Pariksha Biotech
A game changer in IVD

High-Q TIBC Direct

Chromozurol-B Method

HIGH®
Command on Quality

Intended Use:
For use in the determination of Total Iron-Binding Capacity in serum.

Summary and Explanation:
Total Iron-Binding Capacity (TIBC) is the measure of the maximum concentration of iron that the serum proteins can bind. Together with the total serum iron concentration, the TIBC is used in the diagnosis and treatment of iron deficiency anemia, other disorders of iron metabolism, and chronic inflammatory disorders. As an index of nutritional status, TIBC reflects the degree of transferrin saturation by serum iron. Serum TIBC is increased in iron deficiency, and decreased in anemia that is due to chronic disease.

Principle:
Step 1: Reagent 1 (R1), an acidic buffer containing an iron binding dye and ferric chloride, is added to the serum sample. The low pH of R1 releases iron from transferrin.

Step 2: The iron then forms a colored complex with the dye present in R2. The colored complex at the end of this first step represents both the serum iron and excess iron. The neutral buffer in R2 shifts the pH and resulting in a large increase in affinity of transferrin for iron. The serum transferrin rapidly binds to the iron by forming a dye-iron complex. The observed increase in absorbance of the colored dye-iron complex is directly proportional to the total iron binding capacity of the serum sample.

Methodology: Colorimetric
Reagents:
Reagent 1 (R1) contains: Cetrimide, Ferric chloride, acetate buffer, stabilizers, and preservatives

Reagent 2 (R2) contains: Chromazurol B, Sodium Bicarbonate, buffer, stabilizers, and preservatives

TIBC Calibrator: Reconstitute the TIBC Calibrator with 1 ml of Distilled water and keep it for 30 minutes at room temperature. Gently mix and aliquot the calibrator at - 20^{0}C for extended use up to 3 months. Reconstituted Calibrator at 2-8 ^{0}C can be used for 30 days

Preparation:
The Direct TIBC Reagents (D TIBC), R1 and R2 are ready to use as supplied.

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.**

Test Procedure:
System Parameters:

Mode :	**End Point**
Wavelength:	**630 nm (600-700 nms)**
Temperature:	**37^{o}C**
Blank:	**Distilled Water Blank**
Direction:	**Increasing**
Units	**µg/dL**
Reagent 1	**500 µl**
Reagent 2	**100 µl**
Sample volume	**5 µl**
Calibrator Concentration:	**Lot Specific** (See on labels)
Linearity	**700 µg/dl**
High Normal	**450 µg/dl**

Let reagents reach the working temperature before use.

Pipette in a test tube or cuvette so labeled:

Reagent	Calibrator	Sample
Reagent-1	500 µL	500 µL
Calibrator	20 µl	-
Sample	-	20 µl
Reagent-2	200 µL	200 µL

Mix well and Incubate at **37^{oc}** for 5 Minutes. Then measure the absorbance of Calibrator and Sample against Distilled Water Blank on a Photocolorimeter which is set at 630 nms

Calculations:

$$\text{TIBC in µg/dl} = \frac{\text{Abs of Calibrator}}{\text{Abs of Sample}} \times \text{Calibrator Concentration (On the label)}$$

Expected Values:
250 – 450 µg/dL
Since these ranges vary with different populations, it is recommended that each laboratory establish its own expected range.

Low TIBC Values are attributed to 1) Excess Iron Levels (Iron Overload) 2) Inflammation 3) Liver Disease 4) Malnutrition 5) Kidney Disease 6) Hemolysis.

High TIBC Values are attributed to 1) Iron Deficiency 2) Polycythemia vera

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Low TIBC Levels:
Causes of Low TIBC:
Causes shown below are commonly associated with low TIBC.
1) Excess Iron Levels (Iron Overload)
The most common cause of low TIBC is excess iron in the body.Iron overload can happen due to poisoning, or in some hereditary disorders, such as hemochromatosis, thalassemia, or sickle cell anemia
However, not everyone with iron overload will have low TIBC. A lot of people with iron overload will have TIBC in the normal range.

