

# SALIVA TEST SPECIFICATIONS

## Dehydroepiandrosterone Sulfate

### Clinical Information

Dehydroepiandrosterone (DHEA), a hormone produced by the adrenal glands, is the precursor for the production of estrogens and testosterone, and is therefore normally present in significantly greater quantities than all the other steroid hormones. It is mostly found in the circulation in the form of its sulfate ester, DHEA sulfate (DHEA-S), which is measured in saliva in preference to free DHEA because its levels are higher and more stable. Its production is highest in the late teens to early 20s, and declines gradually with age in both men and women. Levels of DHEA-S reflect adrenal gland function. Low DHEA-S indicates adrenal insufficiency and/or androgen deficiency, and can be associated with reduced libido and general malaise. High DHEA-S levels are seen in hyperadrenal states such as congenital adrenal hyperplasia, and in polycystic ovarian syndrome; high levels in women are associated with masculinizing effects because of its local metabolism to testosterone. DHEA supplementation has been successfully used to treat adrenal insufficiency and can restore normal levels of testosterone in women with androgen deficiency, particularly as a consequence of removal of the ovaries. Because of its conversion to potent estrogens and androgens, levels should be closely monitored during supplementation to avoid excess. The saliva reference range for DHEA-S is 2– 23 ng/mL in both men and women, dependent on age.

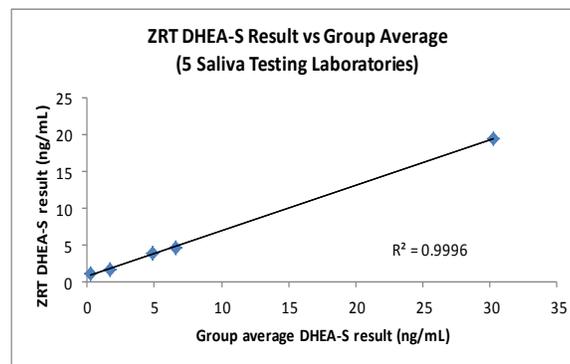
### References:

Allolio B, Arlt W, Hahner S. DHEA: why, when, and how much--DHEA replacement in adrenal insufficiency. *Ann Endocrinol (Paris)*. 2007;68:268-73.  
Baulieu EE, Thomas G, Legrain S, et al. Dehydroepiandrosterone (DHEA), DHEA sulfate, and aging: contribution of the DHEAge Study to a sociobiomedical issue. *Proc Natl Acad Sci U S A*. 2000;97:4279-84.  
Arlt W. Androgen therapy in women. *Eur J Endocrinol* 2006;154:1-11.  
Labrie F, Luu-The V, Bélanger A, et al. Is dehydroepiandrosterone a hormone? *J Endocrinol* 2005;187:169-96.

### Assay Method: ELISA

#### Accuracy

ZRT has established the first salivary proficiency testing program, which includes most of the major saliva testing laboratories in the US. Twice yearly, results from carefully selected pooled samples are compared to those from 4 other laboratories that test DHEA-S. As shown in the graph below, ZRT results compare very favorably to the consensus of all 5 saliva testing laboratories for the DHEA-S assay.



#### Precision/Reproducibility

Inter-assay precision was determined by choosing pooled saliva samples spanning the reference range for DHEA-S, and analyzing them multiple times over a 30-60 day period. Results are shown below:

Mean DHEA-S Concentration (ng/mL)	Coefficient of Variation (C.V. %)
1.0	20.0
6.0	7.6
8.1	14.3

#### Linearity

The ZRT saliva DHEA-S assay gives excellent linearity over the reportable range of 1.0-125 ng/mL. Samples giving results >125 ng/mL are diluted and re-assayed for accurate reporting. Values below 1.0 ng/mL are not sufficiently precise and are reported as <1.0 ng/mL.

#### Sensitivity

The analytical limit of detection for DHEA-S is 0.17 ng/mL.

#### Stability

Saliva samples are stable at room temperature for 30 days for DHEA-S determination, but customers are advised to mail samples as soon as possible after collection. Samples are rejected for analysis if they were not received within 30 days of collection and were not refrigerated or frozen.

#### Accreditation

ZRT Laboratory is a CLIA and New York State certified testing laboratory.