Audit Diagnostics

CE

FERR-TURBI

Turbilatex Ferritin

Latex Turbidimetry

Quantitative determination of Ferritin

IVD

Store at 2 - 8ºC.

RECOMMENDED USE

Turbidimetric immunoassay for the quantitative determination of ferritin in human serum or plasma.

PRINCIPLE OF THE METHOD

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.

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.

REAGENTS

Diluent (R1)	Tris Buffer 20 mmol/L, pH 8,2. Preservative.
Latex (R2)	Anti-human ferritin antibody coated latex particles, pH, 8,2. Preservative.
FERR-CAL	Calibrator. Ferritin concentration is stated on the vial.
Opcional	Ferritin Control.

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

Ferritin Calibrator: Reconstitute (→) with 3.0 mL of distilled water. Mix gently and incubate at room temperature for about 10 minutes before testing.

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). Recalibrate when control results are out of specified values; when using a 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
Calibrator FERR (µL)	--	33,3	66,6	100
NaCl 9 g/L (µL)	100	66,6	33,3	--
Dilution Factor	0	1/3	2/3	1,0

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. Do not use reagents over the expiration date.

Reagent deterioration: Presence of particles and turbidity.

Do not freeze; frozen Latex or Diluent could change the functionality of the test.

ADDITIONAL EQUIPMENT

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC 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 (A_1) and after 5 minutes (A_2) of the sample addition.

Audit Diagnostics has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

CALCULATIONS

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

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) 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 may interfere [5].

NOTE

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

BIBLIOGRAPHY

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