FERRITIN - TURBILATEX

IMMUNOPAK

(Latex Immunoturbidimetric Assay)

Last update 09-2020

Ref. IM-FER.079, R1 - 2x20 ml
R2 - 2x10ml

INTENDED USE

Ferritin Reagent is a latex Immunoturbidimetric assay intended for *in vitro* quantitative detection of Ferritin in human serum on automated clinical chemistry analyzers.

DIAGNOSTIC SIGNIFICANCE

In clinic, the determination of blood Ferritin is a good marker to check the iron stored in human body. It indicates the lack of iron in human body and the status of iron treatment. Alkalinity Ferritin is associated with long-term iron storage in the liver, spleen, and bone marrow; Acidic Ferritin is mainly present in myocardium and placenta, and is related to myocardial diseases. The increased ferritin could be caused by cell necrosis and blocked erythropoiesis.

PRINCIPLE

The ferritin in the sample and the corresponding antibody in the reagent are combined in the solution to form an antigen antibody complex immediately and form a certain turbidity. The turbidity is directly proportional to the antigen content in the presence of a certain amount of antibody. The content of ferritin in unknown samples was calculated by comparing with the same treated calibration solution.

PRESENTATION

All reagents to be stored at 2-8^{0}C	No. of Bottles
	2 x 30 ml
• 1 - Ferritin Turbilatex (Diluent)	2 x 20 ml
• 2 - Ferritin Turbilatex (Latex)	2 x 10 ml
• Ferritin Calibrator (Value stated on vial label)	4 x 0.5 ml/Set

FINAL REAGENT COMPOSITION

Active Ingredients	Concentration
• Aminoacetic acid buffer NaCl	pH 8.3 100mmol/L
• Aminoacetic acid buffer Latex particles coated with anti-ferritin antibody	pH 7.3 >0.15%
• NaCl	100mmol/L

PRECAUTION

1. The results are only for clinical reference. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment reactions; The reagent is only for in vitro diagnosis use, not oral administration;
2. To detect the same sample, the result may be different from different manufacturers;
3. The reagent shall be sealed and stored according to the specified method after unsealing.
4. The test tube and other instruments that have contacted the test sample shall be disposed according to the treatment method of medical waste.
5. Different batches of reagents cannot be mixed. When changing the batch number of reagents, please re calibrate!
6. Please refer to the corresponding label for the target value and range of different batches of calibrators and quality control products.

REAGENT STORAGE AND STABILITY

The reagents are in liquid form and ready to use.

The reagents shall be stored at 2-8℃. Do not freeze. The reagents are stable when stored as instructed until the expiration date on the label. The on-board stability shall be 30 days.

Ferritin calibrator shall be stored at 2-8℃. It shall be stable for 12 months when stored properly. The on-board stability is stable up to 4 weeks when stored at 2-8℃.

SPECIMEN COLLECTION

1. Fresh serum without hemolysis.
2. The samples shall be stored at 4℃ for 7 days, or - 20℃ for 4 weeks.
3. No significant interference was affected:
   Bilirubin ⩽ 85mg/dL,
   Hemoglobin ⩽ 300mg/dL,
   Triglyceride ⩽ 1000mg/dL.

CALIBRATION

Multi-point calibration is adopted. The calibrator set which offered are recommended and ready to use. If you use other manufacturer's calibrator, please verify by yourself. Please do re-calibration if the reagent lot number change, quality control drift, instrument maintenance or important parts replacement.

TEST PROCEDURE

Sample Volume	7 µL
Reagent 1 (R1)	140 µL
Mix Sample and R1 well and incubate for 5 minutes at 37℃, then add:	
Reagent 2 (R2)	70 µL
Mix well and incubate for another 5 minutes and read the absorbance.	
Main wavelength	570 nm
Test method	Endpoint
Reaction direction	Increase

CALCULATIONS

$$\text{Concentration} = \frac{\Delta A_{sample}}{\Delta A_{calibrator}} \times \text{Calibrator value}$$

NORMAL VALUE

Male and female (> 50 ages): 30-400ng/ml
Female (⩽50 ages): 15-150ng/ml

EXPLANATIONS OF TESTING RESULT

Human error, sample processing, deviation of analytical instrument and so on can affect the measurement results; when individual samples deviate from the expected value too far, it needs to be re measured.

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LIMITATIONS OF TEST

The determination of ferritin (FER) is only one of the indicators for clinicians to diagnose patients. Clinicians should make a comprehensive judgment according to patients' physical symptoms, medical history, other diagnostic items and diagnostic methods.

PERFORMANCE CHARACTERISTICS

1. **Appearance:**
   R1: Colorless clarifying liquid;
   R2: Milky white liquid;
   FER Calibrator: White to yellowish liquid;
   When testing at 37 ℃, 570nm wavelength and 1cm optical path, the blank absorbance of the reagent is ≤2.

2. **Linearity:**
   In the linear range of 10-500 ng/ml, the linear correlation coefficient R ≥0.990. In the range of [10, 50] ng/ml, the linear absolute deviation shall be≤±10.0ng/ml; In the range of (50, 500) ng/ml, the linear relative deviation shall be ≤±10%.

3. **Precision:** CV<10%;

4. **Inter-batch deviation:** <10%;

5. **Accuracy:**
   The measured value shall be fallen within the range of quality control target value.

6. **Analytical sensitivity**
   When testing 10ng/ml ferritin, 0.01≤△A≤0.04

REFERENCES

1. Yingwu Ye, Yusan Wang, National Clinical Laboratory Procedures, 3rd edition, P195.
2. Xiuming Zhang, Mordern Clinical Biochemical Laboratory Science, P596-602

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