

## Smart Hormone Management

Smart hormone management relates to the diagnosis and treatment of diseases characterized by abnormal levels of circulating sex steroids. These diseases are common, varied in nature, spanning everything from aging to cancer to infertility to menopause. Determining free and bioavailable levels of sex steroids is key to diagnosis and treatment.

The sex steroid androgens of interest are testosterone, dihydrotestosterone, androstenediol, androstenedione, androsterone, dihydroandrosterone, and DHEA, while the estrogens of interest include estrone, estradiol, and estriol. These androgens and estrogens circulate free and bound in various fractions to plasma proteins. Some of these protein bound fractions allow the androgens and estrogens to remain biologically active, while other proteins bind so tightly that androgen and estrogen bound fractions become biologically inactive. Measurement of the total androgen or estrogen alone can be misleading in many clinical situations; therefore, measurement of the free and bioavailable fractions yield a more accurate assessment of the androgen and estrogen status.

During the last decade, there has been a dramatic surge in interest in testosterone testing of adults. Many clinics are asking the laboratory to measure testosterone levels for the diagnosis of androgen excess states in women and in the identification and treatment of androgen deficiency in men. There are multiple methods available for assessing testosterone status beyond the measurement of total testosterone. The determination of free and bioavailable testosterone concentrations obtained by mass action equations adds improved and reliable diagnostics of testosterone status, can be performed on simple automated instruments, is comparable to the "gold-standard" equilibrium dialysis method, and is suitable for routine clinical use.



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 B&C Biotech



**Smart  
Hormone  
Management**

## Testosterone: Free & Bioavailable



*Sending out your samples?*

*Losing revenue to outsource lab testing?*

*Running a laborious esoteric method?*

*Tired of waiting days for results of questionable methods?*

***Would you like to increase your revenues  
and improve your diagnostics?***

*There is a better way!*

*Calculation methods that determine the bound and free fractions of sex-steroids are accurate, simple, reduce costs, save time, and are suitable for routine clinical use.*

## Free & Bioavailable Testosterone

### Introduction

Testosterone circulates in plasma either freely (approximately 1-2%), bound nonspecifically with low affinity and high capacity to albumin, and bound specifically with high affinity and low capacity to sex hormone binding globulin (SHBG). The free circulating fraction is referred to as "free testosterone", and the free and albumin bound fractions together make up the "bioavailable testosterone" or "non-SHBG-bound testosterone". The determination of the free and bioavailable fractions of testosterone provides physicians with a complete assessment of the testosterone status.

B&C Biotech has developed an algorithm that accurately and reliably calculates the free and bioavailable fractions of testosterone. The algorithm is comparable to the "gold standard" equilibrium dialysis method but utilizes measurements from routine state of the art automated analyzers. If you are contemplating performing free and bioavailable testosterone testing in your laboratory, B&C Biotech has your testing solution.

### How it Works

The calculation is based on the laws of mass action and requires inputs of the Total Testosterone and SHBG (both of which can be performed on your immunoassay analyzer) and Albumin (performed on your automated chemistry analyzer). Once you have determined the concentrations of the Total Testosterone, SHBG, and Albumin, log on to the Smart Hormone Management (SHM) website and input the results. The website will accurately calculate the Free and Bioavailable fractions of Testosterone and present the data as a complete Free and Bioavailable Testosterone Panel in a report format for your records.

### Instructions.....Easy, Accurate, Fast Results

1. Measure Total Testosterone, SHBG, and Albumin in your lab.
2. Log on to the SHM website.
3. Input the Total Testosterone, SHBG, and Albumin results in to the website calculator.
4. Print the calculated Free and Bioavailable Testosterone results in the panel report format.
5. Bill for the 3 CPT codes of Total Testosterone, SHBG, and Albumin.

