HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

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

1.1 To illustrate the necessary steps required for performing C-peptide assay on COBAS e411.

2. DEFINITONS:

2.1 C-peptide is a single chain 31-amino acid (AA 33-63) connecting (C) polypeptide with a molecular weight of approximately 3021 Daltons.

3. POLICY:

3.1 In the process of biosynthesis of insulin, the C-peptide is formed as a by-product together with insulin by the proteolytic cleavage of the precursor molecule proinsulin, stored in secretory granules in the Golgi complex of the pancreatic β-cells. Proinsulin in turn was cleaved from pre-proinsulin.

3.2 Measurements of C-peptide, insulin and glucose are used as an aid in the differential diagnosis of hypoglycaemia (factitious hypoglycaemia and hypoglycaemia caused by hyperinsulinism) to ensure an appropriate management and therapy of the patients. To quantify the endogenous insulin secretion, C-peptide is measured basally, after fasting and after stimulation and suppression tests. Due to high prevalence of endogenous anti-insulin antibodies C-peptide concentrations reflect the endogenous pancreatic insulin secretion more reliably in insulin-treated diabetics than the levels of insulin itself. Measurements of C-peptide may therefore be an aid in the assessment of a residual β-cell function in the early stages of type-1 diabetes mellitus and for the differential diagnosis of latent autoimmune diabetes of adults (LADA) and type-2 diabetes.

3.3 C-peptide measurements are also used to assess the success of islet transplantation and for monitoring after pancreatectomy.

3.4 Urine C-peptide is measured when a continuous assessment of β-cell function is desired or frequent blood sampling is not practical (e.g. in children). C-peptide excretion in urine has been used to assess pancreatic function in gestational diabetes, and in patients with unstable glycaemic control in insulin-dependent diabetes mellitus (IDDM).

4. PROCEDURE:

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

4.2 **Sample:** Serum collected using standard sampling tubes or tubes containing separating gel. Li-heparin and K3-EDTA plasma 24 h Urine, 1:10 prediluted with Diluent MultiAssay. Stability of the serum and 24 h urine samples: 4 hours at 15°-25 °C, 24 hours at 2°-8 °C, 30 days at -20 °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 ug/dL.

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:**

4.6.1 C-peptide in serum/plasma:1.-4.4 ng/mL

4.6.2 C-peptide in 24 h urine:17.2-181 ug/24h

4.7 **Limitations- interference:**

4.7.1 The assay is unaffected by icterus (bilirubin < 855 µmol/L or < 50 mg/dL), hemolysis (Hb < 0.186 mmol/L or < 0.3 g/dL), lipemia (Intralipid < 2000 mg/dL) and biotin (< 246 nmol/L or < 60 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:** 0.010-40.0 ng/mL.

4.8.1 Values below the lower detection limit are reported as (< 0.010 ng/mL).

4.8.2 Values above the measuring range are reported as (> 40.0 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-C-peptide-Ab~biotin (gray cap), 1 bottle, 9 mL: Biotinylated monoclonal anti-C-peptide antibody (mouse) 1 mg/L, phosphate buffer 50 mmol/L, pH 6.0; preservative

5.1.3 **R2:** Anti-C-peptide-Ab~Ru(bpy) (black cap), 1 bottle, 9 mL: Monoclonal anti-C-peptide antibody (mouse) labeled with ruthenium complex 0.4 mg/L; phosphate 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 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 Multimarker. 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 C-Peptide.

6.2 Hormone staff are responsible for running C-Peptide 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:

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