



IDS-iSYS Free Testosterone

Fertility Hormones

An automated assay for the quantitative determination of free testosterone in human serum or plasma. Measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males; in females hirsutism (excessive hair) and virilisation (masculinisation) due to tumours, polycystic ovaries, and adrenogenital syndromes.

Testosterone (17 β -OH-4-androstene-3-one) is considered to be the principle androgen found in circulation of mature male mammals¹. In males it is synthesised and secreted by the Leydig cells located in the interstitium of the testis, and in females testosterone is produced in various locations such as the ovaries, adrenal gland and peripheral tissues, with additional production due to inter-conversion from other steroid hormones. The secretion of testosterone is regulated by luteinising hormone (LH). Testosterone is found in circulation predominantly linked to carrier proteins, the most common of which being sex-hormone binding protein (SHBG).

Testosterone plays a key part in the development of reproductive tissues and secondary sex characteristics in men. There is an observed and well documented circadian variation of testosterone levels in men with the circulating concentration being higher in the morning and declining throughout the day². Testosterone levels also decline in ageing males (andropause) and are often associated with loss of muscle and bone mass, leading to osteoporosis, loss of libido, erectile dysfunction, depression and impaired cognitive function³.

Measurement of free testosterone can be considered useful in the diagnosis of several conditions including androgen deficiency in men and androgen excess in women⁴. Assessment of free testosterone levels may prove beneficial⁵ and may avoid an incorrect diagnosis of hypogonadism in cases when low concentrations of total testosterone are determined and alterations of SHBG are suspected.

Features and benefits

- Highly specific monoclonal antibody to ensure accuracy of reported result
- Highly reproducible results
- Suitable for measurement of a variety of sample types
- All reagents are ready to use
- Part of a developing panel of steroid hormone assays

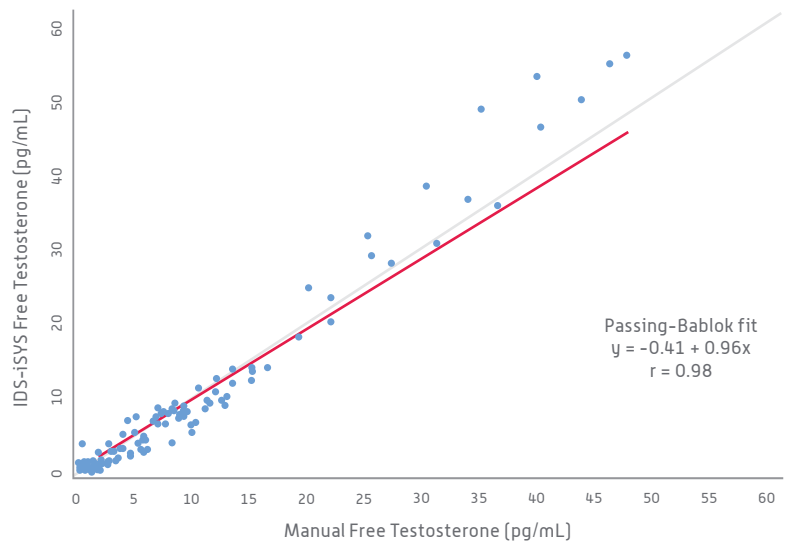
Specifications

Format	Automated competitive immunoassay				
Calibrators	Ready to use – 1 each of 2 concentration levels, 1.0 mL				
Controls	Ready to use – 2 each of 3 concentration levels, 1.0 mL				
Limit of Quantitation	0.24 pg/mL				
Minimum sample volume	20 µL plus dead volume				
Sample Type	Human serum – including serum collected in serum separator tubes. Human plasma – collected in lithium or sodium heparin or potassium EDTA tubes				
Reagent stability	The IDS-iSYS Free Testosterone reagent cartridge may be stored after opening on-board the IDS-iSYS Multi Discipline Automated System or at 2 - 8 °C for up to 28 days				
Calibration stability	The calibration of the IDS-iSYS Free Testosterone assay is stable for up to 28 days				
Time to first result	48 minutes				
Precision	Sample ID	n	Mean (pg/mL)	CV Within Run	CV Total
	1	80	1.68	5.4%	7.4%
	2	80	8.43	5.4%	6.6%
	3	80	35.84	3.1%	5.4%

Method Comparison

IDS-iSYS Free Testosterone vs predicate manual free testosterone assay

127 samples (0.17 to 49 pg/mL) from normal 'healthy' patients were assessed with both the IDS-iSYS Free Testosterone and the manual predicate free testosterone assays



Ordering information

Product Name	Description	Code
IDS-iSYS Free Testosterone	Reagent Pack: 100 tests	IS-5300
IDS-iSYS Free Testosterone Control Set	Control Set: 3 levels	IS-5330

Other assays in the Fertility portfolio

Product Name	Code
IDS-iSYS Total Testosterone	IS-5000
IDS-iSYS 17-OH Progesterone	IS-5100
IDS-iSYS 17-β Estradiol*	IS-5200
IDS-iSYS SHBG*	IS-5600

*In development

Visit www.idsplc.com for an extended range of IDS assays

References

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