Ferritin-Turbilatex

INTENDED USE

Vitro Ferritin -Turbilatex is a quantitative turbidimetric test for the measurement of Ferritin in human serum or plasma on both manual and automated systems.

METHOD

Highly sensitive immunoturbidimetric assay.

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.

ASSAY 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.

REFERENCE VALUES

Newborn	25 - 200	µg/L
≤ 1 month	200 - 600	µg/L
2 - 5 months	50 - 200	µg/L
6 months – 15 years	7 - 142	µg/L
Men	30 - 220	µg/L
Women	20 - 110	µg/L

Each laboratory should establish its own reference range.

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 label.

Preparation of Calibrator

Use Ferritin Calibrator.

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

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.

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).
Re-calibrate 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	¼	½	1

Storage & 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.

FERR Calibrator: Stable for 1 month at 2-8ºC or 3 months at –20ºC.
Do not freeze; frozen Latex or Diluent could change the functionality of the test

SPECIMEN

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 hemolyzed or lipemic samples.

PROCEDURE

Wavelength: 540 nm (530-550)
Temperature: 37ºC
Cuvette light path: 1 cm
Zero adjustment against distilled water.

Pipette into a cuvette:

Diluent R1	400 µl
Latex R2	100 µl
Calibrator or sample	45 µl

Mix and read the absorbance immediately (A1) and after 5 minutes (A2) of the sample addition.

CALCULATION

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

It is recommended that controls (normal and abnormal) be included in:

- Each set of assays, or
- At least once a shift, or
- When a new bottle of reagent is used, or
- After preventive maintenance is performed or a clinical component is replaced.

Commercially available control material with established ferritin values may be routinely used for quality control.
Failure to obtain the proper range of values in the assay of control material may indicate:

- Reagent deterioration,
- Instrument malfunction, or
- Procedure errors.

The following corrective actions are recommended in such situations:

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results on fresh control material still remain outside the limits, then repeat the test with fresh reagent.
- If results are still out of control, contact Vitro Technical Services.

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.
Detection 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.

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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):

EP5	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.

INTERFERING SUBSTANCES

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

NOTES

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However, handle the material as if infectious.
3. Reagent contains 0.1% Sodium azide as a preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures.
5. Shake the Vitro FERRITIN latex reagent well before use to disperse the latex particles uniformly and improve test readability.

BIBLIOGRAPHY

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SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
	Batch code (Lot #)
	Catalog number
	Temperature limitation
	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

REF	SIZE
70401	100 TEST

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ISO 13485:2016 CE

EC REP **Medical Device Safety Services**
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