HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

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

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

2. DEFINITONS:

2.1 Prolactin is synthesized in the anterior pituitary and is secreted in episodes. The hormone is made up of 198 amino acids and has a molecular weight of approximately 22-23 kD.

3. POLICY:

3.1 The target organ for prolactin is the mammary gland, the development and differentiation of which is promoted by this hormone. High concentrations of prolactin have an inhibiting action on steroidogenesis of the ovaries and on hypophyseal gonadotropin production and secretion.

3.2 The target organ for prolactin is the mammary gland, the development and differentiation of which is promoted by this hormone. High concentrations of prolactin have an inhibiting action on steroidogenesis of the ovaries and on hypophyseal gonadotropin production and secretion.

3.3 Hyperprolactinemia (in men and women) is the main cause of fertility disorders. The determination of prolactin is utilized in the diagnosis of anovular cycles, hyperprolactinaemic amenorrhea and galactorrhoea, gynecomastia and azoospermia. Prolactin is also determined when breast cancer and pituitary tumours are suspected.

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 or tubes containing separating gel. Li-heparin and K3-EDTA plasma. Stable for 14 days at 2°-8°C, 6 months at -20°C (± 5°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 Adult F:6.0–29.9 ng/mL
- 4.6.2 Adult M: 4.6–21.4ng/mL
- 4.6.3 For children reference range refer to roche reference range booklet 2008.

4.7 **Limitations- interference:**

- 4.7.1 The assay is unaffected by icterus (bilirubin < 513 µmol/L or < 30 mg/dL), hemolysis (Hb < 0.932 mmol/L or < 1.5 g/dL), lipemia (Intralipid < 1500 mg/dL) and biotin (< 164 nmol/L or < 40 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:** 0.0470-470 ng/mL

4.8.1 Values below the lower detection limit are reported as < 0.0470 ng/mL.

4.8.2 Values above the measuring range are reported as > 470 ng/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-prolactin-Ab~biotin (gray cap), 1 bottle, 10 mL: Biotinylated monoclonal anti-prolactin antibody (mouse) 0.7 mg/L; phosphate buffer 50 mmol/L, pH 7.0; preservative.

5.1.3 **R2:** Anti-prolactin-Ab~Ru(bpy) (black cap), 1 bottle, 10 mL: Monoclonal anti-prolactin antibody (mouse) labeled with ruthenium complex 0.35 mg/L; phosphate buffer 50 mmol/L, pH 7.0; 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 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 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 Prolactin.

6.2 Hormone staff are responsible for running Prolactin 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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