LiquiMAX IRON
(Ferene-s Method)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVIRN - 25	25 ml	(1 X 25 ml Mono Reagent with Calibrator)
AVIRN - 50	50 ml	(2 X 25 ml Mono Reagent with Calibrator)

INTENDED USE:

LiquiMAX IRON is an in-vitro diagnostic kit is use for the quantitative determination of IRON in human serum on photometric systems.

PRODUCT FEATURES

1. Liquid Stable Mono Reagent
2. Aqueous ready to use calibrator provided
3. Measuring wavelength 630 nms (578-630 nms)
4. 10 Minutes End Point Method
5. Linearity: 1000 µg/dL

CLINICAL SIGNIFICANCE :

The majority of iron in the body (3 - 3.5 g) is found in the haemoglobin of the red blood cells or their precursors in the bone marrow. Plasma contains very small fraction of iron (2.5 mg). Iron is transported from one organ to another as a complex formed of ferric ions and a protein called apotransferrin, this iron-protein complex is called transferrin. The major iron-storage compound in the body is ferritin; it occurs in almost all body cells but particulary in hepatocytes. Serum iron is measured by the quantity of iron bound to transferrin, while TIBC is a direct measurement to transferrin. Elevated serum iron levels have been found in cases of hemochromatosis, hepatitis, hepatic necrosis and hemolytic anemia. Decreased levels have been associated with iron defeciency anemia, chronic blood loss, chronic disorders and insufficient dietary iron. The TIBC varies in disorders of iron metabolism so, TIBC is elevated in iron deffeciency anemia. The measurements of both serum iron and TIBC is fundamental in evaluation and differential diagnosis of various types of anemia, liver disease and chronic illness.

PRINCIPLE:

Iron reacts with Ferene-s and cetyltrimethyl-ammonium bromide (CTMA) to form a coloured ternary complex with an absorbance measured at 578 nm. The incresae in the intensity of the colour is directly proportional to the concentration of iron in the sample.

STORAGE AND STABILITY:

All the reagents are stable until the expiration date shown on the label when stored at 2-8°C when the contamination is avoided

KIT COMPONENTS

1. Iron Reagent
2. Iron Calibrator : Concentration as stated on the label

COMPOSITION

Acetate buffer PH 4.7	50 mM
Ferene-S	3.0 mM
CTMA	0.82 mM
Thio Urea	120 mM
preservatives and stabilizers	

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

Iron Calibrator:

Iron Calibrator is the aqueous suspension of Ferrous sulphate

MATERIAL REQUIRED BUT NOT PROVIDED

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

REAGENT DETERIORATION

Discard any turbid reagent if blank reagent absorbance exceeds 1.2 at 630 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN & COLLECTION STORAGE

1. Serum is the specimen of choice. DO NOT USE PLASMA.
2. Samples should be separated from the red cells and analyzed promptly.
3. If the sample cannot be analyzed promptly or is being transported to a reference laboratory, the serum must be separated from the cells immediately after collection.
4. Once separated from the cells, serum may be stored at either 2-8°, or at -20°C for up to one month. Serum may also be stored at room temperature (22-28°C) for two weeks.

SYSTEM PARAMETERS:

Reaction Type (Mode)	:	End Point
Reaction Direction	:	Increasing
Main Wave Length	:	630 nm (578-630)
Flow Cell Temp.	:	37°C
Zero Setting with	:	Reagent Blank
Reagent Volume	:	500 µl
Calibrator / Sample Volume	:	50 µl

TEST PROCEDURE

Let the reagents reach the working temperature before use.

Pipette in a test tube or cuvette labeled as:

Reagent	Reagent Blank	Calibrator	Sample
Iron Reagent	500 µL	500 µL	500 µL
Calibrator	----	50 µL	----
Sample	----	----	50 µL

Mix carefully and incubate at 37°C for 10 Minutes
Read the absorbance of Calibrator and Serum at 630 nms (578 to 630 nms) against Reagent Blank

CALCULATIONS

$$\text{Iron (µg/dL)} = \frac{\text{Absorbance of Sample}}{\text{Absorbance of Calibrator}} \times \text{Conc. Calibrator (µg/dL)}$$

Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

EXPECTED VALUE

Iron:	Men	:	73 - 158 µg/dL
	Women	:	57 - 145 µg/dL
	Moderate Iron Deficiency Men	:	59-73 µg/dL
	Moderate Iron Deficiency Women	:	37-57 µg/dL
	Chronic Iron Deficiency Women	:	Below 37 µg/dL
	Chronic Iron Deficiency Men	:	Below 59 µg/dL
	New Born	:	113 - 250 µg/dL
	Infant	:	45 -100 µg/dL
	Children	:	57-120 µg/dL

Iron Values above 160 µg/dL should be evaluated for Iron Poisoning, Hemolytic Anemia and Hemochromatosis based on the clinical conditions and by cross examining Transferrin, TIBC and Ferritin

The above reference ranges are given as per the method adopted and should not be compared with the reference ranges of other methods. We have tested approximately 300 Normal and 50 Deficient samples while arriving at reference range.
It is recommended that each laboratory should establish its own reference interval.

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result. Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:
a) When using a new reagent or lot.
b) When QC values are out of range.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 1000 µg/dL

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 4.5 µg/dL

3. Interferences

The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Bilirubin	30 mg/dl
Haemoglobin	4 g/L
Intralipid	0.1 %
VC	0.5 g/L(50 mg/dL)

4. Precision:

Reproducibility was determined using controls. The following results were obtained:

Intra-Assay

Sample	Mean (µg/dL)	SD (µg/dL)	% CV
Control 1	103	1.35	1.32
Control 2	158	0.98	0.62
Control 3	180	0.99	0.55

Inter-Assay

Sample	Mean (µg/dL)	SD (µg/dL)	% CV
Control 1	124	1.71	1.38
Control 2	162	3.13	1.93
Control 3	186	1.97	1.06

5. Method Comparison:

A comparison of the iron determination using the LiquiMAX IRON versus with another commercially available method (x) gave the following correlation (µg/dL):

y = 1.6480 + 1.0189 x
r = 0.9986

Number of samples measured: 68
The concentrations of the samples were between 13 µg/dL and 125 µg/dL

LIMITATIONS

Measuring range: 0.2-25 mg/dl. Determine samples having higher concentrations manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

NOTES

- For in vitro diagnostic use only.
- Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
- Exercise the normal precautions required for handling all laboratory reagents.

REFERENCES

1. CARTA, M., "Le proteine del metabolismo del ferro". Riv Med Lab - JLM, Vol 4, N. 1, 2003.
2. Henry RJ, Cannon DC, Winkleman W. Clinical Chemistry Principles and Techniques Hagerstown, MD, Harper & Row, Inc: 1974; 684.
3. Weippl G, P et al. Normal values and distribution of single values of serum iron in cord blood . Clin Chim Acta 1973; 44:147-149.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

Manufactured in India by :
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