TECO DIAGNOSTICS
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FERRITIN
TC MATRIX-240/480

INTENDED USE
The test is applied for the quantitative determination of Ferritin in serum.

TEST SUMMARY AND PROCEDURE [1, 2, 3, 4, 5]
Ferritin is the major iron storage compound in the body. It consists of a protein shell enclosing a core of a variable amount of iron. Ferritin is present at particularly high concentrations in liver, bone marrow and spleen.

The plasma ferritin is in equilibrium with body stores and variations in the quantity of iron in the storage compartment are reflected in plasma ferritin concentration.

Serum ferritin concentration decreases very early in the development of iron deficiency, and it serves as a very sensitive indicator of iron deficiency. On the other hand, a large number of chronic concentrations, plasma ferritin is also increased in patients with hemosiderosis.

Serum ferritin causes agglutination of latex particles coated with anti-human ferritin antibodies. The agglutination of the latex particles is proportional to the ferritin concentration and can be measured turbidimetrically.

Clinical diagnosis should not be made only with the findings of test results, integration of the laboratory data should be used in clinical diagnosis as well.

TEST PARAMETERS
Method :Turbidimetric
Wavelength : 540 ± 20 nm
Linearity : 500 µg/L

REAGENT COMPONENTS
Reagent 1:

Glycine buffer	≤ 185 mmol/L
Sodium chloride	≤ 125 mmol/L
Sodium azide	≤ 1.00 g/L
pH	8.2

Reagent 2:
Suspension of latex particles coated with anti-human ferritin antibodies
Sodium azide ≤ 1.00 g/L

REAGENT PREPARATION
Reagents are ready for use.

REAGENT STABILITY AND STORAGE [6]
The reagent should be stored at 2 - 8°C till the expiration stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at 2 - 8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SAMPLE
Serum is collected according to the standard procedures.
Ferritin in serum is stable for
7 days at 2-8ºC,
24 hours at 20-25ºC,
1 year at -20°C.

For reagents which are related to antigen antibody reaction, do not shake the sample, R2, control and calibrator; just gently mix.

REFERENCE INTERVAL
Serum:
Children : 7 - 140 µg/L
Men : 20 - 250 µg/L
Women : 20 - 200 µg/L

It is recommended that each laboratory establish its own normal range.

Reference interval has been verified by using CLSI EP28- A3c protocol.

QUALITY CONTROL AND CALIBRATION
Commercially available control material with established values determined by this method may be used.
Control Level I
Control Level II

The assay requires the use of an Auto Calibrator.
Ferritin Standard/Calibrator

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyzer and capacity of cooling. Calibration stability is 30 days.

Ferritin concentration is given on the label. Concentration value is traceable to the Biological Reference Material 94/572 (World Health Organization).

If controls are not within acceptable limits, calibration is required, and each laboratory should establish its own Quality Control diagrams and corrective and preventive action procedures.

Daily Quality control is recommended. Calibration is not recommended if quality control values are acceptable. Reagent should be calibrated after lot changes.

PROCEDURE
Settings for TC-Matrix 240/480

Test Name:	Ferritin	R1:	107
Full Name:	Ferritin	R2:	50
Pri. Wave:	546 nm	Sample volume:	6.0
Sec. Wave:	/	Calibration Type:	Spline
Assay/ Point:	Fixed-Time	K Value:	/
Start - End:	19 - 34	Point:	5
Decimal place:	2	Blank Type:	Reagent
Unit:	µg/L	Point 0 (Blank) Con.:	0.0
Linearity Range:	2.000-600.0000	Point 1 (STD) Con.:	Standard/ Calibrator
Correlation Factor:	1.000-0.0000	Point 2 (STD) Con.:	Standard/ Calibrator
		Point 3 (STD) Con.:	Standard/ Calibrator
		Point 4 (STD) Con.:	Standard/ Calibrator

PERFORMANCE CHARACTERISTICS
Limit of Detection (LoD): The limit of detection is 2 µg/L.
Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) ≤ 20%]**:** [8]7 µg/L

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 600 µg/L.

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.
Linearity may vary considerably depending on the instrument used.

Precision Studies:[9]

Repeatability (Within Run) (Intra-Assay)

Mean Concentration	CV%	n
35.0 µg/L	3.20	40
108.0 µg/L	1.80	40

Repeatability (Day to Day) (Inter-Assay)

Mean Concentration	CV%	n
35.0 µg/L	3.90	40
108.0 µg/L	2.10	40

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Prozone Effect: No prozone effect has been observed up to 7500 µg/L value which is tested for Ferritin.

Interference:[3, 4, 12]
No significant interactions were observed for hemoglobin, conjugated bilirubin, rheumatoid factors, lipemia up to the interferent concentration given.

Hemoglobin	: ≤ 4.5 g/L
Lipemia	: ≤ 220 mg/dL
Bilirubin	: ≤ 9 mg/dL
Rheumatoid Factors	: ≤ 650 IU/mL

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only. Do not use expired reagents.

Reagents with two different lot numbers should not be interchanged.

For professional use.

Follow Good Laboratory Practice (GLP) guidelines. Contains sodium azide

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

References

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