Ferritin Kit
CliniQuant

Latex Turbidimetry

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF FRTFSR-01	R1 Ferritin Reagent	R2 Ferritin Reagent	R3 Ferritin Standard
Pack size	1 x 30ml	1 x 10 ml	1 x 1 ml

INTENDED USE

This reagent is intended for quantitative determination of Ferritin concentration in serum by latex turbidimetry.

CLINICAL SIGNIFICANCE

This product is used to determine to the level of ferritin in serum . Ferritin is a spherical, hollow iron stage 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 diagnosis, treatment and prognosis of iron metabolism abnormalities such as anemia and iron excess, liver diseases, etc.

PRINCIPLE OF THE METHOD

Iron antigen + latex coated ferritin antibody → the turbidity of insoluble complexes was measured at 578 nm, and the ferritin content of samples could be calculated by calibration.

KIT COMPONENTS

R1 - Ferritin Reagent : PBS Buffer solution

R2 - Ferritin Reagent : Latex particles coated with human FER Antibody.

R3 - Ferritin Standard : Concentration is lot specific, see vial label.

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath, controls, saline

REAGENT PREPARATION , STORAGE & STABILITY

Reagent is ready to use, three liquid reagent. Keep away from direct light sources.

Stability : up to expiration date on labels at 2-8°C. Do not freeze the reagent.

Mix reagent R2 well before processing.

WARNINGS AND PRECAUTIONS

1. For *in vitro* use only.
2. This pack insert must be completely understood prior to operation. Do not modify the test procedure or substitute reagents from other manufacturers or other lots unless the reagent is stipulated as interchangeable. It is recommended to handle carefully by entitled and professionally educated person.
3. Do not pipette by mouth. Use disposable gloves while performing the assay. Wash hands thoroughly when finished.
4. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
5. Do not use reagents beyond the expiry date.
6. In case of skin contact with any of the reagents, wash thoroughly with running water.

   Fresh serum : Stable for 7 days at 2 - 8°C. Do not use hemolysed or lipemic sample.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	2 - Point Nonlinear
Standard Conc.	lot specific
Filter- 1 (nm)	578 nm
Temperature	37 ° C
Volume (µl)	500
Delay Time (Sec)	10
Read Time (Sec)	300
Reaction Direction	Increase
Reference Low	20
Reference High	250
Linearity Limit	1000

TEST PROCEDURE

Dispense	Blank	Standard	Sample
Reagent 1	600 µl	600 µl	600 µl
Distilled water	30 µl	-	-
Standard	-	30 µl	-
Sample	-	-	30 µl
Mix well and incubate for 5 minutes at 37° C			
Reagent 2	200 µl	200 µl	200 µl
Mix well and read the absorbance after 10 sec. A1 and after 5 minutes A2 of the sample addition			

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RESULT CALCULATION

The corresponding ΔA is calibrated by the calibrator concentration.The ferritin concentration in the sample is read out from the calibration curve through ΔA of the sample.

EXPECTED VALUES

Male 20-250 ng/ml

Female 20-200 ng/ml

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal and assayed abnormal to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended Calibrator or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

QUALITY CONTROL

It is recommended to perform internal quality control with commercial available assayed normal and assayed abnormal control, to confirm the validity of the test and assure the accuracy of patient result.

PERFORMANCE CHARACTERISTICS

1.Linearity

The linearity up to 1000 ng/ml

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 1.28 ng/ml.

The limit of quantification is 3.91 ng/ml.

3. Interferences

No interference has been observed for the following

Bilirubin up to 40 mg/dl

Hemoglobin up to 500 mg/dl

Triglycerides up to 500 mg/dl

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	ng/ml	ng/ml	%
Control L1	102.82	1.13	1.10
Control L3	299.61	2.29	0.76

Inter-assay precision

	Mean	SD	CV
n = 20	ng/ml	ng/ml	%
Control L1	103.65	2.58	2.46
Control L3	291.41	4.15	1.42

5. Methods Comparison

Comparison was done between Ferritin Reagent (y) & reference Ferritin Kit (x) using 20 samples gave following results:

y = 0.9998x - 0.2633 r2 = 0.9993

LIMITATIONS

Samples with values above 1000 ng/ml should be diluted with 0.9% saline, re-run and multiply results by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 2059 - 2067.

2. Data on file: Meril Diagnostics.

IFU/FRTFSR01/00

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged