HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

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

1.1 To illustrate the necessary steps required for performing Parathyroid Hormone (PTH) assay on COBAS e411.

2. DEFINITONS:

2.1 PTH: Parathyroid hormone (PTH) is formed in the parathyroid glands and secreted into the blood stream. Intact PTH consists of a single polypeptide chain containing 84 amino acids and has a molecular weight of approx. 9500 daltons.

3. POLICY:

3.1 PTH, together with vitamin D and calcitonin, brings about mobilization of calcium and phosphate from the skeletal system and increases the uptake of calcium in the intestine and the excretion of phosphate via the kidneys. The constancy of the blood calcium level is ensured by the interaction of PTH and calcitonin.

3.2 Parathyroid gland disorders lead to elevated or depressed blood calcium levels (hyperkalaemia or hypocalcaemia) brought about by a change in the secretion of PTH.

3.3 Hyper functioning of the parathyroid glands results in an increased secretion of PTH (hyperparathyroidism). Primary causes are adenomas of the parathyroid glands. In secondary hyperparathyroidism the blood calcium level is low because of other pathological states (e.g. vitamin D deficiency).

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. K3-EDTA plasma. Because of the short half-life of PTH, it is recommended that, when serum is needed, the blood should be centrifuged immediately. *Preference should be given to K3-EDTA plasma*, as it is stable longer than serum.

4.2.1 Serum: Stable for 8 hours at 15°-25 °C, 2 days at 2°-8 °C, 6 months at -20 °C.

4.2.2 Plasma: Stable for 2 days at 15°-25 °C, 3 days at 2°-8 °C, 6 months at -20 °C.

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 pg/mL.

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:** 15-65 pg/mL

4.7 **Limitations- interference:**

4.7.1 The assay is unaffected by icterus (bilirubin < 1112 µmol/L or < 65 mg/dL), lipemia (Intralipid < 1500 mg/dL) and biotin (< 205 nmol/L or < 50 ng/mL).

4.7.2 The assay is affected by hemolysis ≥ 0.15 g/dL. Do not analyze samples that show visible signs of hemolysis.

4.7.3 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:** 1.20-5000 pg/mL

4.8.1 Values below the lower detection limit are reported as < 1.20 pg/mL.

4.8.2 Values above the measuring range are reported as > 5000 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-PTH-Ab~biotin (gray cap), 1 bottle, 7 mL: Biotinylated monoclonal anti-PTH antibody (mouse) 2.3 mg/L; phosphate buffer 100 mmol/L, pH 7.0; preservative.

5.1.3 **R2:** Anti-PTH-Ab~Ru(bpy) (black cap), 1 bottle, 7 mL: Monoclonal anti-PTH antibody (mouse) labeled with ruthenium complex 2.0 mg/L; phosphate buffer 100 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 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 Varia. 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 PTH.

6.2 Hormone staff are responsible for running PTH samples every morning.

7. APPENDICES:

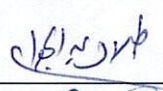
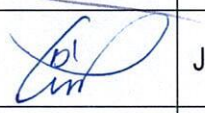
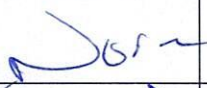
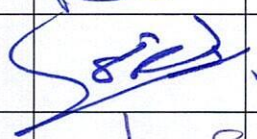
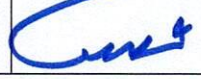
7.1 N/A

8. REFERENCES:

8.1 Operator's manual for the analyzer

8.2 Company Leaflets of reagents

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Talal Abdelgawad	Clinical Pathologist		January 06, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 08, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 09, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 12, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025