



# TECHNICAL NOTICE

## THE MEDICAL FOUNDATION

### Calculated Free Testosterone to Replace the RIA Method for Measurement of Free Testosterone

**Effective Date:** January 23, 2017

**Performing Department:** Chemistry and Immunoassays

**Clinical Significance:** Calculation of free testosterone (FT), rather than measurement by analog method, is recommended in the diagnosis and follow-up of androgen-related disorders<sup>1,2</sup>. Calculation of FT provides superior correlation with FT measured by the gold standard methodology of equilibrium dialysis.

**Method:** Starting January 23, 2017, all orders for free testosterone by RIA (Radioimmunoassay) method will be completed by using calculated free testosterone (cFT). The concentration of free testosterone is calculated, which incorporates the measured total serum testosterone, sex hormone binding globulin (SHBG) values, the average albumin concentration (4.3 g/dL) and testosterone association constants.

**Use:** Serum free testosterone is an adjunct test for the evaluation of patients with suspected abnormal serum levels of total testosterone. Current clinical guidelines recommend total testosterone as the first-line test for suspected androgen deficiency in men. Free testosterone should be ordered in cases with discrepant clinical symptoms, when total testosterone levels are consistently close to the lower limit of normal or when SHBG levels are altered. Other established uses of free testosterone include assessment of polycystic ovarian syndrome in women and androgen abnormalities in puberty<sup>2</sup>. Free testosterone evaluation is not recommended in children<sup>2</sup>. cFT levels should be interpreted with caution in patients with significant hypoalbuminemia, although the calculation works well within the albumin physiologic range (40 – 50 g/L). cFT has limited utility in pregnancy and other states of altered albumin<sup>3</sup>.

**Reference Range:** Previous and new reference intervals for free testosterone are listed below:

Free Testosterone Reference Intervals

	Previous RIA method	New (calculated method)
Adult male	8.7-54.7 pg/mL	47-244 pg/mL
Adult female	0.29-3.18 pg/mL	1-7 pg/mL

Please note the significantly higher reference values for cFT due to differences in methodology and calibration. Patient results are expected to be 7-10 fold higher compared to the previous RIA method. Comparison with the results obtained prior to January 23, 2017 will not be possible. However, it is possible to use an equation generated from our correlation study to estimate the previous free testosterone values by RIA method based on the new values from cFT.

$$\text{Free Testosterone}_{(RIA)} = (\text{cFT} + 8.01) / 8.42$$

Example: Calculated Free Testosterone = 70 pg/mL  
 $(70 + 8.01) / 8.42 = 9.26 \text{ pg/mL}$

#### SPECIMEN REQUIREMENTS AND COLLECTION:

**Collect:** Gold top (SST) or Red top (serum) tube. Mix by inverting tube 5 times.

**Processing:** Allow specimen to clot completely at room temperature.

Centrifuge to separate serum from cells.

**SST:** Submit properly centrifuged specimen in the original collection tube.

**Red top:** Transfer 1 mL serum to a plastic transport tube. (Min: 0.6 mL)

**Storage and Transport:** Refrigerated.

**Stability:** Room temperature: 48 hours

Refrigerated: 1 week

Frozen: 2 months (avoid repeated freeze/thaw cycles)

**Testing Schedule:** Monday through Friday

**Order:** Testosterone, Free Calculation and Total by ECLIA (Includes SHBG)  
Testosterone, Free Calculation by ECLIA

**Test #:** 30010

**CPT:** 84270; 84403

**Test #:** 30009

**CPT:** 84402

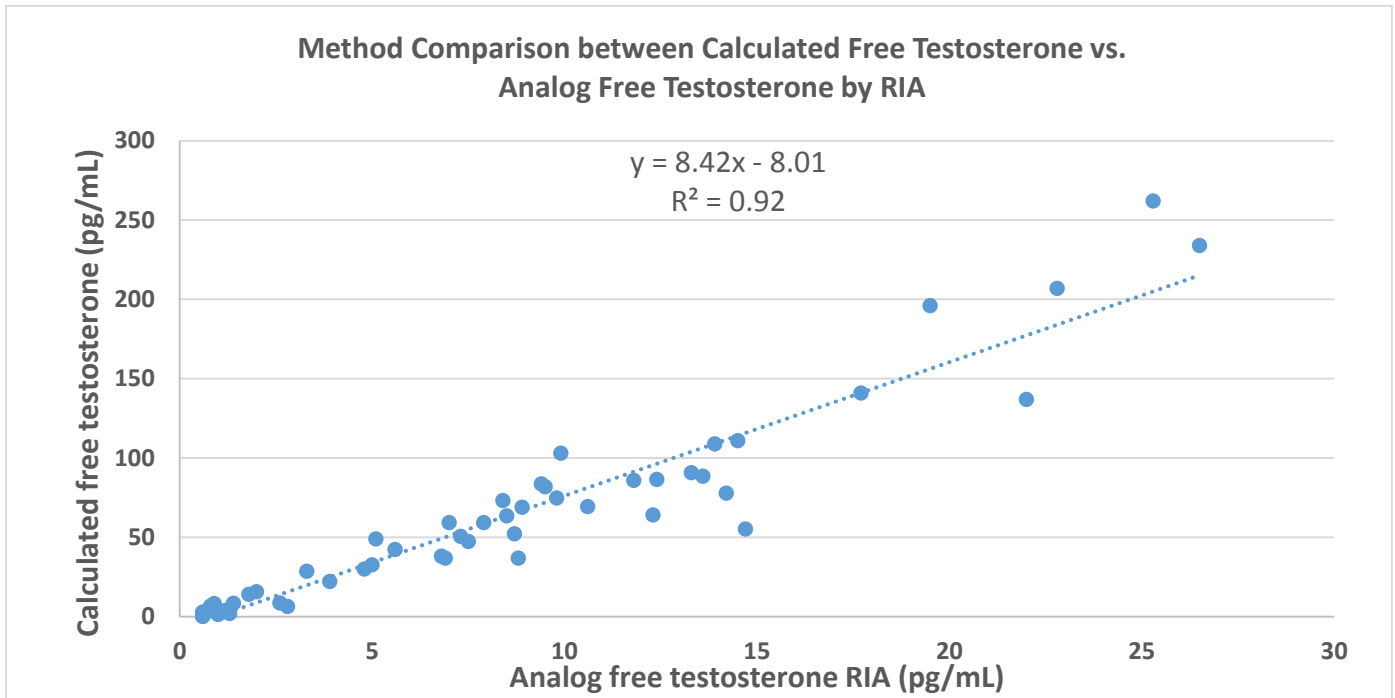
Please direct any questions, or comments regarding this notice to Paul Moorman ([pmoorman@sbfm.org](mailto:pmoorman@sbfm.org)) at extension 1415, Qing Li, Ph.D. ([QLiPh.D@sbfm.org](mailto:QLiPh.D@sbfm.org)) at extension 1584 or call The Medical Foundation, (574) 234-4176 or (800) 544-0925.

