



The FastPack® IP SHBG and Total Testosterone Immunoassays

Testosterone is the primary sex hormone in men. It performs a vital function in regulating male sex drive, bone mass, fat distribution, muscle mass, and the production of red blood cells and sperm. Women also have testosterone, but in much smaller amounts. This article focuses on the measurement of testosterone in adult men.

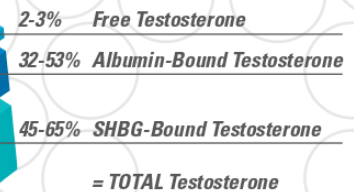
Most testosterone circulating in the bloodstream is bound to either Sex Hormone-Binding Globulin (SHBG) or albumin, the main protein in blood. Only a small percentage (2-3%) is immediately available to target tissues as free testosterone.

Testosterone testing plays a fundamental role in the diagnosis of androgen disorders. However, a total testosterone test determines the overall amount of testosterone in the bloodstream. It does not differentiate between bound and unbound forms of the hormone.

Measurement of SHBG in addition to total testosterone enables the calculation of free and bio-available testosterone. Physicians can better interpret their patients' androgen status with a comprehensive understanding of the differences between total, free, and bio-available testosterone. This is particularly important when total testosterone levels are not consistent with clinical symptoms.

The FastPack® IP system enables physicians to diagnose androgen disorders, monitor testosterone therapy, and make adjustments in a single patient visit. This fully automated in-office analyzer delivers quantitative test results in minutes with the push of a single button.

TESTOSTERONE RATIO IN MALES*



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Because every result matters™

The FastPack® IP SHBG and Total Testosterone Immunoassays

FAST / SIMPLE / ACCURATE



Assay Performance

ASSAY	LOWER LIMIT DETECTION	UPPER LIMIT DETECTION	ASSAY TIME	PART NUMBER (30 TESTS)
SHBG	0.80 nmol/L	174 nmol/L	8 mins	25000081
Testosterone	23 ng/dL	1600 ng/dL	12 mins	25000041

Pretreat Sample (SHBG Only):

- 1) Pipette 100 µL of sample into pre-filled vial
- 2) Recap and invert 3 times



Dispense sample into the FastPack® Injection Port



Place FastPack® into the FastPack® IP Instrument



Press the START button

CPT Codes and Reimbursement

ASSAY	CPT CODE	2019 MEDICARE REIMBURSEMENT
SHBG	84270	\$24.15
Testosterone	84403	\$28.68

*References <https://labtestsonline.org/tests/sex-hormone-binding-globulin-shbg>
FastPack® IP is for In Vitro Diagnostic Use

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