



Fully Automated Insulin-like Growth Factor Binding Protein-3 (IGFBP-3)

A fully automated assay for the measurement of IGFBP-3 in human serum or plasma on the IDS-iSYS system. The assay is intended for the *in vitro* diagnostic use in the diagnosis and management of growth-hormone related disorders.

Measurement of both Insulin-like Growth Factor-I and Insulin-like Growth Factor Binding Protein-3 appears superior to determining either analyte alone, for assessing growth hormone-related disorders including acromegaly and gigantism; adult growth hormone deficiency (GHD) and for monitoring recombinant growth hormone treatment.

IGFBP-3 measurement is particularly useful in diagnosing pediatric GHD. Patients with GHD have subnormal IGFBP-3 levels whereas small statured children with normal growth hormone secretion have IGFBP-3 levels within the normal range.

Features and Benefits

- Excellent correlation to existing automated assay.
- Exceptional lot to lot consistency – use of two monoclonal antibodies guarantees consistent and reproducible results required for monitoring patient therapy.
- Low sample volume – suitable for paediatric samples.
- Calibrated to NIBSC 93/560.
- Insulin-like Growth Factor-I (IGF-I) and human Growth Hormone (hGH) also available – allowing fully automated testing of all 3 analytes from a single sample tube.

Specifications

Format	Automated chemiluminescence (CLIA)						
Calibrators	2 each of 2 concentration levels, 1 mL						
Controls	3 each of 3 concentration levels, 1 mL						
Limit of Quantitation*	80 ng/mL						
Dynamic Range	80 - 10,000 ng/mL						
Minimum Sample Volume	6 µl plus dead volume						
Sample Type	Human serum (standard sampling tubes or tubes containing serum separating gel) Human plasma (collected in lithium heparin, sodium heparin and potassium EDTA)						
Reagent Stability	The IDS-iSYS IGFBP-3 assay reagent cartridge may be stored on-board the IDS-iSYS System for a maximum of 14 days.						
Calibration Stability	The calibration of IDS-iSYS IGFBP-3 assay is stable for a maximum of 14 days						
Throughput	74 tests per hour						
Precision*	Sample ID	N	Mean (ng/mL)	Within Run SD	%CV	Total** SD	%CV
	1	80	754	16.6	2.2	43.6	5.8
	2	80	2042	54.0	2.6	141.0	6.9
	3	80	3675	51.9	1.4	213.2	5.8
	4	80	4682	83.3	1.8	295.4	6.3
	5	80	7686	122.4	1.6	550.9	7.2

* Representative data; results in individual laboratories may vary from these data.
** Total is an accumulation of within run, between run and between day.

Reference Range



An extensive reference range study was completed using the IDS-iSYS IGFBP-3 assay. The assay is calibrated to the NIBSC 93/560 reference material. Over 6000 samples including paediatric samples from Europe and North America were tested. These samples were also tested using the IDS-iSYS IGF-I assay (IDS-iSYS IGF-I Reference Range brochure available). The IGFBP-3 values are displayed below in 5 year intervals separated by gender¹.



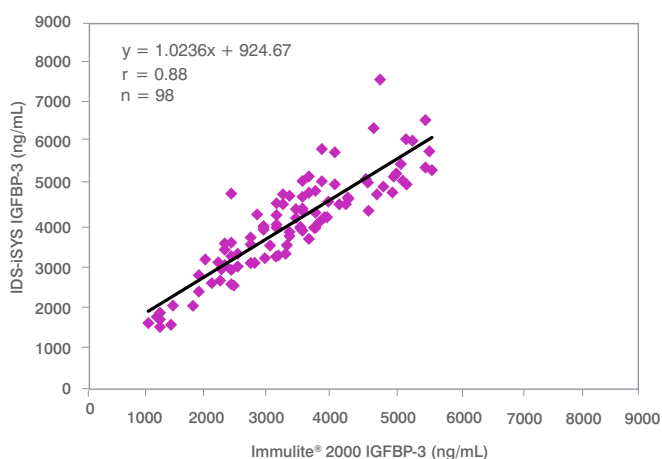
Gender	Age (Years)	n	2.50% (ng/mL)	25% (ng/mL)	Median (ng/mL)	75% (ng/mL)	97.5% (ng/mL)
Male	0-5	141	1177	1789	2352	3016	4171
Male	5-10	298	1995	2964	3387	3871	4904
Male	10-15	436	2472	3637	4298	4803	5920
Male	15-20*	285	2210	3734	4340	4830	6490
Male	30-35	75	3126	3739	4262	4813	5915
Male	35-40	151	3264	3853	4184	4684	5968
Male	40-45	154	2919	3771	4298	4833	5868
Male	45-50	152	2805	3606	4205	4800	6121
Male	50-55	155	2654	3588	4239	4741	5839
Male	55-60	168	2155	3521	4063	4653	5683
Male	60-65	179	2437	3390	3914	4665	6077
Male	65-70	289	1851	3154	3752	4332	5912
Male	70-75	244	1915	2898	3413	3998	5316
Male	75-80	257	1837	2567	3263	3800	5128
Male	80-85	119	1691	2483	2955	3571	4793
Male	>85	53	1466	2508	2851	3221	4311

Gender	Age (Years)	n	2.50% (ng/mL)	25% (ng/mL)	Median (ng/mL)	75% (ng/mL)	97.5% (ng/mL)
Female	0-5	299	1078	1769	2430	2966	4329
Female	5-10	713	1674	3040	3655	4240	5411
Female	10-15	408	2321	3684	4411	4962	6195
Female	15-20*	189	2999	3926	4678	5261	6170
Female	30-35	86	2995	3993	4441	5001	5701
Female	35-40	170	3105	3833	4251	4734	5868
Female	40-45	182	2888	3776	4228	4645	5852
Female	45-50	160	2916	3589	4091	4484	5715
Female	50-55	190	2929	3585	4022	4693	6779
Female	55-60	199	2558	3575	4137	4722	5959
Female	60-65	173	2793	3558	4063	4682	6129
Female	65-70	277	2381	3467	4018	4577	5947
Female	70-75	257	2074	3311	3846	4474	5616
Female	75-80	222	2049	3137	3658	4237	5394
Female	80-85	120	2247	3022	3525	4012	5048
Female	>85	56	1815	2892	3280	3937	5319

* Data not available between 20-30 years.

Method Comparison

IDS-iSYS vs. Immulite®



98 samples were measured using the IDS-iSYS and Immulite® 2000 systems by an external clinical laboratory. Good correlation and regression values between methods were observed.

References

- Reference centiles were obtained using the LMS method (Cole, T.J. and Green, P.J. "Smoothing reference centile curves: The LMS method and penalized likelihood." *Statistics in Medicine*, 11, 1305-1319 (1992)).

Ordering Information

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IS-4400TSInt
Issue: 1
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Product Name

IDS-iSYS Insulin-like Growth Factor Binding Protein-3 (IGFBP-3)

Description

Reagent Pack: 100 tests
Control Set: 3 levels
(3 bottles per level, 1 mL per bottle)

Code

IS-4400
IS-4430

Related Products

IDS-iSYS human Growth Hormone (hGH)
Bio-Rad Lyphochek® Immunoassay Plus Control

Reagent Pack: 100 tests
Control Set: 3 levels

IS-3700

IDS-iSYS Insulin-like Growth Factor-I (IGF-I)

Reagent Pack: 100 tests
Control Set: 3 levels

IS-3900
IS-3930