HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

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

1.1 To illustrate the necessary steps required for performing Estradiol III assay on COBAS e411.

2. DEFINITONS:

2.1 Estradiol III: Estrogens are responsible for the development of the secondary female sex characteristics. Together with gestagens they control all the important female reproductive processes. The biologically most active estrogen is 17β-estradiol. This is a steroid hormone having a molecular weight of 272 daltons.

3. POLICY:

3.1 Estrogens are produced primarily in the ovary (follicle, corpus luteum), but small quantities are also formed in the testes and in the adrenal cortex. During pregnancy, estrogens are mainly formed in the placenta. In human plasma the bulk of estradiol is bound specifically to SHBG (= sex hormone binding globulin) and non-specifically to human serum albumin.

3.2 Estrogen secretion is biphasic during the menstrual cycle. The determination of estradiol is utilized clinically in the elucidation of fertility disorders in the hypothalamus-pituitary-gonad axis, gynecomastia, estrogen-producing ovarian and testicular tumors and in hyperplasia of the adrenal cortex. Further clinical indications are the monitoring of fertility therapy and determining the time of ovulation within the framework of in vitro fertilization (IVF).

4. PROCEDURE:

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

4.2 **Specimen collection and preparation:** Serum collected using standard sampling tubes or tubes containing separating gel. Li-heparin, K2-EDTA and K3-EDTA plasma. Li-heparin plasma tubes containing separating gel can be used. Stable for 1 day at 20°-25 °C, 5 days at 2°-8 °C, and 6 months at -20 ° C. Freeze only once.

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

4.4 **Calculation:** The analyzer automatically calculates the analyte concentration of each sample in µIU/mL

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:**

- 4.6.1 1–10yr Female: 6.0–27pg/Ml
- 4.6.2 1-10yr Male: 0–20pg/Ml
- 4.6.3 F Follicularphase: 12.5–166 pg/mL
- 4.6.4 Ovulatoryphase: 85.5–498pg/m
- 4.6.5 Lutealphase: 43.8–211pg/mL
- 4.6.6 Postmenopause: 5.0–54.7pg/mL18.4–201pmol/L
- 4.6.7 Pregnancy,1st trimester: 215–4300pg/mL

4.7 Limitations- interference:

4.7.1 The assay is unaffected by icterus (bilirubin ≤ 1129 µmol/L or ≤ 66 mg/dL), hemolysis (Hb ≤ 0.621 mmol/L or ≤ 1.0 g/dL), lipemia (Intralipid ≤ 1000 mg/dL) and biotin (≤ 147 nmol/L or ≤ 36 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:** (5-3000 pg/mL)

4.8.1 Values below the Limit of Detection are reported as < 5 pg/mL

4.8.2 Values above the measuring range are reported as > 3000 pg/mL

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-estradiol-Ab~biotin (gray cap), 1 bottle, 9 mL: Two biotinylated monoclonal anti-estradiol antibodies (rabbit) 2.5 ng/mL and 4.5 ng/mL; mesterolone 130 ng/mL; MESb) buffer 50 mmol/L, pH 6.0; preservative.

5.1.3 **R2:** Estradiol-peptide~Ru(bpy) (black cap), 1 bottle, 9 mL: Estradiol derivative, labelled with ruthenium complex 4.5 ng/mL; MES buffer 50 mmol/L, pH 6.0; 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).
Calibration interval may be extended based on acceptable verification of calibration by the laboratory

5.2.3 Renewed calibration is recommended as follows:

5.2.3.1 After 8 weeks when using the same reagent lot.

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

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

5.3 **Quality control:**

5.3.1 For quality control, use PreciControl Universal. 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 Estradiol III.

6.2 Hormone staff are responsible for running Estradiol III samples every morning.

7. APPENDICES:

7.1 Values above the measuring range are reported as > 3000 pg/mL.

8. REFERENCES:

8.1 Operator's manual for the analyzer

8.2 Company Leaflets of reagents

9. APPROVALS:

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