

### Detection of Ferritin in Human Serum with Roche e801

**Test Name:** This immunoassay is for the in vitro quantitative determination of ferritin (FERR) in human serum and plasma.

**Method Name:** The Elecsys FERR assay makes use of a sandwich principle using a monoclonal antibody specifically directed against FERR. Endogenous FERR in the sample, a biotinylated monoclonal ferritin-specific antibody, and a monoclonal ferritin-specific antibody labeled with a ruthenium complex form a sandwich complex.

**Results:** Technical Range: 0.5-2000 ng/mL  
Reportable Range: 2.36-1584 ng/mL

#### Reference Ranges:

Male Age	Ferritin ng/mL
0-5 months	13-273
6-12 months	12-95
1-5 years	12-64
6-11 years	16-77
12-19 years	16-124
≥ 20 years	30-400

Female Age	Ferritin ng/mL
0-5 months	12-219
6-12 months	12-110
1-5 years	12-71
6-11 years	15-79
12-19 years	15-77
≥ 20 years	13-150

**Clinical Significance:**

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

Ferritin tends to form oligomers, and when it is present in excess in the cells of the storage organs there is a tendency for condensation to semicrystalline hemosiderin to occur in the lysosomes.

At least 20 isoferritins can be distinguished with the aid of isoelectric focusing. This microheterogeneity is due to differences in the contents of the acidic H and weakly basic L subunits. The basic isoferritins are responsible for the long term iron storage function, and are found mainly in the liver, spleen, and bone marrow.

Acidic isoferritins are found mainly in the myocardium, placenta, and tumor tissue. They have a lower iron content and presumably function as intermediaries for the transfer of iron in various syntheses.

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.

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 hemoglobin 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, microcytal anemia, then manifest iron deficiency is present.

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 leukemia, 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.

**Submission Criteria:**

For specimen collection and preparation, only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

Serum

Plasma: Li-heparin and K<sub>2</sub>-EDTA plasma

Do not use fluoride plasma

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, therefore not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Storage and Stability: 12 months at -20°C  
7 days at 2-8°C  
48 hours at 20-25 °C

**Rejection Criteria:**

Rejection criteria include but are not limited to:

1. Specimens containing fibrin or clots.
2. Excessive platelet clumping
3. Leaking specimens
4. Substandard mixing or collection
5. Expired or improperly stored collection tubes.
6. Improperly filled tubes based on collection tube manufacturer's guidelines.
7. Contaminated specimens (IV fluid, foreign particles, etc.)
8. Specimens not analyzed within the appropriate time frame.
9. Samples not shipped at appropriate temperature.
10. Samples without 2 proper identifiers or samples having identifiers that do not match the electronic or paper lab requisition.

**Authorization:**

Diagnostic testing can only be performed with approval from an authorized provider/agency.

**Turn Around Time:**

1 day.

## Instructions for Serum Specimen Submission

### General Information

The detection of ferritin in human serum and plasma is performed using a Roche cobas i58 analyzer. However, serum specimens are preferred.

Specimens must be collected and stored at 20-25 °C if to be analyzed within 48 hours, at 2-8°C if to be analyzed within 7 days and stored at -20°C if to be analyzed within 12 months. Please be aware that storing specimens at  $\leq -70^{\circ}\text{C}$  ( $\leq -94^{\circ}\text{F}$ ) is not permissible.

**Specimens MUST be received at Reditus Laboratories within 48 hours of collection.**

### Collection Instructions for Serum Specimen

1. Do not use expired collection tubes. Store collection tubes as per manufacturers recommendations. Use standard venipuncture practices for collecting samples. Filled gold top serum tubes are preferred.
2. Ensure that the patient's name, date-of-birth, and time/date of collection are recorded on the specimen tube along with the name or initials of the individual collecting the sample.
3. Complete all the demographic information on a sample requisition form through the approved electronic submission process
4. Refrigerate the specimen between 2-8°C (36-46°F) and ship or courier the specimen(s) within 48 hours.
5. The specimen(s) *must* be received at the laboratory **no later than** 48 hours *from the time of collection*.
  - a. **Avoid shipping specimens over weekends or holidays** as they may not be received at the laboratory and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.
  - b. Ensure that specimens shipped by commercial carrier are shipped with **overnight delivery**. If shipping on a Friday for Saturday delivery, ***you must include Saturday Delivery*** during shipment, or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result in specimens being rejected from testing.
6. For any questions pertaining to sample collection, storage, or shipping, please contact the Reditus Laboratories using the below contact information.

### Instructions for Specimen Transport

1. **Messenger/Courier by ground transport.** Place specimen(s) into a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed biohazard bag and test requisition(s) inside the shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. The shipping container must be rigid, such as a Styrofoam cooler, and labeled with the UN 3373 Biological Substance Category B marking. Close securely.
2. **Commercial carrier by ground/air transport.** Place the specimen(s) inside a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed bag and completed test requisitions(s) inside the outer shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. Label the outer shipping container with Reditus Laboratories address listed below. Complete the return address section to include the name of the person shipping the package, business name and address, and a business phone number. The shipping container must include the UN3373 Biological Substance Category B marking.
3. *Ship specimens by overnight delivery* to the attention of Clinical Chemistry at Reditus Laboratories. This can be accomplished by use of local courier, shipping corporations or U.S. Postal Service.
  - a. **If specimens are shipped on a Friday for Saturday delivery, you must include/indicate Saturday delivery** during shipment, or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result

- in specimens being rejected from testing.
4. The specimen(s) must be received at the laboratory **no later than** 48 hours *from the time of collection* and 24 hours from the time of shipment. Do not ship specimens over weekends or holidays as they will not be received, and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.

**NOTE:** Testing may be delayed, or specimens may be considered UNSATISFACTORY if the above instructions are not followed or the requisition form is not filled out completely. If there are any questions about specimen collection, handling, or shipping please contact the Reditus Laboratories to speak with laboratory personnel.

Ship specimens by a local courier or overnight by commercial carrier to the designated laboratories indicated below.

**Send to:** Reditus Laboratories  
200 Enterprise Drive  
Pekin, IL 61554

**Phone:** (469) 498-0222

**Website:** <https://www.redituslabs.com/>