FERRITIN - TURBILATEX

IMMUNOPAK

(Latex Turbidimetric Test)

Last update 08-2023

Ref. IM-FER.079, 2x30 ml

INTENDED USE

Reagent kit for *in vitro* quantitative detection of Ferritin in human serum on semi-automated & fully 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	**Pack Size 2 x 30 ml** No. of Bottles
• Ferritin Turbilatex (R1 Diluent)	2 x 20 ml
• Ferritin Turbilatex (R2 Latex)	2 x 10 ml
• Ferritin Turbilatex 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.

PREPARATION OF WORKING REAGENT

The reagents are in liquid form and ready to use.

REAGENT STORAGE AND STABILITY

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.

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.

PROCEDURE FOR SEMI AUTOMATED ANALYZER

REACTION PARAMETERS

- Type of Reaction : End Point (Increase)
- Wavelength : 570 nm
- Flowcell Temperature : 37°C
- Incubation : 5 min + 5 min at 37°C
- Calibration : Multi point calibration
- Cali. Concentration : Value stated on vial label
- Sample volume : 20 µl
- Reagent volume R1 : 400 µl
- Reagent volume R2 : 200 µl
- Light Path : 1.0 cm
- Zero setting with : Reagent blank

TEST PROCEDURE

Pipette into test tubes	Blank	Calibrator	Test
Reagent (R1) (µl)	400	400	400
Calibrator (µl)	-	20	-
Sample (µl)	-	-	20

Mix and Incubate for 5 min at 37^{0}C than add,

Reagent (R2) (µl)	200	200	200

Mix well and incubate for five minutes at 37°C and Read absorbance of test and calibrator against reagent blank at 570 nm.

PROCEDURE FOR FULLY AUTO ANALYZER

REACTION PARAMETERS

- Type of Reaction : End Point (Increase)
- Wavelength : 570 nm
- Flowcell Temperature : 37°C
- Incubation : 5 min + 5 min at 37°C
- Calibration : Multi point calibration
- Cali. Concentration : Value stated on vial label
- Sample volume : 7 µl
- Reagent volume R1 : 140 µl
- Reagent volume R2 : 70 µl
- Light Path : 1.0 cm
- Zero setting with : Reagent blank

FERRITIN - TURBILATEX

(Latex Turbidimetric Test)

IMMUNOPAK

Last update 08-2023

TEST PROCEDURE

Pipette into test tubes	Blank	Calibrator	Test
Calibrator (µl)	-	7	-
Sample (µl)	-	-	7
Reagent (R1) (µl)	140	140	140

Mix well and incubate for five minutes at 37°C then add,

Reagent (R2) (µl)	70	70	70

Mix well and incubate for five minutes at 37°C and Read absorbance of test and calibrator against reagent blank at 570 nm.

TEST RESULTS

Ferritin levels are determined using the prepared calibration curve.

LIMITATIONS FOR INTERFERENCE

No significant interference was affected:
Bilirubin ⩽ 85mg/dL,
Hemoglobin ⩽ 300mg/dL,
Triglyceride ⩽ 1000mg/dL.

NORMAL VALUE

Male: 20-300 ng/ml
Female: 10-120 ng/ml

NOTE

1. 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.
2. 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 10-750 ng/ml, the linear correlation coefficient R ⩾0.990. In the range of [10, 750] ng/ml, the linear absolute deviation shall be⩽±10.0ng/ml; In the range of (50, 750) 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 10 ng/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

Regd. Office.3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com Ph: +91·265·2281631
Email: mail@reckondiagnostics.com
An ISO 13485:2016 & GMP Certified Company

RECKON DIAGNOSTICS P. LTD.
THE TEST OF CONFIDENCE - SINCE 1989