Ferritin - Turbidimetric

Turbilatex Method

1x50ml

Intended Use:

Ferritin test reagent /kit is a medical device intended for the estimation of Ferritin in serum or plasma.

Clinical Significance

Ferritin is the major iron storage compound in the body and is considered one of the most reliable indicators of iron status of patients. A clinical evaluation of serum ferritin is an index of iron stores. Whereas low serum concentrations of ferritin are always indicative of an iron deficiency, elevated concentrations can occur for variety of reasons. Thus, although elevated concentrations often indicate an excessive iron intake, they are also caused by liver disease, chronic inflammation and malignancies. Pregnant women, blood donors, hemodialysis patients, adolescents and children are groups particularly at risk. Plasma ferritin is also increased in patients with hemosiderosis or hemochromatosis.

Principle

The latex particles coated with anti human ferritin are agglutinated when they react with samples that contain ferritin. The latex particles agglutination is proportional to the concentration of the ferritin in the sample and can bemeasured by Turbidimetry

Reagents

Diluent (R1)	Glycine buffer, 20 mmol/L, pH 8.5
Latex (R2)	Latex particles coated with polyclonal anti- human ferritin antibodies, pH 8.2
Ferritin - CAL	Calibrator Human ferritin. Ferritin concentration is stated on the label vial and it is trazable to the *3rd International Reference Material for Ferritin, 94/572 WHO (NIBSC).*

Precautions

The reagents contain sodium azide 0.95 g/L. Avoid any contact with skin or mucous.

The reagents from human donors have been given negative results to anti-HIV 1/2, HBsAg and anti-HCV. Handle cautiously is recommended

Reagent Preparation

R1 Ready to use.

R2 Ready to use, shake the vial before use.

CAL Ready to use.

Calibration Curve:

Prepare dilutions of the Calibrator using NaCl 9 g/L as diluent. Multiply the concentration of the Calibrator by the corresponding factor indicated in the table below to obtain the ferritin concentration of each point of the curve.

Dilution	1	2	3	4	5
Ferritin-CAL (µL)	--	25	50	75	100
NaCl 9 g/L (µL)	100	75	50	25	--
Factor	0.0	0.25	0.5	0.75	1.0

Storage And Stability

The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use the reagents after the expiration date.

Reagent deterioration: :

Presence of particles, turbidity and increment of blank reagent.

Materials required

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC with a 650 ± 20 nm filter

Specimen and Stability

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC. Samples with presence of fibrin should be centrifuged before testing. Hemolyzed or contaminated samples are not suitable for testing.

Assay Procedure

1.Bring the working reagent and the photometer (cuvette holder) to 37ºC.

2. Assay conditions:

Wavelength: . . . . . 650 nm

Temperature: 37ºC

Cuvette light path: . . . . . .1 cm

3. Adjust the instrument to zero with distilled water.

4. Pipette into a cuvette:

Diluent R1	800
Calibrator or sample (µL)	100
Latex R2	200

5. Mix well and record the absorbance inmediatelly (A_1) and after 480 Seconds (A_2) of the reagent R2 addition.

Application sheets for automated systems are available on request.

Calculations

$$\frac{(A_2\text{-}A_1)_{sample}}{(A_2\text{-}A_1)_{calibrator}} \times \text{Calibrator concentration} = \mu g/L$$

Calculate the absorbance difference (A_2-A_1) of each point of the calibration curve and plot the values obtained against the ferritin concentration of each calibrator dilution. Ferritin concentration in the sample is calculated by interpolation of its (A_2-A_1) in the calibration curve.

Quality Control

Control sera are recommended to monitor the performance of manual and automated assay procedures. It is recommended to use Plasma Protein Control N-I (ref:3915010) and N-II (ref: 3915015).

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

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Reference Values

Children: 7 – 140 µg/L
Men: 20 – 250 µg/L
Women:20 – 200µg/L
Each laboratory should establish its own reference range.

Performance Characteristics

Linearity limit: Up to 300 ug/L, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again.

Detection limit: Values less than 3 µg/L may give non-reproducible results.

Prozone effect: No prozone effect was detected upon 4000 µg/L

Sensitivity: 2.07 mA / µg/L

Precision:

	Intra assay(n=10)		Inter assay(n=10)	
Mean(IU/mL)	65	178	65	178
CV	3.56	1.87	5.16	2.9

Accuracy: Results obtained with this reagents did not show systematic differences when compared with commercial reagents of similar characteristics. Studies of comparison are available on request

Interferences: Bilirubin (20 mg/dL), hemoglobin (10 g/L) and rheumatoid factors (600 IU/mL), do not interfere. Lipemia interferes. Other substances may interfere[8].

SYSTEM PARAMETERS

Mode	:	Two Point/Fixed time
Reaction	:	Ascending
Wavelength	:	650nm (600 – 650 nm)
Blank with	:	Distilled water
Sample Volume	:	100 µL
Reagent Volume	:	1000 µL
Delay Time	:	10 (Sec)
Read Time	:	480 (Sec)
Calibrator	:	stated on the vial
Normal range	:	20-250 µg/L
Linearity limit	:	Up to 300 µg/L
Unit	:	µg/L

Notes

1. Calibrator dilutions in plastic tubes should be avoided.Ferritin antigen may coat to the walls of plastic tubes.

2. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meets the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.

3. The linearity limit depends on the sample/reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

4. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

Only for invitro use in Clinical laboratory (IVD)

Literature

1. Newman DJ, Henneberry H, Price CP. *Ann Clin Biochem* 29: 122-42 (1992).
2. Bernard A, Lauwerys R. *J Immunol Methods.* 71:141-147 (1984).
3. Wiedermann, Jonetz-Mentzel. *Eur J Clin Chem Clin Biochem* 31: 453 - 457 (1993).
4. Worwood M. *Blood Rewiews.* 4 : 259 - 269 (1990).
5. Lipschitz D, Cook JD, Finch CA. *The New England J of Med* 290:
6. 1213-1216 (1974).
7. Mazza J, Barr RM, McDonald JWD. *Can Med Assoc J* 119: 884-886(1978).
8. Tietz Textbook of Clinical Chemistry, 3rd Ed. Burtis CA, Ashwood ER.
9. WB Saunders Co., (1999).
10. Young DS. *Effects of drugs on clinical laboratory tests*. 3th ed. AACC Press (1997).

For *in vitro* Diagnostic use only.