SPECTRUM

The Creative Approach to Bioscience

Direct Serum Total Iron BindingCapacity (TIBC)

REF: 270 001 100 Test

Reagent 1 2 x 50 ml
Reagent 2 1 x 16 ml
Calibrator 1 vial

Intended Use

Spectrum Diagnostics total iron binding capacity (TIBC) reagent is intended for the in-vitro quantitative, diagnostic determination of total iron binding capacity in human serum.

Background

The serum total iron-binding capacity (TIBC) represents the maximum concentration of iron that can be bound by an individual's serum protein. Determination of TIBC is one of several commonly used assays in assessment of iron status and TIBC is highly correlated with serum transferrin (the primary serum iron transport protein) because > 95% of serum nonheme iron is bound by transferrin. Usually, only 30 % of the available serum iron-binding sites are occupied, and changes in ratio of serum iron to TIBC reflec changes in the body iron stores.

Assay Principle

In the first step, the serum sample is added to reagent 1 (R1). R1 contains iron as ferric ion in sufficient quantity to saturate the highest anticipated TIBC in a complex with an excess of chromazurol B in acetate buffer ar pH 4.8. When the serum sample is added, the serum iron is released from transferrin because of the low pH. The iron from sample then forms a complex with the remaining excess of chromazurol B,increasing the absorbance. In the second step, reagent 2 (R2) which is strongly buffered is added. The affinity of transferrin for iron increases and the transferrin extracts iron from the iron-dye complex, decreasing the absorbance. The decrease in absorbance is directly proportional to TIBC.

Reagents

Reagent 1 (R1)

Acetate Buffer pH 4.8	0.4 mol/L
Chromazurol B	300 µmol/L
Surfactant	0.1 %
Non active ingredients.	

Reagent 2 (R2)

MOPs buffer pH 8.0	100 mmol/L

Calibrator (C)

Actual concentration is stated on the vial label

Reagent Preparation, Storage and Stability

Reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2 – 8 °C.Once opened, the reagent is stable for 3 months at specified temperature

Calibrator :

The calibrator is vacuum sealed; therefore the vial should be reconstituted carefully with distilled water as mentioned on vial label. Close the vial carefully and allow the calibrator to stand for 30 minutes occasional swirling . Avoid foaming! Do not shake!
After reconstitution, divide the calibrator into several aliquots. The tightly closed calibrator can be used within 30 days at – 25°C. Avoid repeated freeazing and thawing.

Precautions and Warnings

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.

SYMBOLS IN PRODUCT LABELLING

EC REP Authorised Representative	Temperature Limitation
IVD For in-vitro diagnostic use	Use by/Expiration Date
LOT Batch Code/Lot number	CAUTION. Consult instructions for use
REF Catalogue Number	Manufactured by
Consult instructions for use	

Specimen Collection and Preservation

The recommended specimen is serum . Plasma specimens collected with EDTA, oxalate, or citrate as anticoagulants are unsatisfactory since they bind iron, preventing its reaction with the reagent. Morning specimen is preferrable to avoid low result due to diurnal variation. The biological half life of iron in blood is few hours.

Stability: 7 days at 15 –25 °C ; 3 weeks at 2 – 8 °C;
1 year at -20 °C.

System Parameters

Wavelength	630 nm
Optical path	1 cm
Assay type	End point
Direction	Decrease
Temperature	37 °C

Procedure

	Calibrator Blank	Calibrator	Sample Blank	Sample
Reagent1	500 µl	500 µl	500 µl	500 µl
Calibrator	40 µl	40 µl	-----	-----
Sample	-----	-----	40 µl	40 µl
Mix and incubate for 5 min, at 37 °C, then add R2				
Reagent 2	-----	150 µl	-----	150 µl

Mix and incubate for 7 minutes then read the absorbance of the Calibrator against Calibrator Blank and absorbance of sample against sample Blank.

Calculation

$$\text{Total iron binding capacity} = \frac{A_{sample}}{A_{calibrator}} \times \text{calibrator Conc.}$$

Quality Control

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

Performance Characteristics

Precision

Within run (Repeatability)

	TIBC	
	Level 1	**Level 2**
n	20	20
Mean (µg/dL)	200	299
SD	2.12	1.36
CV%	1.06	0.45

Run to run (Reproducibility)

	TIBC	
	Level 1	**Level 2**
n	20	20
Mean (µg/dL)	203	303
SD	2.19	1.42
CV%	1.12	0.51

Methods Comparison

A comparison between Spectrum Diagnostics TIBC reagents and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.983 was obtained.

Sensitivity

When run as recommended, the sensitivity of this assay is 70 µg/dL.

Linearity

The reaction is linear up to concentration of 700 µg/dl .Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result × 2).

Interfering Substances

Haemolysis
No interference up to haemoglobin level of 5 g/L (0.3 mmol/L) in determining serum iron and up to 1 g/L for TIBC.

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.

Others
Pathological albumin levels more than 7 g/dL decrease the TIBC levels.

Expected values

TIBC			
1 day	:	134 – 318 µg/dL	(24 - 57 µmol/L)
1 week	:	190 – 324 µg/dL	(34 - 58 µmol/L)
Infants	:	151 – 340 µg/dL	(27 - 61 µmol/L)
3 – 12 months	:	290 – 436 µg/dL	(52 - 78 µmol/L)
1 – 10 years	:	262 – 497 µg/dL	(47 - 89 µmol/L)
11 – 16 years	:	290 – 441 µg/dL	(49 - 89 µmol/L)
Adults Women	:	274 – 497 µg/dL	(49 - 89 µmol/L)
Men	:	291 – 430 µg/dL	(52 - 77 µmol/L)

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature reference.

Analytical Range

70 – 700 µg/dl (12.5 – 125 µmol/L).

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. Bauer JD. Haemoglobin, porphyrin, and iron metabolism. In:Kaplan LA, Pesce AJ, ed. Clinical Chemistry, theory, analysis, and correlation. ST. Louis:Mosby Company:1984:611-655.
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4. Viollier MA, Gschwind H, Schläpfer P. Neue serumeisenbestimmung auf dem GSA II. Lab Med.1980;4:240-244.
5. Williams HL, Johnson DJ, Haut MJ. Simultaneous spectrophotometry of Fe2+ and Cu2+ in serum denatured with guanidine hydrochloride. Clin Chem.1977;23:237-240.

ORDERING INFORMATION

CATALOG NO.	QUANTITY
270 001	100 Test

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