HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

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

1.1 To illustrate the necessary steps required for performing Vitamin D Assay By-COBASe411.

2. DEFINITONS:

2.1 Vitamin D is a fat-soluble steroid hormone precursor that is mainly produced in the skin by exposure to sunlight. Vitamin D is biologically inert and must undergo two successive hydroxylation in the liver and kidney to become the biologically active 1 ,25-dihydroxyvitamin D.

3. POLICY:

3.1 Vitamin D is essential for bone health. In children, severe deficiency leads to bone-malformation, known as rickets. Milder degrees of insufficiency are believed to cause reduced efficiency in the utilization of dietary calcium.
3.2 Vitamin D deficiency causes muscle weakness; in elderly, the risk of falling has been attributed to the effect of vitamin D on muscle function, Vitamin D deficiency is a common cause of secondary hyperparathyroidism.
3.3 Elevations of PTH levels, especially in elderly vitamin D deficient adults can result in osteomalacia, increased bone turnover, reduced bone mass and risk of bone fractures.
3.4 Low vitamin D (25-OH) concentrations are also associated with lower bone mineral density.
3.5 In conjunction with other clinical data, the results may be used as an aid in the assessment of bone metabolism.

4. PROCEDURE:

4.1 **Principle :** Competition principle
4.2 **Specimen collection and preparation: Serum** collected using standard sampling tubes or tubes containing separating gel. Li-heparin, K2- and K3-EDTA plasma as well as Li-heparin plasma tubes containing separating gel. Stable for 7 days at 2^0-8 ^oc, 1 month at -20 ^oc.7 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 pg/mL.
4.5 **Status:** Stat and Routine
4.6 **Reference ranges:**The preferred level for vitamin D (25-OH) by many experts is now recommended to be 30 ng/mL.
4.7 **Limitations- interference:**
4.7.1 Samples showing visible signs of haemolysis may cause interference. Haemoglobin concentrations > 2 g/L (> 0.124 mmol/L) may lead to elevated results. The assay is unaffected by icterus (bilirubin < 1129 µmol/L or < 66 mg/dL), lipemia (Intralipid < 400 mg/dL) and biotin (< 287 nmol/L or < 70 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.

4.7.3 For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings

4.8 **Measuring range:** 3.00-70.0 ng/mL

4.8.1 Values below the Limit of Detection are reported as < 3.00 ng/mL (< 7.50 nmol/L).

4.8.2 Values above the measuring range are reported as > 70.0 ng/mL (> 175 nmol/L).

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 **RI**: Anti-TSH-Ab-biotin (gray cap), 1 bottle, 14 mL: Biotinylated monoclonal anti-TSH antibody (mouse) 2.0 mg/L; phosphate buffer 100 mmol/L, pH 7.2; preservative

5.1.3 **R2**: Anti-TSH-Ab-Ru(bpy) (black cap), 1 bottle, 12 mL: Monoclonal anti-TSH antibody (mouse/human) labeled with ruthenium complex 1.2 mg/L; phosphate buffer 100 mmol/L, pH 7.2; 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 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 Preci Control 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, control and samples of total vit B12.

6.2 Hormone staff are responsible for running total vit B12 samples every morning.

7. APPENDICES:

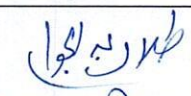
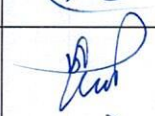
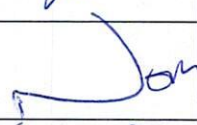
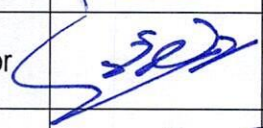
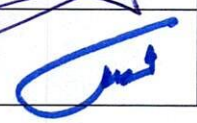
7.1 N/A

8. REFERENCES:

8.1 Operator's manual for the analyser

8.2 Company Leaflets of reagents

9. APPROVALS:

	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