HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Hormone)		
Document:	Internal Policy and Procedure		
Title:	Analysis of Free T4 Level		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To illustrate the necessary steps required for performing Free T4 (fT4) assay on COBAS e411.

2. DEFINITONS:

2.1 Free T4 (fT4): is the main thyroid hormone secreted into the bloodstream by the thyroid gland.

3. POLICY:

3.1 Thyroxine (T4) is the main thyroid hormone secreted into the bloodstream by the thyroid gland. Together with triiodothyronine (T3) it plays a vital role in regulating the body's metabolic rate, influences the cardiovascular system, growth and bone metabolism, and is important for normal development of gonadal functions and nervous system.

3.2 The determination of free T4 has the advantage of being independent of changes in the concentrations and binding properties of these binding proteins; additional determination of a binding parameter (T-uptake, TBG) is therefore unnecessary. Therefore, free T4 is a useful tool in clinical routine diagnostics for the assessment of the thyroid status. It should be measured together with TSH if thyroid disorders are suspected and is also suitable for monitoring thyrosuppressive therapy.

4. PROCEDURE:

4.1 **Principle:** Competition principle.

4.2 **Specimen collection and preparation:** Serum collected using standard sampling tubes or tubes containing separating gel. Undiluted Li-heparin, K2-EDTA and K3-EDTA plasma. Stable for 7 days at 2°-8°C, 30 days at -20 °C.6 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:** Euthyroid: 12-22 pmol/L

4.6.1 Detailed information about reference intervals in children, adolescents and pregnant women, refer to the brochure "Reference Intervals for Children and Adults", English: 04640292.

4.7 **Limitations- interference:**

4.7.1 The assay is unaffected by icterus (bilirubin < 701 µmol/L or < 41 mg/dL), hemolysis (Hb <0.621 mmol/L or < 1 g/dL), lipemia (Intralipid< 1500 mg/dL), biotin (< 102 nmol/L or < 25 ng/mL), IgG < 2 g/dL and IgM< 0.5 g/dL.

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 The presence of autoantibodies may induce high molecular weight complexes (macro-TSH) which may cause unexpected high values of TSH.8 In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

4.7.4 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:** 0.3-100 pmol/L

4.8.1 Values below the Limit of Blank are reported as< 0.3 pmol/L.

4.8.2 Values above the measuring range are reported as> 100 pmol/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 **R1:** Anti-T4-Ab~Ru (bpy) (gray cap), 1 bottle, 18 mL: Polyclonal anti-T4-antibody (sheep) labeled with ruthenium complex 75 ng/mL; phosphate buffer 100 mmol/L, pH 7.0; preservative.

5.1.3 **R2:** T4~biotin (black cap), 1 bottle, 18 mL: Biotinylated T4 2.5 ng/mL; 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 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 PreciControl Universal or PreciControl Thyro Sensitive. 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 FT4.

6.2 Hormone staff are responsible for running FT4 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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