



<b>Department:</b>	Laboratory and Blood Bank ( Hormone)		
<b>Document:</b>	Internal Policy and Procedure		
<b>Title:</b>	Analysis of Cortisol Level		
<b>Applies To:</b>	All Laboratory Staff		
<b>Preparation Date:</b>	January 06, 2025	<b>Index No:</b>	LB-IPP-097
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## 1. PURPOSE:

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

## 2. DEFINITONS:

2.1 Cortisol (hydrocortisone) is quantitatively the major glucocorticoid product of the adrenal cortex.

## 3. POLICY:

3.1 The main reason to measure cortisol is to diagnose human diseases which are caused by the overproduction of cortisol in Cushing's syndrome (CS), deficiency of adrenal steroid excretion in Addison's disease, and for therapy monitoring (e.g. dexamethasone suppression test in Cushing's syndrome and hormone replacement therapy in Addison's disease).

3.2 Cortisol plays an important role in the regulation of many essential physiological processes, including energy metabolism, maintenance of electrolyte balance and blood pressure, immunomodulation and stress responses, cell proliferation as well as cognitive functions.

3.3 The major fraction of cortisol circulates bound to plasma proteins as corticosteroid binding globulin and albumin. The biologically active free fraction comprises only 2–5 % of the total hormone concentration

3.4 Elevated serum levels can be found in stress responses, psychiatric diseases, obesity, diabetes, alcoholism and pregnancy, which may cause diagnostic problems in patients with Cushing's syndrome. Low levels of cortisol are seen in patients with rare adrenal enzyme defects and after long-lasting stress.

## 4. PROCEDURE:

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

4.2 **Sample:** Li-heparin, K2-EDTA and K3-EDTA plasma as well as plasma tubes containing separating gel.

4.2.1 Stable for 24 hours at 20°-25 °C, 4 days at 2°- 8 °C, 12 months at -20 °C. Freeze only once.

4.2.2 Saliva: Collect a saliva sample using a Salivette device.

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 mIU/ml.

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:**

4.6.1 Morning hours 6-10 a.m.: 166-507 nmol/L (6.02-18.4 µg/dL)

4.6.2 Afternoon hours 4-8 p.m.: 73.8-291 nmol/L (2.68-10.5 µg/dL)

4.7 **Limitations- interference:**

4.7.1 When performed in serum and plasma, the assay is unaffected by icterus:

4.7.1.1 Bilirubin  $\leq$  428 µmol/L or  $\leq$  25 mg/dL

4.7.1.2 Hemolysis (Hb  $\leq$  0.311 mmol/L or  $\leq$  0.5 g/dL), lipemia (Intralipid  $\leq$  1500 mg/dL), biotin ( $\leq$  123 nmol/L or  $\leq$  30 ng/mL), IgG  $\leq$  50 g/L, IgA  $\leq$  10 g/L and IgM  $\leq$  10 g/L

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:** 1.5-1750 nmol/L or 0.054-63.4 µg/dL:

- 4.8.1 Values below the Limit of Detection are reported as < 1.5 nmol/L (< 0.054 µg/dL).
- 4.8.2 Values above the measuring range are reported as > 1750 nmol/L (> 63.4 µg/dL).

**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-cortisol-Ab~biotin (gray cap), 1 bottle, 10 mL: Biotinylated monoclonal anti-cortisol antibody (ovine) 20 ng/mL; danazol 20 µg/mL; MESb) buffer 100 mmol/L, pH 6.0; preservative.
- 5.1.3 **R2:** Cortisol-peptide~Ru(bpy) (black cap), 1 bottle, 10 mL: Cortisol derivative (synthetic), labeled with ruthenium complex 20 ng/mL; danazol 20 µg/mL; MES buffer 100 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 analyser).
- 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 Cortisol Saliva. 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 Cortisol.
- 6.2 Hormone staff are responsible for running Cortisol samples every morning.

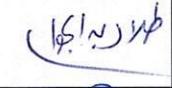
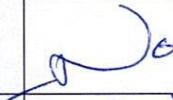
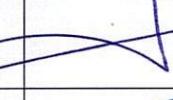
**7. APPENDICES:**

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