FER-F

[Intended Use]

The FER-F is an in vitro assay for the quantitative determination of Ferritin in serum or plasma.

[Summary and explanation of the test]

Ferritin is a 450 kDa protein consisting of 24 subunits that stores iron and releases it in a controlled fashion. The ferritin levels measured have a direct correlation with the total amount of iron stored in the body including cases of anemia of chronic disease. So, the measurement of Ferritin in serum is useful in determining changes in body iron storage. If the ferritin level is low, there is a risk for lack of iron, which could lead to anemia. If ferritin is high there is iron in excess. it may be early stage of idiopathic hemochromatosis. Ferritin levels in serum have also been used to evaluate clinical conditions not related to iron storage, including inflammation, chronic liver disease, and malignancy.

[Principle of method]

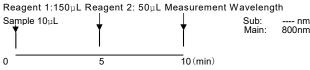
When a latex reagent is made to react with a specimen, the Ferritin in the specimen and anti-human Ferritin mouse monoclonal antibody-sensitized latex in the latex reagent produce a specific antigen-antibody reaction, resulting in turbidity.

As the degree of turbidity is in proportion to the concentration of Ferritin in a specimen, the turbidity is measured optically to determine the concentration of Ferritin in a specimen.

[Reagent preparation]

Reagent 1 : Use Reagent 1 as supplied. Reagent 2 : Use Reagent 2 as supplied.

[Procedure]



Temperature: 37 degree C

This is the standard procedure. Instrument applications are available upon request.

[Precautions on procedure]

- (1) Specimen
 - (a) Use serum or plasma as a specimen. It is recommended to measure Ferritin immediately after collection.
 - (b) Ascorbic acid, bilirubin and hemoglobin do not have a significant effect on the measurement.
- (2) Interfering substances

The anticoagulants used (heparin, citrate, EDTA, and sodium fluoride) hardly affect the measured values under normal use.

[Expected values]

Male : 15 – 270 ng/mL Female : 8 – 143 ng/mL

[Performance characteristics]

(1) Sensitivity

Absorbance change of a sterile saline sample is 0.02 or less.

Absorbance change of a 150ngm/L Ferritin sample is 0.04 or more.

(2) Specificity

Obtained values of control serum samples with known amount of Ferritin fall within plus minus 10%.

(3) Precision

Within-run CV of 5 repeated assays is 10% or less.

(4) Measurable range

 5° 1000 ng/mL Ferritin (In the case of using the standard procedure) .

(5) Correlation

Correlation coefficient: r=0.999 (n=90) Regression equation: y= 0.998x +5.647 y= FER-F, x= Company A

[Primary Standard]

In-house standard material.

[Warning and precautions]

- (1) Be careful about the handling of serum, etc., which involve the risk of infection with HBV, HCV, HIV, etc.
- (2) After opening the reagent, it is not recommended to store it for a long period of time. When the opened reagent is stored, cap the bottle and keep it at the specified temperature.
- (3) Before determining, reagents should be mixed thoroughly.
- (4) Do not use the reagents described above for any purpose other than described herein.
- (5) When concentration of a sample exceeds measurement range, dilute the sample with a saline solution.
- (6) Do not use mixed reagent from different lots.
- (7) Some specimens may not allow correct measurement because of unspecific turbidity that occurred during measurement. If measurement results are questionable, presence or absence of unspecific turbidity should be confirmed by the time course for the reaction or by a dilution test.
- (8) Use an optional Ferritin Calibrator for the calibration. It should be used according to the manufacturer's instructions.
- (9) Avoid contact with eyes and skin. If contacted, flush eyes or rinse skin with a large amount of water. If irritation, persists, consult a physician.
- (10) Sodium azide, which is contained in the reagent as an antiseptic, combines with heavy metals, such as copper and lead, and forms an azide. Heavy metal azides easily explode when given a shock in dryness. After drainage, they should be flushed with a sufficient amount of water so that they are cleared away from the water pipe.
- (11) Clinical diagnosis should be made synthetically based on clinical symptoms and examination results, etc.

[Package, Storage and Expiry]

| Product | Package | Storage | Expiry |
|------------|-------------|-------------|--------|
| Reagent 1 | 60 mL | 2-10degreeC | 1 year |
| Reagent 2 | 20 mL | 2-10degreeC | 1 year |
| Calib. Set | 1mL×6Levels | 2-10degreeC | 1 year |

[Reference]

References

1) In-house data

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