with a best-fit curve.
4. To determine the concentration of IGF-1 for an unknown, locate the average absorbance of the duplicates for each unknown on the vertical axis of the graph, find the intersecting point on the curve, and read the concentration (in ng/ml) from the horizontal axis of the graph (the duplicates of the unknown may be averaged as indicated). In the following example, the average absorbance (1.375) intersects the dose response curve at 404.4 ng/ml IGF-1 (See Figure 1).

Note: Computer data reduction software designed for ELISA assay may also be used for the data reduction. If such software is utilized, the validation of the software should be ascertained.

EXAMPLE 1

Sample I.D.	Well Number	Abs (A)	Mean Abs (B)	Value (ng/ml)
Cal A	A1	0.013	0.013	0
	B1	0.013		
Cal B	C1	0.128	0.127	25
	D1	0.125		
Cal C	E1	0.469	0.475	100
	F1	0.482		
Cal D	G1	1.004	0.978	250
	H1	0.953		
Cal E	A2	1.788	1.793	600
	B2	1.798		
Cal F	C2	2.358	2.355	1200
	D2	2.352		
Sample	E2	1.374	1.375	401.4
	F2	1.376		

FIGURE 1



*The data and figure above are for example only. Do not use it for calculating your results.

11.0 Q.C. PARAMETERS

In order for the assay results to be considered valid the following criteria should be met:

1. The absorbance (OD) of calibrator F should be $\geq$ 1.3.
2. Four out of six quality control pools should be within the established ranges.

12.0 RISK ANALYSIS

The MSDS and Risk Analysis Form for this product are available on request from Monobind Inc.

12.1 Assay Performance

1. It is important that the time of reaction in each well is held constant to achieve reproducible results.
2. Pipetting of samples should not extend beyond ten (10) minutes to avoid assay drift.
3. Highly lipemic, hemolyzed or grossly contaminated specimen(s) should not be used.
4. If more than one (1) plate is used, it is recommended to repeat the dose response curve.
5. The addition of substrate solution initiates a kinetic reaction, which is terminated by the addition of the stop solution. Therefore, the substrate and stop solution should be added in the same sequence to eliminate any time-deviation during reaction.
6. Plate readers measure vertically. Do not touch the bottom of the wells.
7. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor replication and spurious results.
8. Use components from the same lot. No intermixing of reagents from different batches.
9. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed are essential. Any deviation from Monobind's IFU may yield inaccurate results.
10. All applicable national standards, regulations and laws, including, but not limited to, good laboratory procedures, must be strictly followed to ensure compliance and proper device usage.
11. It is important to calibrate all the equipment e.g. Pipettes, Readers, Washers and/or the automated instruments used with this device, and to perform routine preventative maintenance.
12. Risk Analysis- as required by CE Mark IVD Directive 98/79/EC - for this and other devices, made by Monobind, can be requested via email from Monobind@monobind.com.

12.2 Interpretation

1. ***Measurements and interpretation of results must be performed by a skilled individual or trained professional.***
2. Laboratory results alone are only one aspect for determining patient care and should not be the sole basis for therapy, particularly if the results conflict with other determinants.
3. The reagents for the test system procedure have been formulated to eliminate maximal interference; however, potential interaction between rare serum specimens and test reagents can cause erroneous results. Heterophilic antibodies often cause these interactions and have been known to be problems for all kinds of immunoassays (Boscato LM Stuart MC. 'Heterophilic antibodies: a problem for all immunoassays' *Clin.Chem.* 1988:3427-33). For diagnostic purposes, the results from this assay should be used in combination with clinical examination, patient's history and, all other clinical findings.
4. For valid test results, adequate controls and other parameters must be within the listed ranges and assay requirements.
5. If test kits are altered, such as by mixing parts of different kits, which could produce false test results, or if results are incorrectly interpreted, Monobind shall have no liability.
6. If computer controlled data reduction is used to interpret the results of the test, it is imperative that the predicted values for the calibrators fall within 10% of the assigned concentrations.

13.0 EXPECTED RANGES OF VALUES

In agreement with established reference intervals for a "normal" population the approximate expected ranges for the IGF-1 AccuBind® ELISA Test System are abbreviated for convenience in Table 1. A full table of reference intervals is available in the device technical file.

