

Detection of Testosterone in Human Serum with Roche e801

Test Name: This immunoassay is for the in vitro quantitative determination of testosterone in human serum and plasma.

Method Name: In the Elecsys TESTO assay, a TESTO specific antibody labeled with a ruthenium complex is used to determine the testosterone concentration.

Results: Technical Range: 2.50-1500 ng/dL
Reportable Range: 3.05-1340 ng/dL

Reference Ranges:

Pediatric Males and Females by age:

MALES	ng/dL
2-10	<8-31
11	<8-321
12	<8-531
13	<8-609
14	23-652
15	126-792
16-17	116-779
FEMALE	ng/dL
2-10	<8 – 80
11-15	< 8 -49
16 – 17	20 – 56

Pediatric Males and Females by Tanner Stage:

MALES	ng/dL
Tanner Stage 1	< 8 – 64
Tanner Stage 2	< 8 – 166
Tanner Stage 3	< 8 – 609
Tanner Stage 4	43-756
Tanner Stage 5	66- 841
FEMALES	ng/dL
Tanner Stage 1	< 8 – 79
Tanner Stage 2	< 8 – 45
Tanner Stage 3	< 8 – 49
Tanner Stage 4	8 – 54
Tanner Stage 5	14 – 71

Adult Male Testosterone (ng/dL)

18 -39 years	264- 916
40 – 49 years	232-928

50- 59 years	210-962
60 – 69 years	234-990
70 – 79 years	167 – 895

Adult Female Testosterone (ng/dL)

Pre-menopausal	9 -53
Post – menopausal	< 8 – 48

Clinical Significance:

Measurements of testosterone are 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 and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

The androgen testosterone (17 β hydroxyandrostene) has a molecular weight of 288 daltons. In men, testosterone is synthesized almost exclusively by the Leydig cells of the testes. The secretion of testosterone is regulated by luteinizing hormone (LH) and is subject to negative feedback via the pituitary and hypothalamus.

Testosterone promotes the development of the secondary sex characteristics in men and serves to maintain the function of the prostate and seminal vesicles. Most of the circulating testosterone is bound to carrier proteins (SHBG, sex hormone binding globulin). In women, small quantities of testosterone are formed in the ovaries. In physiological concentrations, androgens have no specific effects in women. Increased production of testosterone in women can cause virilization (depending on the increase).

The Elecsys Testosterone II assay is based on a competitive test principle using a high affinity monoclonal antibody (sheep) specifically directed against testosterone. Endogenous testosterone released from the sample by 2 bromoestradiol competes with the added testosterone derivative labeled with a ruthenium complex for the binding sites on the biotinylated antibody.

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Submission Criteria:

For specimen collection and preparation, only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

Serum

Plasma: Li-heparin and K₂-EDTA plasma

Do not use fluoride plasma

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, therefore not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Storage and Stability: 6 months at -20°C
14 days at 2-8°C
5 days at 20-25 °C

**Rejection
Criteria:**

Rejection criteria include but are not limited to:

1. Specimens containing fibrin or clots.
2. Excessive platelet clumping
3. Leaking specimens
4. Substandard mixing or collection
5. Expired or improperly stored collection tubes.
6. Improperly filled tubes based on collection tube manufacturer's guidelines.
7. Contaminated specimens (IV fluid, foreign particles, etc.)
8. Specimens not analyzed within the appropriate time frame.
9. Samples not shipped at appropriate temperature.
10. Samples without 2 proper identifiers or samples having identifiers that do not match the electronic or paper lab requisition.

Authorization:

Diagnostic testing can only be performed with approval from an authorized provider/agency.

**Turn Around
Time:**

1 day.

Instructions for Serum Specimen Submission

General Information

The detection of testosterone in human serum and plasma is performed using a Roche cobas i58 analyzer. However, serum specimens are preferred.

Specimens must be collected and stored at 20-25 °C if to be analyzed within 5 days, at 2-8°C if to be analyzed within 14 days and stored at -20°C if to be analyzed within 6 months. Please be aware that storing specimens at $\leq -70^{\circ}\text{C}$ ($\leq -94^{\circ}\text{F}$) is not permissible.

Specimens MUST be *received* at Reditus Laboratories within 5 days of collection.

Collection Instructions for Serum Specimen

1. Do not use expired collection tubes. Store collection tubes as per manufacturers recommendations. Use standard venipuncture practices for collecting samples. Filled gold top serum tubes are preferred.
2. Ensure that the patient's name, date-of-birth, and time/date of collection are recorded on the specimen tube along with the name or initials of the individual collecting the sample.
3. Complete all the demographic information on a sample requisition form through the approved electronic submission process
4. Refrigerate the specimen between 2-8°C (36-46°F) and ship or courier the specimen(s) within 48 hours.
5. The specimen(s) *must* be received at the laboratory **no later than** 48 hours *from the time of collection*.
 - a. **Avoid shipping specimens over weekends or holidays** as they may not be received at the laboratory and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.
 - b. Ensure that specimens shipped by commercial carrier are shipped with **overnight delivery**. If shipping on a Friday for Saturday delivery, ***you must include Saturday Delivery*** during shipment, or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result in specimens being rejected from testing.
6. For any questions pertaining to sample collection, storage, or shipping, please contact the Reditus Laboratories using the below contact information.

Instructions for Specimen Transport

1. **Messenger/Courier by ground transport.** Place specimen(s) into a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed biohazard bag and test requisition(s) inside the shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. The shipping container must be rigid, such as a Styrofoam cooler, and labeled with the UN 3373 Biological Substance Category B marking. Close securely.
2. **Commercial carrier by ground/air transport.** Place the specimen(s) inside a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed bag and completed test requisitions(s) inside the outer shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. Label the outer shipping container with Reditus Laboratories address listed below. Complete the return address section to include the name of the person shipping the package, business name and address, and a business phone number. The shipping container must include the UN3373 Biological Substance Category B marking.
3. *Ship specimens by overnight delivery* to the attention of Clinical Chemistry at Reditus Laboratories. This can be accomplished by use of local courier, shipping corporations or U.S. Postal Service.
 - a. **If specimens are shipped on a Friday for Saturday delivery, *you must include/indicate Saturday delivery*** during shipment, or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result

- in specimens being rejected from testing.
4. The specimen(s) must be received at the laboratory **no later than** 48 hours *from the time of collection* and 24 hours from the time of shipment. Do not ship specimens over weekends or holidays as they will not be received, and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.

NOTE: Testing may be delayed, or specimens may be considered UNSATISFACTORY if the above instructions are not followed or the requisition form is not filled out completely. If there are any questions about specimen collection, handling, or shipping please contact the Reditus Laboratories to speak with laboratory personnel.

Ship specimens by a local courier or overnight by commercial carrier to the designated laboratories indicated below.

Send to: Reditus Laboratories
200 Enterprise Drive
Pekin, IL 61554

Phone: (469) 498-0222

Website: <https://www.redituslabs.com/>