

Detection of Sex Hormone Binding Globulin in Human Serum and Plasma with Roche e801

Test Name: This immunoassay is for the in vitro quantitative determination of sex hormone-binding globulin in human serum and plasma.

Method Name: In the Elecsys SHBG assay, a sex hormone binding globulin specific antibody labeled with a ruthenium complex is used to determine the sex hormone binding globulin concentration.

Results: Technical Range: 0.8-200 nmol/L
Reportable Range: 0.908-180 nmol/L

Reference Ranges: **CHILDREN**
Males

Tanner Stages	Mean Age	Reference Interval (nmol/L)
Stage I	10.4	17-135
Stage II	11.1	21-114
Stage III	12.7	12-138
Stage IV	14.5	7.7-67
Stage V	14.2	3.9-40

Females

Tanner Stages	Mean Age	Reference Interval (nmol/L)
Stage I	10.5	16-182
Stage II	10.9	24-121
Stage III	12.5	18-87
Stage IV	14	7.7-108
Stage V	14.9	10-79

ADULTS

Males

≥18 years: 13.3-89.5 nmol/L

Females

18-46 years: 18.2-135.5 nmol/L

47-91 years, post-menopausal: 16.8-125.2 nmol/L

Clinical Significance: Sex hormone binding globulin (SHBG) is the blood transport protein for testosterone and estradiol. It is a large glycoprotein with a molecular weight of about 95 kDa and exists as a homodimer composed of two identical subunits. Each subunit contains two disulfide bridges. Planar C18 and C19 steroids with a 17 α hydroxyl group bind particularly well, whereas C19 17 ketosteroids such as dehydroepiandrosterone (DHEA) and androstendione do not bind so easily. SHBG has a high binding affinity to dihydrotestosterone (DHT), medium affinity to testosterone and estradiol, and only a low affinity to estrone, DHEA, androstendione, and estriol. SHBG binds reversibly to sexual steroids. Albumin, which exists in far higher concentrations than SHBG, also binds sexual steroids - although

with a clearly lower binding affinity (e.g. about 100 times lower for testosterone). SHBG has a half-life of about 7 days and is produced mainly by the liver. Its synthesis and secretion are regulated by estrogen. SHBG serum concentrations depend on the extent, duration, and the kind of estrogen applied, and how regulation takes place. Androgens and gestagens with androgenic residual action have the opposite effect.

In the serum SHBG mainly takes over the transportation of steroids and the reduction/regulation of the effect of androgen. Decreased SHBG serum levels are associated with conditions where elevated androgen levels are present or where the effect of androgen on its target organs is excessive. This explains the gender related differences seen between men and women, especially during puberty.

Measurement of SHBG can be an important indicator of an excessive/chronic androgenic action where androgen levels are normal, but where clinical symptoms would seem to indicate androgen in excess. SHBG is a useful supplementary parameter in the determination of androgen where a relatively high concentration of free androgen (e.g. testosterone) is suspected.

Elevated SHBG levels can be seen in elderly men and are often found in patients with hyperthyroidism and cirrhosis of the liver. SHBG levels also increase when oral contraceptives or antiepileptic drugs are taken. Pregnant women have markedly higher SHBG serum concentrations due to their increased estrogen production. Decreased SHBG concentrations are often seen with hypothyroidism, polycystic ovarian syndrome (PCOS), obesity, hirsutism, elevated androgen levels, alopecia, and acromegaly. The Elecsys SHBG assay employs two monoclonal antibodies specifically directed against human SHBG.

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: 12 months at -20°C
7 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 sex hormone binding globulin 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 7 days and stored at -20°C if to be analyzed within 12 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/>