HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Hormone)		
Document:	Internal Policy and Procedure		
Title:	Analysis of DHEA-S Level		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To illustrate the necessary steps required for performing DHEA-S assay on COBAS e411 .

2. DEFINITONS:

2.1 DHEA-S is a steroid hormone which is produced from the precursor cholesterol in the zona reticularis and broad fascia of the adrenal cortex.

3. POLICY:

3.1 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 tumour of the adrenal cortex.

3.2 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.

3.3 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 tumours (from the adrenal cortex or the ovaries). Tumour relevant values in women are those values exceeding 700 µg/dL DHEA-S.

4. PROCEDURE:

4.1 **Principle:** Competition principle (for details refer to Company Leaflets of reagents).

4.2 **Sample:** Only the specimens listed below were tested and found acceptable. Serum collected using standard sampling tubes or tubes containing separating gel. Li-, Na-, NH -heparin, K3-EDTA, sodium citrate, potassium oxalate and sodium fluoride plasma. Only the specimens listed below were tested and found acceptable. Serum collected using standard sampling tubes or tubes containing separating gel. Li-, Na-, NH -heparin, K3-EDTA, sodium citrate, potassium oxalate and sodium fluoride plasma.

4.3 **Method:** See policy of loading sample on machine (Ref: Operative Manuals' of COBAS e411.

4.4 **Calculation:** The analyser automatically calculates the analytic concentration of each sample in ug/dL.

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:** Age and sex variabilities can be reviewed from DHEA-S kit leaflet.

4.7 **Limitations- interference:**

4.7.1 The assay is unaffected by icterus (bilirubin < 222 µmol/L or < 13 mg/dL), hemolysis (Hb < 0.35 mmol/L or < 0.56 g/dL), lipemia (Intralipid < 2000 mg/dL) and biotin (< 123 nmol/L or < 30 ng/mL).

4.7.2 Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

4.8 Measuring range: 0.100-1000 µg/dL:

4.8.1 Values below the lower detection limit are reported as < 0.100 µg/dL.

4.8.2 Values above the measuring range are reported as > 1000 µg/dL.

5 MATERIALS AND EQUIPMENT:

5.1 **Reagent:** For preparation see package insert

5.1.1 **M:** Streptavidin-coated microparticles (transparent cap), 1 bottle, 12 mL: Streptavidin-coated microparticles 0.72 mg/mL, preservative.

5.1.2 **R1:** Anti-DHEA-S-Ab~biotin (gray cap), 1 bottle, 9 mL: Biotinylated polyclonal anti-DHEA-S antibody (rabbit) 450 ng/mL; phosphate buffer 100 mmol/L, pH 6.8; preservative.

5.1.3 **R2:** DHEA-S~Ru(bpy) (black cap), 1 bottle, 9 mL: DHEA-S derivative (synthetic) labeled with ruthenium complex 0.32 ng/mL; phosphate buffer 100 mmol/L, pH 6.8; preservative.

5.2 **Calibration:**

5.2.1 Every Elecsys reagent set has a barcoded label containing specific information for calibration of the reagent lot. The predefined master curve is adapted to the analyzer using the relevant CalSet.

5.2.2 Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer).

5.2.3 Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

5.2.4 Renewed calibration is recommended as follows:

5.2.4.1 After 8 weeks when using the same reagent lot.

5.2.4.2 After 7 days when using the same reagent kit on the analyser.

5.2.4.3 As required: e.g. quality control findings outside the defined limits.

5.3 **Quality control:**

5.3.1 For quality control, use PreciControl Multimarker. In addition, other suitable control material can be used.

5.3.2 Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

6. RESPONSIBILITIES:

6.1 Hormone shift on charge is responsible for, running calibration and control and samples of DHEA-S

6.2 Hormone staff are responsible for running DHEA-S samples every morning

7. APPENDICES:

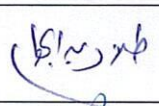
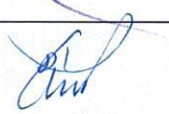
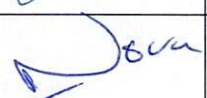
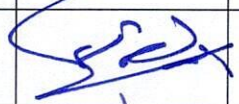
7.1 N/A

8. REFERENCES:

8.1 Operator's manual for the analyser

8.2 Company Leaflets of reagents

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Talal Abdelgawad	Clinical Pathologist		January 06, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 08, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 09, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 12, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025