GENESIS

Instructions For Use

Ferritin Turbilatex (9+1) (Turbidimetric Method)

Cat no.	size
6104 101	50 TEST
6104 102	100 TEST
6104 103	200 TEST

INTENDED USE
Ferritin Turbi Latex Reagent is intended for the in vitro Quantitative diagnostic 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

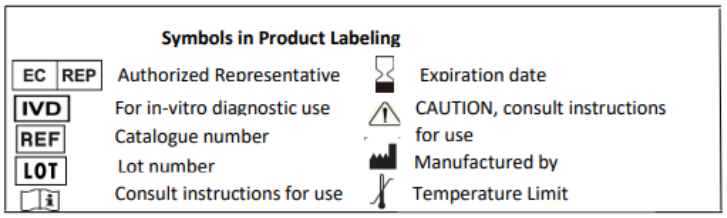
Reagent(R1)	Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.95 g/L
Reagent(R2)	Latex particles coated with anti-human ferritin, pH 8.2. Preservative
FERR-CAL	Ferritin Calibrator concentration is stated on the vial label. Ferritin control

PRECAUTIONS
Components from human origin have been tested and found to be negative for the presence of HBs Ag, 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). Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted
Calibration curve: Prepare the following FERR calibrator dilutions in physiological saline. To obtain the concentration of each dilution, multiply using the dilution factor To obtain the concentration of each dilution, multiply using the dilution factor shown in the next table: As EX:-

Calibrator NO.	1	2	3	4	5
Calibrator concentration	0	65	130	260	520
Dilution method	Saline	25 µl cal + 175 µl saline	50 µl cal + 150 µl saline	100 µl cal + 100 µl saline	calibrator
Test sample	45 µl	45 µl	45 µl	45 µl	45 µl

PREPARATION
Ferritin Calibrator: Reconstitute (→) with 3.0 mL of distilled water. Mix gently and incubate at room temperature for about 10 minutes before testing.
Reconstituted Calibrator: Stable **1** month at 2-8ºC or **3** months at–20ºC



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

ADDITIONAL EQUIPMENT
-Thermostatic water bath at 37ºC.
-Spectrophotometer or photometer able to read at 540 nm.

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

PROCEDURE
1. Bring the working reagent and the photometer (cuvette holder) to 37ºC.
2. Assay conditions:
   Mode : FIXED TIME
   Wavelength: 540nm (530-550)
   Temperature: 37ºC
   Cuvette light path: 1 cm
   Delay time: 5 sec
   Measuring time: 300 sec
3. Adjust the instrument to zero with distilled water.
4. Pipette into cuvette:

(R1) Diluent (µL)	450
(R2) Latex (µL)	50
Calibrator or Sample (µL)	45

5. Mix and read the absorbance (A1) after **5 sec** and after **5 minutes** read the absorbance (A2).

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.

(Optional) one point linear Calibration and using ferritin table conversion to get nonlinear value.

QUALITY CONTROL
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.

REFERENCE VALUES
Men: 30 – 220 µg/L **Children (6 months -15 years) 7-150 µg/L**
Women: 20 – 110 µg/L
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Linearity limit: Up to 600 µg/L. Samples with higher values should be diluted **1/3** with physiological saline and retested. The upper linearity limit increases as the sample volume and the sensitivity decrease.

Detection limit: 5.04 µg/L

Quantification limit: Values below 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= 20)			Inter-assay (n= 20)		
Mean (µg/L)	35.0	115	290	35	115	290
SD	1.5	1.7	2.0	2.0	3.0	7.0
CV (%)	4.3	1.5	0.68	5.7	2.6	2.4

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 (10 mg/dL), hemoglobin (5 g/L), and rheumatoid factors (750 IU/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.

BIBLIOGRAPHY

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