Detection of Free PSA in Human Serum with Roche e801

Test Name: Immunoassay for the in vitro quantitative determination of free prostate-specific antigen in human serum and plasma. This immunoassay is indicated for measurement of fPSA in conjunction with the Elecsys total PSA assay to develop a ratio (% fPSA) of fPSA to tPSA.

Method Name: In the Elecsys FPSA assay an FPSA specific antibody labeled with a ruthenium complex is used to determine the free prostate specific antigen concentration.

Results: Technical Range: 0.018-50 ng/mL
Reportable Range: 0.02-44.4 ng/mL

Reference Ranges:

Free:Total PSA ratio	50-59 years	60-69 years	70 years and older
≤0.10	49%	58%	65%
0.11-0.18	27%	34%	41%
0.19-0.25	18%	24%	30%
>0.25	9%	12%	16%

Clinical Significance: This immunoassay is indicated for measurement of fPSA in conjunction with the Elecsys total PSA assay to develop a ratio (% fPSA) of fPSA to tPSA. This ratio is useful when used in conjunction with the Elecsys total PSA test as an aid in distinguishing prostate cancer from benign prostatic conditions in men aged 50 years or older who have a digital rectal examination (DRE) that is not suspicious for prostate cancer and an Elecsys total PSA value in the range 4.00 ng/mL to 10.0 ng/mL. Prostate biopsy is required for the diagnosis of prostate cancer.

Prostate-specific antigen (PSA) is a glycoprotein (molecular weight 30000-34000 daltons) having a close structural relationship to glandular kallikrein. It has the function of a serine protease.

The proteolytic activity of PSA in blood is inhibited by the irreversible formation of complexes with proteinase inhibitors such as alpha 1 antichymotrypsin, alpha 2 macroglobulin and other acute phase proteins. In addition to being present in these complexes, PSA is also present in blood in the free form but is proteolytically inactive.

PSA tests lack sufficient sensitivity and specificity to be considered ideal or absolutely diagnostic for screening or early detection because PSA is not specific for prostate cancer. PSA is organ specific, being produced primarily by prostatic secretory epithelium, but has long been known to be elevated in non malignant conditions such as benign prostatic hyperplasia

(BPH). A number of studies have found that the % free PSA was significantly lower in patients having prostate cancer than those with benign disease or normal controls. The ratio fPSA/tPSA has been demonstrated to improve the sensitivity and specificity in patients with tPSA values in the "gray zone" of 4.00 10.0 ng/mL.

An equimolar tPSA determination is the prerequisite for reliable ratios. In patients receiving therapy, particularly hormone withdrawal therapy, the fPSA/tPSA ratio cannot be utilized to differentiate prostate hyperplasia from cancer of the prostate. Combining tests from different manufacturers to determine tPSA and fPSA can produce erroneous values, since total PSA tests may be standardized by differing methods or detect free PSA to differing degrees.

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 K_2-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: 3 months days at -20°C
5 days at 2-8°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 free prostate specific antigen 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 2-8°C if to be analyzed within 5 days and stored at -20°C if to be analyzed within 3 months. Please be aware that storing specimens at ≤ -70°C (≤ -94°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/