

Quantitative determination of Ferritin

IVD

Store at 2 - 8°C.

RECOMMENDED USE

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

PRINCIPLE OF THE METHOD

Ferritin-turbilatem 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. Sodium azide 0,95 g/L.
Latex (R2)	Anti-human ferritin antibody coated latex particles, pH, 8.2. sodium azide 0,95 g/L.
FERR-CAL	Calibrator. Ferritin concentration is stated on the vial.
Opcional	Ref: 1107044 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 Reference 1107042.

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

- Laboratory equipment
- Spintech 240 analyzer.

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 hemolyzed or lipemic samples.

SPINTECH 240 APPLICATION

Item Name FERR			
DATA INFORMATION		CALIBRATION	
Units	ug/L	TYPE	Spline
Decimals	0		
ANALYSIS		STANDARD	
Type	END	#1	0,0625 x Cal. Val
		#2	0,125 x Cal. Val
W.Length 1	546	#3	0,250 x Cal. Val.
		#4	0,50 x Cal. Val
		#5	1,00 x Cal. Val
		#6	
Method		NORMAL RANGE	
		LOW	HIGH
CORR		SERUM	MALE
SLOPE			FEMALE
1.000 x +		URINE	
INTER			
0			
Item Name FERR			
ASPIRATION		DATA PROCESS	
KIND	Single	READ	ABSORBANCE LIMIT
	✓ Double	START	LOW
		END	-3.000
VOLUME**		MAIN	HIGH
SAMPLE	18 μL	51	52
REAGENT 1	160 μL	SUB	33
REAGENT 2	40 μL	34	
			ENDPOINT LIMIT 3
			LINEAR CHECK (%)
Third Mix		FACTOR	
R1 Blank	✓ OF	Blank Correction	1.000
	✓ Water		
	ON		
	R1-B		
MONITOR		PROZONE CHECK	
0 LEVEL POINT	1	START	END
SPAN	3.000	LIMIT (%)	
		FIRST	
		SECOND	✓ Low High
		THIRD	✓ Low High

*** Modify reagents and sample volumes according to the range accepted but keeping always the mentioned ratio.*

Blank parameter must be performed in order to get good results in CALIB screen from main menu. This parameter calibration is stable for 30 days

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. It should be used the SPINREACT Ferritin Control (Ref.: 1107044).

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.

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

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.

PACKAGING

Ref: TK1107140

Cont.

R1. Diluent: 2 x 24 mL

R2. Latex: 1 x 12 mL

FERR-CAL: 1 x 3 mL