Spectrum For Diagnostic Industries

IVD

Total Iron Chromazurol B

REF.	Pack size
209 01 050	(1 x 50 ml) 50 tests
209 02 030	(2 x 30 ml) 60 tests
209 05 030	(5 x 30 ml) 150 tests

Intended Use

Iron reagent is intended for in-vitro quantitative and diagnostic determination of Iron in human serum or plasma on manual and automated systems.

Introduction

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 deficiency anemia, chronic blood loss, chronic disorders and insufficient dietary iron. The TIBC varies in disorders of iron metabolism , so it is elevated in iron deficiency 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.

Method

Colorimetric CAB Method.

Principle

Iron reacts with chromazurol B and cetyltrimethyl-ammonium bromide (CTMA) to form a coloured ternary complex with an absorbance measured at 623 nm.The intensity of the colour produced, is directly proportional to the concentration of iron in the sample.

Reagents

Reagent

Acetate buffer(pH 4.7)	50 mM
CAB	0.13 mM
CTMA	0.82 mM
preservatives and stabilizers	

Standard Iron 200 µg/dL
35.8 µmol/L

Reagents preparation, storage and stability

The reagent and standard are supplied ready-to-use and stable till the expiration date stated on label when stored at 15-25^{o}C .Once opened, the reagent and the standard vials are stable for 3 months at the specified temperature.

Deterioration

Failure to recover the control values within assigned range may indicate reagent deterioration.

Precautions and Warnings

Iron test is very sensitive against contamination: Use only bidistilled water.
Contaminated glasswares are a source of error.
Disposable plastic ware is recommended for the test.

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Specimen collection and preservation

The recommended specimen is serum or heparinized plasma. Plasma specimens collected with EDTA, oxalate, or citrate as anticoagulants are unsatisfactory since they bind iron, preventing its reaction with the chromogen. Morning specimen is preferrable to avoid low result due to diurinal variation. The biological half life of iron in blood is few hours.
Stability: 7 days at 15 –25 ^{o}C ;3 weeks at 2 – 8 ^{o}C;
1 year at -20 ^{o}C.

Procedure

Wavelength	623 nm
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample : Reagent Ratio	1 : 25
e.g.: Reagent volume	1 ml
Sample volume	40 µl
Temperature	25 ^{o}C ,30 ^{o}C or 37 ^{o}C
Incubation time	5 minutes
Zero adjustment	Reagent Blank
Reagent Blank Limits	Less than 1 AU

	Reagent blank	Standard	Specimen
Reagent (R)	1.0 ml	1.0 ml	1.0 ml
Standard	------	40 µl	------
Specimen	------	------	40 µl

Mix, and incubate for 5 minutes at 25, 30 or 37 ^{o}C. Read the absorbance of the standard and specimen against reagent blank.

Calculation

$$\text{Iron conc. (µg/dL)} = \frac{(A_{specimen})}{(A_{standard})} \times 200$$

SI units

(µg/dL) x 0.1791 = µmol/L

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Sensitivity

When run as recommended, the sensitivity of this assay is 12 µg/dL for serum iron.

Linearity

The reaction is linear up to iron concentration of 500 µg/dL. Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result × 2).

Interference

Haemolysis
No interference up to haemoglobin level of 5 g/L (0.3 mmol/L) in determining serum iron.

Icterus
No significant interference up to a bilirubin level of 30 mg/dL.

Lipemia
Lipemic specimens are not recommended since they may cause negative bias. Lipemic specimens can be diluted before assay and the dilution factor should be considered during calculation.

Anticoagulants
Citrate, EDTA and oxalate should be avoided.

Expected Values

1- Neonates	:	36 – 184 µg/dL	(6. 4 - 33 µmol/L)
2- < 7 months	:	37 – 145 µg/dL	(7.7 - 33 µmol/L)
3- Adults			
a) Women	:	37 – 145 µg/dL	(6.6 - 26 µmol/L)
b) Men	:	59 – 158 µg/dL	(10.6 - 28 µmol/L)

Performance characteristics

A comparison between SDI Iron reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.983 was obtained.

Precision
Within run (Repeatiblity)

	Total Iron	
	Level 1	**Level 2**
n	20	20
Mean (µg/dL)	159	344
SD	2.1	1.9
CV%	2.3	0.57

Run to run (Reproducibility)

	Total Iron	
	Level 1	**Level 2**
n	20	20
Mean (µg/dL)	162	351
SD	2.9	2.6
CV%	2.9	0.68

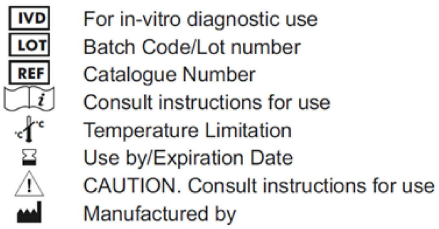
Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Stookey LL. Ferrozine-a new spectrophotometric reagent for iron. Anal Chem. 1970;42:779-781.
2. Williams HL, Johnson DJ, Haut MJ. Simultaneous spectrophotometry of Fe2+ and Cu2+ in serum denatured with guanidine hydrochloride. Clin Chem.1977;23:237-240.
3. Viollier MA, Gschwind H, Schläpfer P. Neue serumeisenbestimmung auf dem GSA II. Lab Med.1980;4:240-244.

SYMBOLS IN PRODUCT LABELLING



Spectrum For Diagnostics Industries - Free Zone
Ismailia Free Zone Industerial Area, Block 5 .
Cairo- Port said Avenue.
Ismailia,Egypt
Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015
www.sdi-fz.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

ISO 13486:2016