TABLE 1
Expected Values for the IGF-1 Test

Age (years)	Range (ng/ml)	Age (years)	Range (ng/ml)
< 1	14-192	18-25	66-442
1-7	14-312	26-50	40-329
8-10	51-495	51-70	32-245
11-17	79-729	> 70	32-200

It is important to keep in mind that establishment of a range of values, which can be expected to be found by a given method for a population of "normal" persons, is dependent upon a multiplicity of factors: the specificity of the method, the population tested and the precision of the method in the hands of the analyst. For these reasons, each laboratory should depend upon the range of expected values established by the manufacturer only until an in-house range can be determined by the analysts using the method with a population indigenous to the area in which the laboratory is located. Additionally, values obtained greater than two standard deviations from the mean of an established demographic should be considered abnormal and investigated further by related tests.

14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision

The within-run and total precision of the IGF-1 AccuBind® ELISA Test System were determined by analyses on six different levels of pool control and patient sera. The mean values, standard deviation and coefficient of variation for each of these control sera are presented in Table 4.

TABLE 4
Precision data for the IGF-1 Test System

Sample	Mean Value (ng/ml)	Within-Run Precision		Total Precision (n=80)	
		SD	CV%	SD	CV%
Control 1	48.4	1.94	4.01	3.12	6.44
Control 2	181.3	3.90	2.15	13.71	7.56
Control 3	394.8	9.36	2.37	24.80	6.28
Patient 1	150.3	4.22	2.81	14.42	9.60
Patient 2	69.6	2.17	3.12	5.86	8.43
Patient 3	217.0	6.78	3.13	20.87	9.62

*As measured in forty experiments in duplicate over a 20 day period.

14.2 Sensitivity

The IGF-1 AccuBind® ELISA Test System has a Limit of Blank (LoB) of 1.69 ng/ml. The Limit of Detection (LoD) is equal to the Limit of Quantitation (LoQ) and is 2.76 ng/ml.

14.3 Accuracy

14.3.1 Linearity

The linearity of the IGF-1 AccuBind® ELISA test system was tested by diluting human serum samples containing high levels of IGF-1 (324 to 1364 ng/ml). Samples were diluted after extraction with a low (<25 ng/ml) sample or equal volumes of IGF-1 Releasing Agent and IGF-1 Neutralizing buffer. The system demonstrates excellent linearity through the range of the test up to 1364 ng/ml.

14.3.2 Recovery

The recovery of the IGF-1 AccuBind® ELISA Test System was tested for five serum samples spiked with 25, 100, 250, 600, and 1200 ng/ml IGF-1. The average recovery of all samples was 92.6%.

14.4 Cross-Reactivity and Interference

The specificity of the IGF-1 antibodies to selected substances was evaluated by adding the potentially cross-reacting or interfering substance to a serum matrix at an extremely high concentration (10,000 ng/ml).

Substance	Cross-Reactivity
hGH	ND*
IGF-2	ND*
IGFBP-3	ND*
Insulin	ND*
Proinsulin	ND*

**ND=Not Detectable*

Substance	Interference
hGH	Insignificant
IGF-2	Insignificant
Insulin	Insignificant
Proinsulin	Insignificant

14.5 High Dose Hook Effect

The IGF-1 AccuBind® ELISA Test System does not exhibit a hook effect for concentrations up to 20,000 ng/ml.

15.0 REFERENCES

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Effective Date: 2024-Jul-08 Rev. 0 **DCO: N/A**
MP13325 **Product Code: 13325-300**

Size		96(A)	192(B)
Reagent (fill)	A)	1.0 ml set (dry)	1.0 ml set (dry)
	B)	1.0 ml set (dry)	1.0 ml set (dry)
	C)	1 (13 ml)	2 (13 ml)
	D)	1 plate	2 plates
	E)	1 (20 ml)	2 (20 ml)
	F)	1 (13 ml)	2 (13 ml)
	G)	1 (8 ml)	2 (8 ml)
	H)	1 (13 ml)	2 (13 ml)
	I)	1 (13 ml)	2 (13 ml)

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Please visit our website to learn more about our products and services.

Glossary of Symbols
(EN 980/ISO 15223)

IVD — In Vitro - Diagnostic Medical Device
Temperature Limitation Storage Condition (2-8° C)
Consult Instructions for Use
REF — Catalogue Number
Contains Sufficient Test for Σ
LOT — Batch Code
Used By (Expiration Day)
Date of Manufacturer
Manufacturer