HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

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

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

2. DEFINITONS:

2.1 Like FSH, TSH and hCG, LH is a glycoprotein consisting of two subunits (α-and β-chains). This proteohormone, which consists of 121 amino acids2 and three sugar chains, has a molecular weight of 29500 daltons.3.

3. POLICY:

3.1 LH (luteinizing hormone), together with FSH (follicle stimulating hormone), belongs to the gonadotropin family. LH and FSH regulate and stimulate the growth and function of the gonads (ovaries and testes) synergistically.

3.2 LH and FSH are released in pulses from the gonadotropic cells of the anterior pituitary and pass via the bloodstream to the ovaries. Here the gonadotropins stimulate the growth and maturation of the follicle and hence the biosynthesis of estrogens and progesterones. The highest LH-concentrations occur during the mid-cycle peak and induce ovulation and formation of the corpus luteum, the principal secretion product of which is progesterone. In the Leydig cells of the testes, LH stimulates the production of testosterone.

3.3 The determination of LH in conjunction with FSH is utilized for the following indications: congenital diseases with chromosome aberrations (e.g. Turner's syndrome), polycystic ovaries (PCO), clarifying the causes of amenorrhea, menopausal syndrome, and suspected Leydig cell insufficiency.

4. PROCEDURE:

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

4.2 Specimen collection and preparation: Serum collected using standard sampling tubes. Li-, Na-, NH - heparin, K3-EDTA and sodium fluoride/potassium oxalate plasma. When sodium citrate is used, the results must be corrected by + 10 %. Stable for 14 days at 2°-8 °C, 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 analyser automatically calculates the analytic concentration of each sample in mIU/ml.

4.5 **Status**: Stat and Routine

4.6 **Reference ranges:**

- 4.6.1 Men: 1.7- 8.6
- 4.6.2 Women (Follicular phase): 2.4- 12.6 mIU/ml
- 4.6.3 Women(Ovulation phase): 14.0 95.6 mIU/ml
- 4.6.4 Women(Luteal phase): 1.0 -11.4 mIU/ml
- 4.6.5 Women(Post menopause): 7.7 -58.5 mIU/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 g/dL), lipemia (Intralipid < 1900 mg/dL) and biotin (< 205 nmol/L or < 50 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**: 0.100-200 mIU/mL

4.8.1 Values below the lower detection limit are reported as < 0.100 mIU/mL.

4.8.2 Values above the measuring range are reported as > 200 mIU/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-LH-Ab~biotin (gray cap), 1 bottle, 10 mL: Biotinylated monoclonal anti-LH antibody (mouse) 2.0 mg/L; TRIS buffer 50 mmol/L, pH 8.0; preservative.

5.1.3 **R2:** Anti-LH-Ab~Ru(bpy) (black cap), 1 bottle, 10 mL: Monoclonal anti-LH antibody (mouse) labelled with ruthenium complex 0.3 mg/L; TRIS buffer 50 mmol/L, pH 8.0; 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).

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 analyzer

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 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 LH

6.2 Hormone staff are responsible for running LH samples every morning

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 Operator's manual for the analyzer

8.2 Company Leaflets of reagents

9. APPROVALS:

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