HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

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

1.1 To illustrate the necessary steps required for performing HCG+β assay on COBAS e411.

2. DEFINITONS:

2.1 HCG+β: human chorionic gonadotropin (hCG) is a member of the glycoprotein family and consists of 2 subunits (α- and β-chains) which are associated to form the intact hormone.

3. POLICY:

3.1 Immunoassay for the in vitro quantitative determination of the sum of human chorionic gonadotropin (hCG) plus the hCG β–subunit in human serum and plasma.

3.2 This assay is intended for use as an aid in:

- 3.2.1 Early detection and monitoring of pregnancy.
- 3.2.2 The test is also intended for the use as one component in combination with other parameters to evaluate the risk of trisomy 21 (Down syndrome). Further testing is required for diagnosis of chromosomal aberrations.
- 3.2.3 Oncology, to serve the management of patients with trophoblastic diseases.

3.3 This assay is useful in the detection and monitoring of hCG–producing tumour cells of either ovarian, placental or testicular origin.

4. PROCEDURE:

4.1 **Principle:** Sandwich principle.

4.2 **Specimen collection and preparation:** Serum collected using standard sampling tubes or tubes containing separating gel. Li-, Na-, NH -heparin, K3-EDTA, sodium citrate and sodium fluoride/potassium oxalate plasma. Stable for 3 days at 2°–8°C, 12 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 analyser automatically calculates the analyte concentration of each sample in µIU/mL.

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:** Refer to kit insert sheet.

4.7 **Limitations:** Interference:

- 4.7.1 The assay is unaffected by icterus (bilirubin < 410 µmol/L or < 24 mg/dL), haemolysis (Hb < 0.621 mmol/L or < 1.0 g/dL), lipemia (Intralipid < 1400 mg/dL) and biotin (< 327 nmol/L or < 80 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: 0.100–10000 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 repeated with machine dilution 1:100.

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-hCG-Ab~biotin (gray cap), 1 bottle, 9 mL:

5.1.2.1 Biotinylated monoclonal anti−hCG antibodies (mouse) 2.6 mg/L;

5.1.2.2 Phosphate buffer 40 mmol/L, pH 7.5; preservative.

5.1.3 R2: Anti-hCG-Ab~Ru(bpy) (black cap), 1 bottle, 10 mL:

5.1.3.1 Monoclonal anti−hCG antibody (mouse) labeled with ruthenium

5.1.3.2 Complex 4.6 mg/L; phosphate buffer 40 mmol/L, pH 6.5; 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) (L calibration), if more than 24 hours it will be RP calibration which must be repeated with another reagent pack otherwise of the same lot.

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.

5.2.5 Calibration procedure: Refer to βHCG CalSet leaflet.

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.

5.3.3 QC procedure: Refer to PreciControl Universal leaflet.

6. RESPONSIBILITIES:

6.1 Hormone shift on charge is responsible for, running calibration and control and samples of β HCG.

6.2 Hormone staff are responsible for running β HCG 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:

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