



Fully Automated human Growth Hormone (hGH)

A fully automated assay for the measurement of human Growth Hormone in serum or plasma.

The recently published Consensus Statement on the Standardization and Evaluation of Growth Hormone and Insulin-like Growth Factor Assays has identified obstacles in measuring human Growth Hormone¹. These obstacles include the heterogeneous isoforms of circulating Growth Hormone (GH), the inconsistency in reference preparation used to calibrate assays and interference from the binding protein, GH analogs and placental GH. The IDS-iSYS hGH assay conforms to the recommendations outlined in the Consensus Statement. The IDS-iSYS hGH assay is specific for 22 kDa GH and does not cross react with the 20 kDa isoform, Pegvisomant, Placental GH or GH Binding Protein, making it one of the most specific and sensitive assays available.

Features and Benefits

- **100% specific for the 22 kDa GH isoform** – total measurement of the most abundant, bioactive GH molecule.
- **No cross reactivity with Pegvisomant** – only measures endogenous hGH in patients under therapy.
- **No interference with Growth Hormone Binding Protein (GHBP)** – allows a more precise and accurate measurement and avoids underestimation of GH present in the sample.
- **Excellent correlation to existing automated methods** – assures total confidence in results.
- **Calibrated against the WHO IS 98/574** – ensures full traceability against the defined reference preparation in the effort towards harmonization of GH measurement.

Specifications

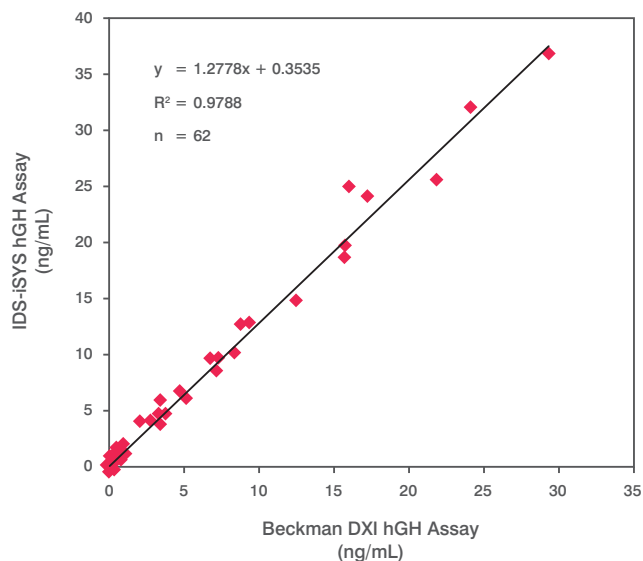
Format	Automated chemiluminescence immunoassay (CLIA)	
Calibrators	Ready to Use, 2 each of 2 concentration levels, 1 mL	
Controls	Bio-Rad Lyphochek® Immunoassay Plus Control, 3 concentration levels	
Limit of Quantitation	0.05 ng/mL	
Dynamic Range	0.05 - 100 ng/mL	
Minimum Sample Volume	50 µL	
Sample Type	Human serum (including serum collected in serum separator tubes) Human plasma (collected in lithium heparin, sodium heparin, sodium citrate, ammonium heparin)	
Reagent Stability	The IDS-iSYS hGH assay reagent cartridge may be stored on-board the IDS-iSYS System for a maximum of 11 days	
Specificity	hGH 22kDa	100%
	hGH 20kDa (10 ng/mL)	Not Detectable
	Placental hGH (200 ng/mL)	Not Detectable
	Human Placental Lactogen (HPL) (10,000 ng/mL)	Not Detectable
	Prolactin (40,000 ng/mL)	Not Detectable
	Pegvisomant (50,000 ng/mL)	Not Detectable
Time to First Result	35 minutes	

Precision*			Within Run			Total**	
	Sample ID	N	Mean (ng/mL)	SD	CV (%)	SD	CV (%)
	1	40	1.49	0.03	1.8	0.16	10.4
	2	40	9.87	0.35	3.5	0.88	8.9
	3	40	25.23	0.55	2.2	1.48	5.9

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

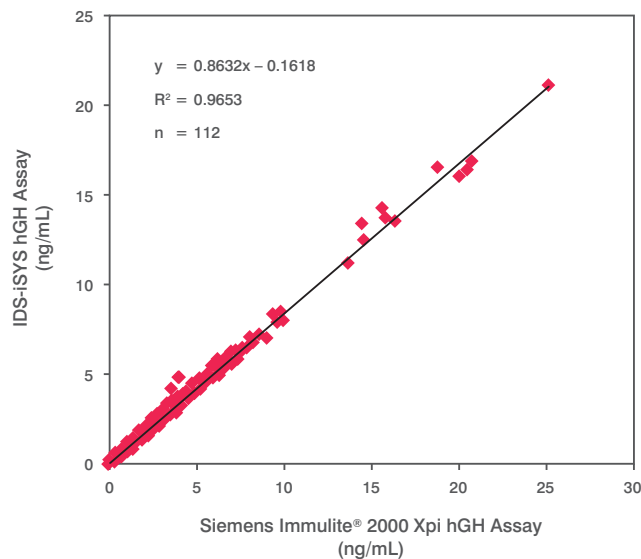
Method Comparison

IDS-iSYS versus Beckman DXI



A total of 62 samples were compared against the Beckman Coulter Unicel DXI Access ultrasensitive hGH assay. The IDS-iSYS hGH assay has good correlation with this method.

IDS-iSYS versus Siemens Immulite® 2000



A total of 112 samples were compared against the Siemens Immulite® 2000 Xpi hGH assay. Linear regression analysis was performed on the comparative data and good correlation was shown.

Ordering Information

Product Name	Description	Code
IDS-iSYS human Growth Hormone (hGH)	Reagent Pack: 100 tests	IS-3700
Bio-Rad Lyphochek® Immunoassay Plus Control	Control Set: 3 levels	Contact Bio-Rad
Related Products		
IDS-iSYS Insulin-like Growth Factor Binding Protein-3 (IGFBP-3)	Reagent Pack: 100 tests	IS-4400
IDS-iSYS Insulin-like Growth Factor Binding Protein-3 (IGFBP-3)	Control Set: 3 levels	IS-4430
IDS-iSYS Insulin-like Growth Factor-I (IGF-I)	Reagent Pack: 100 tests	IS-3900
IDS-iSYS Insulin-like Growth Factor-I (IGF-I)	Control Set: 3 levels	IS-3930

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References

- Clemmons, D.R., 2011. Consensus Statement on the Standardization and Evaluation of Growth Hormone and Insulin-like Growth Factor Assays. Clin. Chem. v. 57, p. 555-559.

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