GENETRACKDiagnostics

Testosterone, Total and FAI

WHAT IS TESTOSTERONE?
Testosterone is the primary sex hormone in males, but it is also important in females. Testosterone is secreted from the testicles in males, and from the ovaries in females (1).

PURPOSE OF A TESTOSTERONE TEST
In males, a testosterone test may be required for:
• Determining the cause of infertility
• Evaluating a lack of sex drive or ability to get and sustain an erection
• Monitoring the effect of testosterone therapy (for males with low testosterone) and testosterone-lowering medicines (such as males being treated for advanced prostate cancer)
• Finding out the cause of osteoporosis

In females, a testosterone test may be required for:
• Determining why male characteristics are present (e.g., deep voice and excessive facial and body hair)
• Finding the cause of irregular menstrual periods

ROLES OF TESTOSTERONE
Testosterone has an important role during the life cycle of both males and females. Testosterone levels before birth are associated with sex formation (2), potentially brain masculinization during early infancy (3), and pubertal effects, including penis or clitoris enlargement, increased libido, remodelling of facial bones, acne, pubic hair, and deepening of voice (4).

In adult males, testosterone is necessary for normal sperm development, enhances muscle growth, and regulates platelet aggregation (5, 6). In females, testosterone also enhances muscle and bone growth, may modulate the physiology of vaginal tissue, and contributes to female genital sexual arousal (7).

FREE ANDROGEN INDEX (FAI)
Most testosterone (~97%) in the blood is bound to proteins. Free testosterone can be calculated from the total testosterone, SHBG, and albumin concentrations, or alternatively, the Free Androgen Index (FAI) can be calculated by:

FAI = Total Testosterone (nmol/L) x 100 / SHBG (nmol/L)

This ratio correlates well with measured values of free testosterone and is a useful measurement for identifying individuals with abnormal testosterone levels (8).

REFERENCE RANGES FOR TESTOSTERONE
Males from 18 to 39 years typically have total testosterone levels of 229 – 902 ng/dL with testosterone levels gradually decreasing with age (9). FAI levels for males are typically 20 – 120 % (10).

Testosterone levels in females are a lot lower, with normal total testosterone levels of 8 – 60 ng/dL, and FAI levels of just 0.5 – 8.7% (10).

LOW TESTOSTERONE IN MALES
Low testosterone is defined by the American Urology Association as total blood testosterone levels less than 300 ng/dL. Symptoms of low testosterone can include low sex drive, fatigue, reduced lean muscle mass, irritability, erectile dysfunction, infertility, weight gain, osteoporosis, and depression (11).

Low testosterone can occur due to conditions that males are born with, such as Klinefelter syndrome. Testosterone levels may also decline for other reasons, including testicle injury, chemotherapy, infection, autoimmune disease, malnutrition, and hormonal imbalances. Testosterone therapy is available for men with low testosterone levels, although often other changes, such as more physical exercise for overweight men, can increase testosterone levels (11).

HIGH TESTOSTERONE IN MALES
Elevated testosterone in males is not a common problem, and is most often observed in athletes who use anabolic steroids, testosterone, or related hormones to increase muscle mass and athletic performance. Elevated testosterone can cause many health complications, including low sperm counts, impotence, liver disease, acne, blood clots, aggressive behaviour, damage to heart tissue, weight gain, mood swings, excessive body hair, and sleep apnea (12).

TESTOSTERONE AND FERTILITY IN WOMEN
In healthy women, testosterone briefly increases mid menstrual cycle to coincide with ovulation and the most fertile period of the cycle. Testosterone helps to promote the development of follicles, which hold and release eggs during ovulation (13). The correct level of testosterone is important, as both too much or too little can interfere with female fertility.

The signs of reduced testosterone include low muscle mass, poor sleep, lack of energy, depression, low libido, and vaginal dryness. Excess testosterone can lead to acne, polycystic ovary syndrome, irregular menstruation, increased body hair, and low HDL (good) cholesterol.

SPECIAL INSTRUCTIONS
Avoid high doses of biotin consumption (e.g. vitamin B7 or B8, vitamin H, or coenzyme R) for at least 72 hours prior to specimen collection.

TEST PROCEDURE
Correct specimen collection and handling is required for optimal assay performance.

This test requires a blood sample from a finger prick. All supplies for sample collection are provided in this kit. First wash and dry hands. Warm hands aid in blood collection. Clean the finger prick site with the alcohol swab and allow to air dry. Use the provided lancet to puncture the skin in one quick, continuous and deliberate stroke. Wipe away the first drop of blood (as it may be contaminated with tissue fluid or skin debris). Massage finger to increase blood flow at the puncture site and hold in a position that gravity facilitates the collection of blood on the fingertip. Transfer the blood to the blood collection card or blood collection tube (microtainer).

Avoid squeezing or 'milking' the finger excessively. If blood flow stops, perform a second skin puncture on another finger if more blood is required.

Dispose of all sharps safely and return sample to the laboratory in the provided prepaid return shipping envelope.

Upon receipt at the laboratory, the blood sample is analyzed by the fully automated Alinity i 2nd Generation Testosterone and Alinity i SHBG chemiluminescent microparticle immunoassays on the Alinity ci series analyzer.

The testosterone assay measures total testosterone levels by binding to monoclonal anti-testosterone coated microparticles. The amount of testosterone in the blood sample is measured in relative light units by a chemiluminescent reaction. This assay has a precision value of <8.2 %CV.

The SHBG assay measures sex hormone binding globulin (SHBG) levels by binding to monoclonal anti-SHBG coated microparticles. The amount of SHBG in the blood sample is measured in relative light units by a chemiluminescent reaction. This assay has a precision value of <6.5 %CV.

The Free Androgen Index (FAI) is calculated by:
FAI = Total Testosterone (nmol/L) x 100 / SHBG (nmol/L)

TEST INTERPRETATION
This assay will provide accurate testosterone values for the tested specimen. This value is to be used in conjunction with other clinical and laboratory information for analyses of general health and fertility.

DISCLAIMERS/LIMITATIONS
Certain medications, (including estrogen, some pain medicines, and some seizure medicines), can influence testosterone levels. Long-term excessive alcohol consumption is associated with lower testosterone levels. Thyroid disorders can also affect SHBG levels, leading to overall changes in total testosterone.

These results should be interpreted in conjunction with other laboratory and clinical information.

Assay interference may occur in specimens from individuals routinely exposed to animals or to animal serum products. Additional clinical or diagnostic information may be required for these specimens.

Additional testing is recommended if testosterone results are inconsistent with clinical evidence.

False results may occur in specimens from individuals that have received preparations of mouse monoclonal antibodies for diagnosis or therapy. Additional clinical or diagnostic information may be required for these specimens.

This assay cannot be used for specimens from patients receiving Nandrolone treatment.

Correct specimen collection and handling is required for optimal assay performance. The assay is unaffected (≤10% interference) by hemoglobin (100 mg/dL), bilirubin (15 mg/dL), triglycerides (1000 mg/dL), biotin (30 ng/mL), and protein (12 g/dL).

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