

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

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

2. DEFINITONS:

2.1 The androgen testosterone (17 β -hydroxyandrostenone) has a molecular weight of 288 daltons. In men, testosterone is synthesized almost exclusively by the Leydig cells of the testes. The secretion of testosterone is regulated by luteinizing hormone (LH), and is subject to negative feedback via the pituitary and hypothalamus.

3. POLICY:

3.1 Testosterone promotes the development of the secondary sex characteristics in men and serves to maintain the function of the prostate and seminal vesicles.

3.2 In women, small quantities of testosterone are formed in the ovaries. In physiological concentrations, androgens have no specific effects in women. Increased production of testosterone in women can cause virilisation (depending on the increase).

3.3 The determination of testosterone in women is helpful in the diagnosis of androgenic syndrome (AGS), polycystic ovaries (Stein-Leventhal syndrome) and when an ovarian tumour, adrenal tumour, adrenal hyperplasia or ovarian insufficiency is suspected.

3.4 Testosterone is determined in men when reduced testosterone production is suspected, e.g. in hypogonadism, oestrogen therapy, chromosome aberrations (as in the Klinefelter's syndrome) and liver cirrhosis.

4. PROCEDURE:

4.1 **Principle:** Competition principle (for details refer to Company Leaflets of reagents).

4.2 **Specimen collection and preparation:** Serum collected using standard sampling tubes. Li-heparin, K2- and K3-EDTA plasma. Stable for 1 week at 2°–8 °C, 6 months at -20 °C (\pm 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 analytic concentration of each sample in ng/L.

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:**

4.6.1	Adult F:	0.06–0.82 ng/ml
4.6.2	Adult M:	2.8–8.0 ng/mL
4.6.3	13–17 yr:	0.28–11.1 ng/mL
4.6.4	7–12 yr :	0.03–0.68 ng/mL
4.6.5	1–6 yr:	0.03–0.32 ng/mL
4.6.6	<1yr:	0.12–0.21 ng/m

4.7 Limitations- interference:

- 4.7.1 The assay is unaffected by icterus (bilirubin < 513 µmol/L or < 30 mg/dL), hemolysis (Hb < 0.372 mmol/L or < 0.600 g/dL), lipemia (Intralipid < 1000 mg/dL) and biotin (< 123 nmol/L or < 30 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: 0.025–15.0 ng/mL

- 4.8.1 Values below the Limit of Detection are reported as < 0.025 ng/mL.
- 4.8.2 Values above the measuring range are reported as > 15.0 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-testosterone-Ab~biotin (grey cap), 1 bottle, 10 mL: Biotinylated monoclonal anti-testosterone antibody (sheep) 40 ng/mL; releasing reagent 2-bromoestradiol; MES buffer 50 mmol/L, pH 6.0; preservative.
- 5.1.3 **R2:** Testosterone-peptide~Ru(bpy) (black cap), 1 bottle, 9 mL: Testosterone derivative, labeled with ruthenium complex 1.5 ng/mL; MES buffer 50 mmol/L, pH 6.0; 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 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 Testosterone.
- 6.2 Hormone staff are responsible for running Testosterone samples every morning.

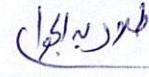
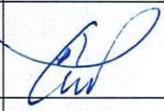
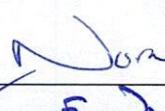
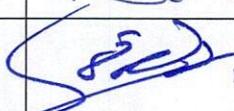
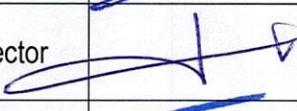
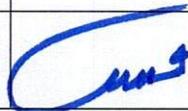
7. APPENDICES:

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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