

<b>Department:</b>	Laboratory and Blood Bank ( Hormone)		
<b>Document:</b>	Internal Policy and Procedure		
<b>Title:</b>	Analysis of Ferritin Level		
<b>Applies To:</b>	All Laboratory Staff		
<b>Preparation Date:</b>	January 06, 2025	<b>Index No:</b>	LB-IPP-101
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## 1. PURPOSE:

1.1 To illustrate the necessary steps required for performing Ferritin Assay By-COBASe411.

## 2. DEFINITONS:

2.1 Ferritin is a macromolecule with a molecular weight of at least 440 kDa (depending on the iron content) and consists of a protein shell (apo ferritin) of 24 subunits and an iron core containing an average of approximately 2500 Fe<sup>3+</sup> ions (in liver and spleen ferritin).

## 3. POLICY:

3.1 The determination of ferritin is a suitable method for ascertaining the iron metabolism situation. Determination of ferritin at the beginning of therapy provides a representative measure of the body's iron reserves. A storage deficiency in the reticulo-endothelial system (RES) can be detected at a very early stage.

3.2 Clinically, a threshold value of 20 µg/L (ng/mL) has proved useful in the detection of prelatent iron deficiency. This value provides a reliable indication of exhaustion of the iron reserves that can be mobilized for haemoglobin synthesis. Latent iron deficiency is defined as a fall below the 12 µg/L (ng/mL) ferritin threshold. These two values necessitate no further laboratory elucidation, even when the blood picture is still morphologically normal. If the depressed ferritin level is accompanied by hypochromic, microcytic anaemia, then manifest iron deficiency is present.

3.3 When the ferritin level is elevated and the possibility of a distribution disorder can be ruled out, this is a manifestation of iron overloading in the body. 400 µg/L (ng/mL) ferritin is used as the threshold value. Elevated ferritin values are also encountered with the following tumors: acute leukaemia, Hodgkin's disease and carcinoma of the lung, colon, liver and prostate. The determination of ferritin has proved to be of value in liver metastasis. Studies indicate that 76 % of all patients with liver metastasis have ferritin values above 400 µg/L (ng/mL). Reasons for the elevated values could be cell necrosis, blocked erythropoiesis or increased synthesis in tumor tissue.

## 4. PROCEDURE:

4.1 **Principle:** Competition principle

4.2 **Specimen collection and preparation:** Serum collected using standard sampling tubes or tubes containing separating gel. Li-heparin, Na-heparin, K3-EDTA and sodium citrate plasma. Serum, Li-heparin, Na-heparin and K3-EDTA plasma is stable for 24 hours at 20°-25 °C, 7 days at 2°-8 °C, 12 months at -20 °C. The samples may be frozen twice.

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 ng/mL

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:**

- 4.6.1 Men from 20-60 years: 30-400 (ng/mL)
- 4.6.2 Women from 17-60 years: 13-150 (ng/mL)

#### 4.7 Limitations- interference:

- 4.7.1 The assay is unaffected by icterus (bilirubin < 1112 µmol/L or < 65 mg/dL), hemolysis (Hb < 0.31 mmol/L or < 0.5 g/dL), lipemia (Intralipid < 3300 mg/dL) and biotin (< 205 nmol/L or < 50 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.
- 4.7.3 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: (0.500-2000 (ng/mL):

- 4.8.1 Values below the lower detection limit are reported as < 0.500 (ng/mL).
- 4.8.2 Values above the measuring range are reported as > 2000 (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-Ferritin-Ab~biotin (gray cap), 1 bottle, 10 mL: Biotinylated monoclonal anti-ferritin antibody (mouse) 3.0 mg/L; phosphate buffer 100 mmol/L, pH 7.2; preservative.
- 5.1.3 **R2:** Anti-ferritin-Ab~Ru(bpy) (black cap), 1 bottle, 10 mL: Monoclonal anti-ferritin antibody (mouse) labeled with ruthenium complex 6.0 mg/L; phosphate buffer 100 mmol/L, pH 7.2; 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 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 Tumor Marker or PreciControl varia. 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 Ferritin
- 6.2 Hormone staff are responsible for running Ferritin samples every morning

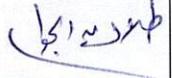
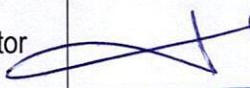
### 7. APPENDICES:

- 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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