ARENA
BioScien

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Total Iron Binding Capacity (TIBC)

Diagnostic reagent for the in-vitro quantitative determination of total iron binding capacity in human serum on both manual and automated systems.

REF: BS.1/TC02.025.0050	50 test	REF: BS.1/TC02.050.0100	100 test
REF: BS.1/TC04.025.0100	100 test		

CLINICAL SIGNIFICANCE

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 reflect changes in the body iron stores.

METHOD PRINCIPLE

Excess iron is added to the sample to give a saturation of the transferring. The remaining iron will be absorbed by magnesium carbonate. The bound iron in the supernatant is called the TIBC which is assayed in the same manner as the iron determination.

REAGENT COMPOSITION

R1: Reagent 1 - $FeCl_3$	- 89.5 mmol/l
R2: Reagent 2 - $MgCO_3$	Magnesium hydroxide carbonate powder

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- 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.
- Respect country requirement for 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.

For further information, refer to the TIBC reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

TIBC reagents are supplied ready-to-use. All reagents are stable until expiration date stated on label when stored at 2-8°C.

Deterioration
The ***BioScien*** TIBC reagent is normally clear, do not use reagent if it is turbid.

SPECIMEN COLLECTION AND PRESERVATION

The recommended specimen is serum.

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

SYSTEM PARAMETERS

Wavelength	578 nm
Optical path	1 cm
Assay type	End-point
Temperature	37 °C
Sensitivity	0.66 µg/dl
Linearity	1000 µg/dl

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Sample
Reagent 1	500 µl
Sample	250 µl
Mix and incubate for 5-30 min, at 25°C	
Reagent 2	One spatula

Let stay for additional 30-60 min. Shake within the period occasionally about 5 times.
Centrifuge 10 min at 4000 r.p.m. and use the clear supernatant for the iron measurement with iron kits.

CALCULATION

TIBC concentration (µg/dl) = Abs. sample x 3183.
TIBC concentration (µmol/l) = Abs. sample x 570.
UIBC:(unsaturated iron binding capacity)
UIBC concentration (µg/dl) = TIBC (µg/dl) – serum iron (µg/dl)
Transferrin:
-Assuming that 1 mg of transferrin may bind max. 1.2 µg iron a very approximated value can be obtained by
TIBC (µg/dl) /1.2=Transferrin (µg/dl)

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range, please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	52	52	52	52
Mean µg/dl	225.1	307.1	221.2	305.7
SD.	1.01	1.82	2.68	4.17
CV. %	0.45	0.59	1.21	1.37

The results of the performance characteristics depend on the analyzer used.

Accuracy (Methods Comparison)
Result obtained from ***BioScien*** TIBC reagent compared with commercial reagent of the same methodology performed on 52 human sera give a correlation of 0.986.

Sensitivity
When run as recommended, the minimum detection limit of the assay is 0.66 µg/dl.

Linearity
The reaction is linear up to concentration of 1000 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

Serum	µg/dl	µmal/L
Children	100-400	18-72
Adult	250-425	45-76

DYNAMIC RANGE

0.66 –1000 µg/dl.

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.
2. Fairbanks VF,Klee GG. Biochemical aspects of hematology. In: Tietz NW, ed. Fundamentals of clinical chemistry. 3rd ed.
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3. Stookey LL. Ferrozine-a new spectrophotometric reagent for iron. Anal Chem. 1970; 42:779-781.
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.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

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