Pariksha Biotech
A game changer in IVD

High-Q Iron-ML

Ferene-s Method

HIGH®
Command on Quality

Intended use :
Kit for the quantitative in vitro determination of IRON in human serum on photometric systems.

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.

Assay Principle:
Iron reacts with Ferene-s and cetyltrimethyl-ammonium bromide (CTMA) to form a coloured ternary complex with an absorbance measured at 630 nm. The incresae in the intensity of the colour is directly proportional to the concentration of iron in the sample.

Iron Reagent : Available as Mono Reagent

Composition :		
	Acetate buffer PH 4.7	60 mM
	Ferene-S	2.0 mM
	CTMA	1.0 mM
	Thio Urea	150 mM

preservatives and stabilizers

Iron Calibrator: Iron Calibrator is the aqueous suspension of Ferrous Sulphate and is ready to use. It does not need any reconstitution Calibrator is stable till the expiry.

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

Specimen Collection and 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 (578-700)
Flow Cell Temp.	:	37°C
Zero Setting with	:	Reagent Blank
Reagent Volume	:	500 µl
Calibrator / Sample Volume	:	50 µl

Assay procedure: Iron
Let the reagents reach the working temperature before use.

Pipette in a test tube or cuvette labeled as:

	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 700 nms) against Reagent Blank

Calculations with calibrator:

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

Reference Range:

Males	(25 Years) :	40 - 155 µg/dL
	(40 Years) :	35 - 168 µg/dL
	(60 Years) :	40 - 120 µg/dL
Females	(25 Years) :	37 - 165 µg/dL
	(40 Years) :	23 - 134 µg/dL
	(60 Years) :	39 - 149 µg/dL
Children	(2 Weeks) :	63 - 201 µg/dL
	(6 Months) :	28 - 135 µg/dL
	(12 Months) :	35 - 155 µg/dL
	(2-12 Years) :	22- 135 µg/dL
Pregnant Women	(12 th Gestational Week) :	42 - 177 µg/dL
	(At Term) :	25 - 137 µg/dL
	(6 Weeks Post Partum) :	16 - 150 µg/dL

Iron Values above 180 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.

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Performance characteristics

Linearity:
The method is linear up to . 1000 µg/dL

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

Analytical sensitivity (Low detection limit)
Iron : 4.5 µg/dL

Interference:
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)

Method comparison:
A comparison of the iron determination using the High-Q 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

Automation:
Special adaptations for automatic analyzers can be made on request.

Precautions and warnings:
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.

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Ordering Information:

Ref./Cat.	Pack Size	Presentation
P-IRN - 50	50 Tests	(25 ml Mono Reagent with Calibrator)
P-IRN - 50	100 Tests	(2 x 25 ml Mono Reagent with Calibrator)

Product Features

- Liquid Stable Mono Reagent
- Aqueous ready to use calibrator provided
- Measuring wavelength 630 nms (578-700 nms)
- 10 Minutes End Point Method
- Linearity: 1000 µg/dL

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
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