**FERRITIN**

Quantitative determination of Ferritin (FER) in human serum by turbidimetric immunoassay.

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<th>Cat.No.</th>
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<tbody>
<tr>
<td>BLT20015</td>
<td>FERR</td>
<td>1 x 24 ml Buffer 1 x 8 ml Latex</td>
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*Important note: R1 and R2 are lot dependent and not interchangeable.*

**Diagnostic Implications**

The plasma Ferritin concentration declines very early in the development of iron deficiency. On the other hand, a large number of chronic diseases result in increased serum Ferritin concentrations. These diseases include chronic infections, chronic inflammatory disorders such as rheumatoid arthritis or renal disease, Gaucher’s disease, and numerous types of malignancies, especially lymphomas, leukaemias, breast cancer and neuroblastoma. Increase in plasma Ferritin concentration also occurs in viral hepatitis or following toxic liver injury because of release of Ferritin from damaged liver cells. Plasma Ferritin concentration is also increased with increases of iron stores, as seen in patients with hemosiderosis or hemochromatosis. Besides the use of Ferritin as an iron metabolism parameter, Ferritin as also gained importance as a tumour marker for therapeutic drug monitoring and follow-up.

**Method**

Measurement of antigen/latex-antibody reaction by the end-point method.

**Reagents Provided**

- **Buffer**
  - Saline (9 g/l)
  - Hepes buffer
  - Sodium azide (< 0.1%).

- **Latex**
  - Solution of suspended latex microparticles sensitized with rabbit IgG anti-human ferritin.

**Preparation and Stability of Reagents**

- **Reagent Preparation**
  - Liquid reagents, ready to use.

- **Stability and Storage**
  - The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

**Sample collection**

Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours. If stored for a longer period, the sample should be frozen.

**General assay Procedure**

Application sheets for automated systems on clinical chemistry analyzers or manual procedures are available upon request.

- **Wavelength 600 nm**

  - **Sample, Control or calibrator**: 20 µl
  - Add Reagent 1 150 µl
  - Mix, incubate for 2 minutes, then add Reagent 2 50 µl
  - Mix and read absorbance, incubate and read absorbance after 5 minutes.

**Reference Values**

- **Men**: 20 - 300 ng/ml
- **Woman**: 15 - 200 ng/ml

  This range is given for orientation only. Each Laboratory should establish his own reference values.

**Performances**

The performance characteristics for the Ferritin reagents were measured on a clinical chemistry analyzer (Selectra Pro M) according to the procedure R1: 150 µl and R2: 50 µl.

- **Measuring Range**: 0 – 500 ng/ml
- **LDD**: 5 ng/ml
- **Hook effect**: No risk.

**Accuracy**

- **Control**: 85.2 (72.4 – 98.0)
- **Assigned**: 92.1
- **Measured**: 224 (190 – 258)
- **SIEMENS**: 87.7 (70.2 – 105.2)

**Comparison with turbidimetry, external ferritin reagents:**

- **y = 0.9261x + 15.596**
- **r = 0.9868**

**Stability at 2 - 8°C**: at least 16 months after production.

**Precautions and warnings**

1. *In vitro* diagnostic use only.
2. Reagents of the kit are not classified as dangerous.
3. Sodium azide has been reported to form lead or copper azide in laboratory plumbing, which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
4. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

**Specifications**

- **Monospecific**
- **Interferences**: No interference for Heparin (50 mg/dl), Na Cl (1000 mg/dl), Triglyceride (2500 mg/dl), Bilirubin (30 mg/dl), EDTA (5 mg/ml)

**Limitations**: None
References

SYMBOLS:
The following symbols are used in the labeling of ERBA kits:

- **REF** Catalogue No
- **CE Mark** - Device comply with the Directive 98/79/EC
- **LOT** Batch Code
- **IVD** In Vitro Diagnostics
- **Expire Date**
- **Consult Instruction for Use**
- **Manufactured by**
- **Storage temperature**
- **CONT** Content