*(Internalizing the testing and generating increased revenues is truly that simple.)*

## Increase Your Revenues

Whether you are running Testosterone testing in your laboratory, sending your Free and Bioavailable Testosterone testing out to a reference laboratory, or running an esoteric free and/or bioavailable testosterone method, converting to the Free and Bioavailable Testosterone Panel will add improved diagnostics for your patients as well as generate increased revenues for your lab and your business.

**Upgrading** your current Testosterone testing to the Free and Bioavailable Testosterone Panel will yield improved diagnostics and allow you to increase your reimbursement from 1 CPT code for your current Testosterone testing to 3 CPT codes for the new panel tests of Testosterone, SHBG, and Albumin.

**Internalizing** your outsourced free and bioavailable Testosterone testing to the Free and Bioavailable Testosterone Panel will allow you to generate accurate results and recover revenue lost to the send-out laboratory.

**Replacing** your current free and/or bioavailable Testosterone testing with the Free and Bioavailable Testosterone Panel can save time and resources and will add improved diagnostics over your current method.

B&C Biotech charges a fee per calculation to generate the Free and Bioavailable Testosterone results for the Panel. However, the calculation fee can easily be recovered with the additional revenue generated by the increased panel testing.

### How to Apply

If you would like a demonstration of how easy it is to use the Free and Bioavailable Testosterone Panel in your laboratory, contact B&C Biotech at:

**Phone: 951-587-8120**

**E-mail: SHM@bandcbiotech.com**

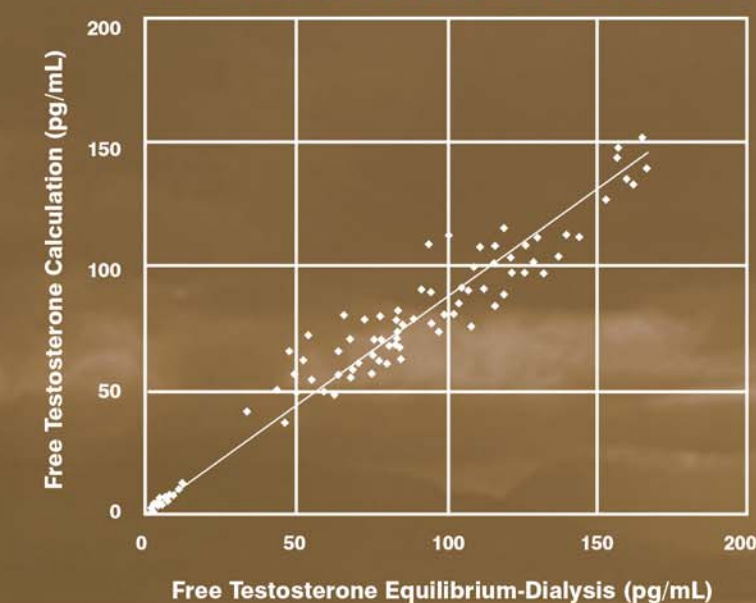
To use the Smart Hormone Management website ([www.smarthormonemanagement.com](http://www.smarthormonemanagement.com)), laboratories must register with B&C Biotech to obtain usernames and passwords to access the calculation.

*Inquire about our future development of other free and bioavailable androgen and estrogen calculations.*

## Calculation Validation

Samples comprised of adult males (n=75) and females (n=90) were tested in a routinely available equilibrium dialysis assay for the measurement of free testosterone. SHBG and albumin results for these same samples were determined, and the free testosterone concentrations were calculated. The graph below shows the correlation of the results.

### Free Testosterone Comparison



Correlation R = 0.99

Slope = 0.86

Intercept = 1.4

## Reference Ranges

### Calculated Free Testosterone

Adults  
Males 46-157pg/mL  
Females 0.6-8.7pg/mL

### Calculated Bioavailable Testosterone

Adults  
Males 108-390ng/dL  
Females 1.3-19.8ng/dL

These reference ranges should be used as guidelines. It is recommended that each laboratory establish its own reference ranges.

Interference may result from high levels of androgen or estrogen medications or clinical states.

FDA Device Number 9803050

Patent Pending