ACCUCARE
Ferritin-Turbilatex
Latex Turbidimetry.

Quantitative determination of Ferritin in serum
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	CONT
TFE 20	1 x 20 ML
TFE 40	1 x 40 ML

CLINICAL SIGNIFICANCE

This product is used to determine the level of ferritin in serum and plasma. Ferritin is a spherical, hollow iron storage protein that stores about 450,000 iron atoms. Ferritin is mainly distributed in liver and spleen, and participates in detoxification and storage. The content of ferritin in serum is very small, but the dynamic change of its value reflects the storage of iron in the body. The determination of serum FER concentration is very useful for the diagnosis, treatment and prognosis of iron metabolism abnormalities such as anemia and iron excess, liver diseases, etc.
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PRINCIPLE

Iron antigen + latex coated ferritin antibody → The turbidity of insoluble complexes was measured at 570 nm, and the ferritin content of samples could be calculated by calibration.

REAGENT COMPOSITION

Reagent I : PBS Buffer Solution, Sodium Azide 0.95 g/L
Reagent II : Latex particles coated with human FER Antibody.
FER – CAL : 4 sets, Conc. is stated on the vial label.

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only.
2. DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the Ferritin Reagent Material Safety Data Sheet.
3. Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.
4. Do not use the reagent after the expiration date printed on the kit.
5. 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 the calibrator cautiously as potentially infectious material.

SAMPLE COLLECTION AND PRESERVATION

Fresh serum : Stable for 7 days at 2-8℃ or 3 months at -20℃.
Samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolysed or lipemic sample.

REAGENT PREPARATION

Working reagent :
Double reagents can be used directly after opening without preparation.
Swirl the latex vial gently before use.

Ferritin calibrator: Liquid Multi-calibrators

Calibration Curve: Multipoint Non-linear curve (Spline, Logic log - 4Para)

REAGENT STABILITY

All the component of the kit are stable until the expiry date on the label when stored tightly closed at 2-8℃ and contaminants prevented during there use, Do not use expired reagents.
Ferritin Calibrator : stable till expiry at 2-8℃. Do not freeze.

Calibration frequency

Recalibration is recommended:

- as a blank calibration after 24 hours
- as a blank calibration after reagent bottle change
- as a two point calibration every 30 days if the reagent always on-board
- as a two point calibration after reagent lot change
- as a two point calibration if required following quality control procedures

Calibration verification: Not necessary

AUTOMATED PARAMETERS	
Wavelength	570 nm
Cuvette	1 cm light path
Reaction Temperature	37 ℃
Measurement	Against Reagent Blank
Reaction	Fix-time Kinetic
Curve	Non-Linear (Spline, Logic Log 4 Para)
Reaction Direction	Increasing
Buffer Reagent R -1	300 µl
Sample/calibrator Volume	15 µl
Incubation (R1 + Sample)	5 minutes
Latex Reagent R2	100 µl
Delay Time	10 Seconds
Read Time	5 minutes
Linearity	1000 ng/mL

ASSAY PROCEDURE

PIPETTE INTO TEST TUBES

	Reagent Blank	CAL	SAMPLE
Buffer Reagent – R1	300 µl	300 µl	300 µl
Saline	15 µl	-	-
Standard	-	15 µl	-
Sample	-	-	15 µl
Mix well and incubate for 5 minutes at 37°C			
Latex Reagent – R2	100 µl	100 µl	100 µl
Mix well, and read the absorbance after 10 sec A1 and after 5 minutes A2 of the sample addition.			

CALCULATION

Result calculation : The corresponding ΔA is calibrated by the calibrator concentration. The FER concentration in the sample is read out from the calibration curve through the ΔA of the sample

LINEARITY

The method is linear to a concentration of 20 -1000 ng/ml.
If the concentration exceeds this value, the sample should be diluted 1:5 with 0.9% saline solution and reassayed.

REFERENCE INTERVAL

Male 20-250ng/ml;
Female 20-200ng/ml
According to the distribution range of 95% of normal people.
It is suggested that each laboratory verify this reference range or establish its own reference range.

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 . Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com

QUALITY CONTROL

To ensure adequate quality control ,Normal and abnormal control with assayed values should be run as unknown samples.

BIBLIOGRAPHY

1. Cook, J.D., Lipschitz,D.A., Laughton, M.B.B., Miles, E.M. & Finch, C.A: Serum Ferritin as a measure of iron stores in normal subjects.
2. Walters,G.O., Miller, F.M & Wormwood, M.: Serum Ferritin Concentration on and iron stores in normal subjects. J. Clin.Pathol. 26:770-, 1973.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

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