### THE MEDICAL FOUNDATION

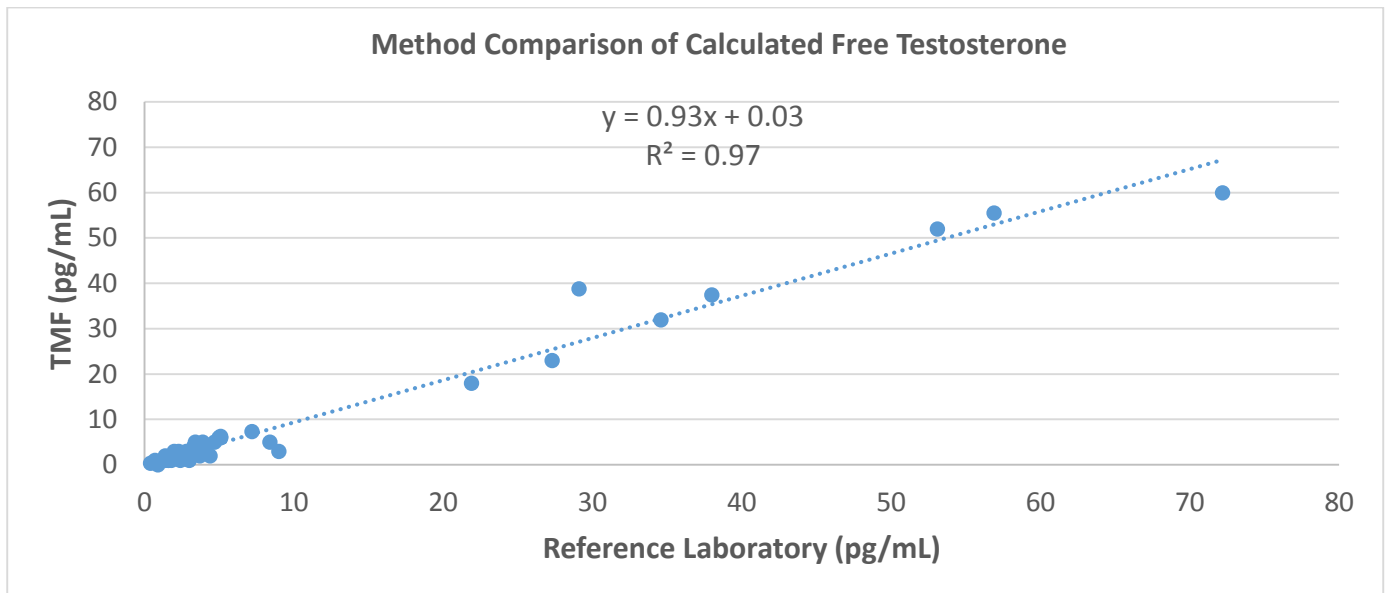
530 North Lafayette Boulevard • South Bend, Indiana 46601

(574) 234-4176 • Elkhart (574) 293-8441 • (800) 544-0925

Joyce Simpson, M.D. • Medical Director



As part of assay implementation TMF has also conducted the comparison of the calculated free testosterone measurement between TMF and a commercial reference laboratory (see the data below). The results for cFT generated from both labs correlated remarkably well.



References:

1. Bashin S, et al. *J Clin Endocrinol Metab*, 2010, 95: 2536-59.
2. Rosner W, *J Clin Endocrinol Metab*, 2007, 92: 405-13.
3. Vermeulen A, et al. *J Clin Endocrin Metab* 1999; 84: 3666-72.

**THE MEDICAL FOUNDATION**

530 North Lafayette Boulevard • South Bend, Indiana 46601  
(574) 234-4176 • Elkhart (574) 293-8441 • (800) 544-0925  
Joyce Simpson, M.D. • *Medical Director*