



HEALTH HOLDING

HAFER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

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

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

2. DEFINITONS:

- 2.1 Like LH, TSH and hCG, FSH 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 daltons³.

3. POLICY:

- 3.1 FSH (follicle stimulating hormone), together with LH (luteinizing 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 FSH and LH 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 oestrogens and progesterone. 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 FSH in conjunction with LH 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, and K3-EDTA plasma. When sodium citrate is used, the values obtained are by 20 % lower as compared to serum, those for sodium fluoride/potassium oxalate are by approx. 14 % lower. 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: 1.5-12.4 mIU/ml
 - 4.6.2 Women (Follicular phase): 3.5- 12.5 mIU/ml
 - 4.6.3 Women(Ovulation phase): 4.7 -21.5 mIU/ml
 - 4.6.4 Women(Luteal phase): 1.7 -7.7 mIU/ml
 - 4.6.5 Women(Post menopause): 25.8- 134.8 mIU/ml
- 4.7 **Limitations- interference:**
 - 4.7.1 The assay is unaffected by icterus (bilirubin < 1094 μ mol/L or < 64 mg/dL), hemolysis (Hb < 0.621 mmol/L or < 1.0 g/dL), lipemia (Intralipid < 1900 mg/dL) and biotin (< 246 nmol/L or < 60 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-FSH-Ab~biotin (gray cap), 1 bottle, 10 mL: Biotinylated monoclonal anti-FSH antibody (mouse) 0.5 mg/L, MES buffer 50 mmol/L, pH 6.0; preservative.
 - 5.1.3 **R2:** Anti-FSH-Ab~Ru(bpy) (black cap), 1 bottle, 10 mL: Monoclonal anti-FSH antibody (mouse) labeled with ruthenium complex 0.8 mg/L, 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 particular 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 FSH.
- 6.2 Hormone staff are responsible for running FSH samples every morning.

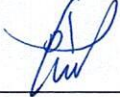


7. APPENDICES:

- 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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