FERRITIN TURBILATEX

IVD CE

Latex Turbidimetry

PRODUCT CODE
TL004

INTENDED USE
Ferritin Turbilatex is a quantitative turbidimetric test for the quantitative determination of ferritin in human serum or plasma.

CLINICAL SIGNIFICANCE
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
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.

REAGENTS COMPOSITION
REAGENT 1 (DILUENT) Tris Buffer 20 mmol/L, pH 8,2. Preservative.

REAGENT 2 (LATEX) Latex particles coated with rabbit IgG anti-human ferritin, pH, 8,2. Preservative.

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.

PREPARATION
Reagent 1 & 2 are ready to use.
Calibrator: Reconstitute with 3.0 mL of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.

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.

STORAGE AND STABILITY
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Reagents should not be left inside the analyzer after use, they must be stored refrigerated at 2-8ºC. 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 (R1, R2) and turbidity (R1).

ADDITIONAL EQUIPMENT
Thermostatic path 37º C
Spectrophotometer or Photometer Thermostable at 37º C with a 540 nm filter.

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

PROCEDURE
1. Bring the reagents and the photometer (cuvette holder) to 37ºC.
2. Assay conditions:
   Wavelength: 540 nm (530-550)
   Temperature: 37ºC
   Cuvette ligth path: 1 cm
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 5 minutes (A2) ofthe sample addition.

Calculation
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 CONTROLS
Control Sera are recommended to monitor the performance of manual and automated assay procedures.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

EXPECTED 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 asthe sample volume and the sensitivity decrease.
Detection limit: 5,04 µg/L.
Quantification limit: Values under 6,6 µg/L may give non-reproducibleresults.
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) was 0,988, and the equation 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 mayinterfere [5].

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

SYMBOL ON LABELS

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Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFRENCES

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.