HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

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

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

2. DEFINITONS:

2.1 Insulin is a 51-residue peptide hormone with a molecular weight of 5808 Da. It is secreted by the β-cells of the islets of Langerhans in the pancreas, and passes into circulation via the portal vein and the liver. Insulin is generally released in pulses.

3. POLICY:

3.1 Serum insulin determinations are mainly performed on patients with symptoms of hypoglycaemia and may be useful in classifying the different types of diabetes.

3.2 A disorder in insulin metabolism can have a significant impact on several metabolic processes. Low concentrations of free, biologically active insulin can lead to the development of diabetes mellitus. Possible causes of this include destruction of the β-cells (type I diabetes), reduced activity of insulin or reduced pancreatic synthesis (type II), circulating antibodies to insulin, delayed release of insulin or the absence (or inadequacy) of insulin receptors.

3.3 Conversely, autonomous, non-regulated insulin secretion is generally the cause of hypoglycaemia. This condition is brought about by inhibition of gluconeogenesis, e.g. because of severe hepatic or renal failure, islet cell adenoma, or carcinoma. Hypoglycaemia can, however, also be facilitated intentionally or unintentionally (factitious hypoglycaemia).

4. PROCEDURE:

4.1 **Principle :** Sandwich 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 24 hours at 2°-8 °C, 6 months 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 µU/mL or pmol/L.

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:** 2.6-24.9 µU/mL (17.8-173 pmol/L)

4.7 **Limitations- interference:**

4.7.1 The assay is unaffected by icterus (bilirubin < 1539 µmol/L or < 90 mg/dL), lipemia (Intralipid < 1800 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:** 0.2-1000 µU/mL or 1.39-6945 pmol/L:

4.8.1 Values below the lower detection limit are reported as < 0.2 µU/mL (< 1.39 pmol/L).

4.8.2 Values above the measuring range are reported as > 1000 µU/mL (> 6945 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-insulin-Ab~biotin (gray cap), 1 bottle, 10 mL: Biotinylated monoclonal anti-insulin antibody (mouse) 1 mg/L; MESb) buffer 50 mmol/L, pH 6.0; preservative.

5.1.3 **R2:** Anti-insulin-Ab~Ru(bpy) (black cap), 1 bottle, 10 mL: Monoclonal anti-insulin antibody (mouse) labeled with ruthenium complex 1.75 mg/L; 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 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 or 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 Insulin

6.2 Hormone staff are responsible for running Insulin samples every morning

7. APPENDICES:

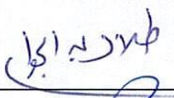
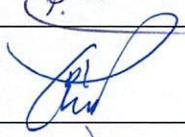
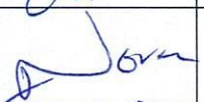
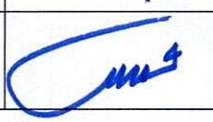
7.1 N/A

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