Ferritin-turbilatex

Latex turbidimetry

CE

Determination of Ferritin in human serum or plasma.
Store at 2-8 °C

REF: KFER-T46B1 / KFER-T46B2

Summary:

Serum ferritin concentration usually reflects body iron stores and is considered one of the most reliable indicators of iron status of patients 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.

Principle:

Ferritin-turbilatex is a quantitative turbidimetric test for the measurement of ferritin in human serum or plasma.
Latex particles coated with specific anti-human ferritin are agglutinated when mixed with samples containing ferritin. The agglutination causes an absorbance change, dependent upon the ferritin contents of the sample that can be quantified by comparison from a calibrator of known ferritin concentration.

Composition:

R1 (diluent): Tris buffer - 20 mmol/L, pH 8,2. Preservative
R1 (Latex): Latex particles coated with rabbit IgG anti-human ferritin, pH, 8,2. Preservative.
FERR-CAL: Calibrator. Ferritin concentration is stated on the vial.

Precautions:

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

Calibration:

Use Ferritin Calibrator.
The sensitivity of the assay and the target value of the calibrator have been standardized against the 3rd International Standard of Ferritin (94/572, 2008 WHO).
The calibration is stable for at least 1 month.
Recalibrate when control results are out of specified values, when using different lot of reagent and when the instrument is adjusted.

Calibration curve:
Prepare the following dilutions of the FERR Calibrator using NaCl 9 g/L. To obtain the concentration of each dilution, multiply using the dilution factor shown in the next table:

Calibrator dilution	1	2	3	4	5	6
Calibrator FERR (µL) NaCl 9 g/L (µL)	- 400	25 375	50 350	100 300	200 200	400 -
Dilution Factor	0	1/16	1/8	1/4	1/2	1

Preparation:

Ferritin Calibrator: Reconstitute (→) with 3,0 mL of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.

Storage and stability:

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Reagents should not be left inside the analyzer after use, they must be stored refrigerated at 2-8°C. Latex may sediment. Mix reagents gently before use. Do not use reagents over the expiration date.
Do not freeze; frozen Latex or Diluent could change the functionality of the test.
Reagent deterioration: Presence of particles and turbidity.

Samples:

Fresh serum. Stable 7 days at 2-8°C or 3 months at –20°C.
The samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

Equipment:

- Thermostatic bath at 37°C.
- Spectrophotometer or photometer thermostatable at 37°C with a 540 nm filter.

Procedure:

1. Bring the reagents and the photometer (cuvette holder) to 37°C.

2. Assay conditions:
Wavelength: . . . . . 540 nm (530-550)
Cuvette: . . . . . .1 cm. light path
Temperature . . . . . .37°C

3. Adjust the instrument to zero with distilled water.

4. Pipette into a cuvette:
Diluent R1: 800 µL
Latex R2: 200 µL
Calibrator or sample: 90 µL
5. Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.

Calculations:

Calculate the absorbance difference (A2-A1) 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 (A2-A1) in the calibration curve.

Quality control:

All clinical laboratories should establish an Internal Quality Control program. Check instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At pre-established intervals following the Q.C. Laboratory recommandations.

Reference values:

Men: 30 – 220 µg/L.
Women: 20 – 110 µg/L.
Each laboratory should establish its own reference range.

Performance characteristics:

Measuring range:
Up to 600 µg/L. Samples with higher values should be diluted 1/5 in NaCl 9 g/L and retested. The upper linearity limit increases as the sample volume and the sensitivity decrease.

Detection limit:
5,04 µg/L.

Quantification limit:
Values under 6,6 µg/L may give non-reproducible results.

Prozone effect:
No prozone effect was detected at least up to 9000 µg/L.

Precision:
According to the EP5-A2 standards (CLSI), the reagent has been tested for 20 days, measuring each level per duplicate twice a day (n=80):

	Intra-assay (n=80)			Total (n=80)		
Mean (µg/L)	33.4	114.5	289.8	33.4	114.5	289.8
SD	1.7	1.4	2.4	2.1	3.4	7.5
%CV	5.1	1.2	0.8	6.3	2.9	2.6

Method comparison:
The reagent was compared to another commercially available Ferritin reagent by testing 144 samples (male and female), with concentrations between 6,97 and 730 ug/L. The coefficient of correlation (r) and the equation (y) were:
r = 0,988
y = 0,96x + 1,15
Performance characteristics depend on the analyzer used.

Interferences:

Bilirubin (40 mg/dL), hemoglobin (5 g/L), y and rheumatoid factor (750 UI/mL), do not interfere. Lipids (≥ 2,5 g/L) do interfere. Other substances may interfere.

Notes:

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

References:

1. Knovich MA et al., Blood Rev. 2009 23(3):95-104.
2. Mazza J et al. Can Med Assoc J 1978; 119: 884-886
3. Rodriguez Perez J et al. Revista Clinica Española 1980: 156 (1): 39-43
4. Milman N et al. Eur J Haematol 1994: 53: 16-20.
5. Young DS. Effects of drugs on clinical laboratory test, 5th ed. AACC Press, 1999.

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