

## Detection of Dehydroepiandrosterone Sulfate (DHEA-S) in Human Serum with Roche e801

**Test Name:** Immunoassay for the in vitro quantitative determination of dehydroepiandrosterone sulfate (DHEA-S) in human serum and plasma.

**Method Name:** The Elecsys DHEA-S assay makes use of a competition test principle using a polyclonal antibody (rabbit) specifically directed against DHEA-S. Endogenous DHEA-S in the sample competes with added DHEA-S derivative labeled with a ruthenium complex for the binding sites on the biotinylated antibody.

**Results:** Technical Range: 0.2-1000 µg/dL  
Reportable Range: 0.247-759 µg/dL

### Reference Ranges:

#### MALES

1-14 days: DHEA-S levels in newborns are very elevated at birth but will fall to prepubertal levels within a few days.

#### Tanner Stages\*

| Mean      | Age        | Reference Range µg/dL |
|-----------|------------|-----------------------|
| Stage I   | >14 days   | 11-120                |
| Stage II  | 11.5 years | 14-323                |
| Stage III | 13.6 years | 5.5-312               |
| Stage IV  | 15.1 years | 29-412                |
| Stage V   | 18.0 years | 104-468               |

\*Puberty onset (transition from Tanner stage I to Tanner stage II) occurs for boys at a median age of  $11.5 \pm 2$  years. For boys, there is no proven relationship between puberty onset and body weight or ethnic origin. Progression through Tanner stages is variable. Tanner stage V (adult) is usually reached by age 18.

18-30 years: 105-728 µg/dL

31-40 years: 57-522 µg/dL

41-50 years: 34-395 µg/dL

51-60 years: 20-299 µg/dL

61-70 years: 12-227 µg/dL

≥71 years: 6.6-162 µg/dL

#### FEMALES

1-14 days: DHEA-S levels in newborns are very elevated at birth but fall to prepubertal levels within a few days.

#### Tanner Stages\*

| Mean      | Age        | Reference Range (µg/dL) |
|-----------|------------|-------------------------|
| Stage I   | >14 days   | 16-96                   |
| Stage II  | 10.5 years | 22-184                  |
| Stage III | 11.6 years | 11-296                  |
| Stage IV  | 12.3 years | 17-343                  |
| Stage V   | 14.5 years | 57-395                  |

\*Puberty onset (transition from Tanner stage I to Tanner stage II) occurs for girls at a median age of  $10.5 \pm 2$  years. There is evidence that it may occur up to 1 year earlier in obese girls and in African American girls.

Progression through Tanner stages is variable. Tanner stage V (adult) is usually reached by age 18.

18-30 years: 83-377  $\mu\text{g/dL}$

31-40 years: 45-295  $\mu\text{g/dL}$

41-50 years: 27-240  $\mu\text{g/dL}$

51-60 years: 16-195  $\mu\text{g/dL}$

61-70 years: 9.7-159  $\mu\text{g/dL}$

$\geq 71$  years: 5.3-124  $\mu\text{g/dL}$

**Clinical Significance:**

DHEA-S is a steroid hormone which is produced from the precursor cholesterol in the zona reticularis and broad fascia of the adrenal cortex. The determination of elevated DHEA-S values is an important aid in the diagnosis of hirsutism and virilism. In addition to a differential diagnosis of hirsutism and virilism further indications for this parameter are all forms of androgenisation, hyperprolactinemia, polycystic ovarian syndrome, and the exclusion of an androgen producing tumor of the adrenal cortex. DHEA-S exhibits only a weak androgenic activity but can be metabolized to more active androgens such as androstendione and testosterone, which can indirectly cause hirsutism and virilism.

From 7 years of age onwards, an increase in DHEA-S levels is observed which then gradually after the age of 30 begins to fall again. Only elevated DHEA-S concentrations are of clinical importance; other factors which can be responsible for DHEA-S excess production are genetic enzyme defects of the adrenal cortex (adrenogenital syndrome), hyperplasia of the adrenal cortex as well as androgen producing tumors.

The rate of secretion of DHEA-S into the blood stream is only slightly more than the rate observed for DHEA. Because of the DHEA-S half-life of approximately 1 day, the DHEA-S level is however about a thousand-fold greater. DHEA-S is relatively strongly bound to albumin, only a small portion is non-protein bound, and none appears to be bound to sex hormone-binding globulin (SHBG). Due to its high concentration and low inter- and intra-day variability, DHEA-S is an excellent indicator of adrenal cortex androgen production.

Together with testosterone, DHEA-S assays represent the assay of choice for initial screening tests to determine whether androgen values are elevated in hirsutism. Approximately 84 % of the women suffering from hirsutism exhibit elevated androgen levels. The main purpose of this is to exclude the presence of androgen producing tumors (from the adrenal cortex or the ovaries). Tumor relevant values in women are those values exceeding 700  $\mu\text{g/dL}$  DHEA-S.

**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  $\text{K}_2$ -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: 365 days 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 dehydroepiandrosterone sulfate (DHEA-S) 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 365 days. 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/>