2) Inflammation
Transferrin is a negative acute phase protein. This means that in inflammation, as the liver increases the production of inflammation-associated proteins (e.g. CRP, ferritin) it decreases the production of transferrin. As transferrin decreases, so does iron binding capacity and therefore TIBC. TIBC is decreased in people who have anemia of inflammation also known as anemia of chronic disease This type of anemia is caused by inflammatory cytokines and associated with underlying conditions such as infections, inflammatory disease, autoimmune disease, and cancer.

3) Liver Disease
The liver helps keep iron levels in balance. During liver diseases and injury, more iron is absorbed in the gut, causing TIBC to decrease. Also, in liver disease, the liver can't produce transferrin effectively, which decreases total iron-binding capacity

4) Malnutrition
TIBC levels can be low in malnutrition

5) Kidney Disease
Low TIBC can also be caused by kidney disease accompanied by protein loss (wasting)

6) Hemolysis
Abnormal destruction of red blood cells (hemolysis).

High TIBC
Causes of High TIBC
Causes shown below are commonly associated with high TIBC.

1) Iron Deficiency
TIBC increases during iron deficiency. Iron deficiency can be due to dietary deficiency, bleeding (e.g. menstrual bleeding or ulcers), and gut disorders that decrease iron absorption (e.g. celiac disease)

A study suggests that pregnant women may also commonly experience iron deficiency due to low dietary intake and higher demand, especially during the third trimester.

2) Polycythemia vera
Polycythemia vera is a disease in which the bone marrow makes too many red blood cells that use up a lot of iron. Polycythemia vera patients may have a functional iron deficiency, which can increase TIBC

Precision:

Two levels of TIBC were tested, using quality control material. Within-run and run-to-run precision (seven day) studies yielded the following:

Within-Run Precision (N=25)

	Level 1	Level 2
Mean (µg/dL)	250	446
S.D (µg/dL)	9.0	8.2
c.v. (%)	3.6	1.8.

Within-Run Precision (N=25)

	Level 1	Level 2
Mean (µg/dL)	247	451
S.D (µg/dL)	9.5	10.4
c.v. (%)	3.8	2.3

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
Pariksha Biotech Pvt Ltd,
Plot no.1/B-14, SVICE,
Balanagar,
Hyderabad-500037
Telangana State

Limitations:
1. Using normal sera (average TIBC: approx. 350 µg/dL), several substances were tested for possible interference. The following DID NOT INTERFERE as demonstrated by less than 5% bias to the limits shown:

Bilirubin	up to at least	32 mg/dL
Copper	up to at least	3 mg/dL
Zinc	up to at least	250 µg/dL
Nickel	up to at least	500 µg/dL
Chromium	up to at least	5 µg/dL
Cuprimine	up to at least	250 µg/dL
Iron Dextran (Imferon)	up to at least	1430 µg/dL
Hemoglobin	up to at least	500 mg/dL
Triglycerides	up to at least	1300 mg/dL

2. Ascorbate demonstrated less than 5% bias up to 10 mg/dL and less than 10% bias up to 20 mg/dL. Greater than 20 mg/dL
of ascorbic acid causes significantly decreased TIBC results.

3. Desferal demonstrated less than 5% bias up to 11.5 µg/mL and less than 10% positive bias up to at least 23 µg/mL. Greater than 250 µg/mL Desferal causes significantly increased TIBC results.

4. Greater than 460 µg/dL of iron (Ferrous Sulfate) causes significantly decreased TIBC results.

References:
1. Tietz NW (ed). Textbook of Clinical Chemistry, ed. 3.Philadelphia, PA: WB Saunders; 1701-1703; 1999.

2. NCCLS. Determination of Serum Iron and Total Iron Binding Capacity; Proposed Standard, NCCLS Document H17-P. Wayne, PA: NCCLS, Vol. 10, No. 4; 1990.

3. Gambino R., et al. The Relation Between Chemically Measured Total Iron-Binding Capacity Concentrations and Immunologically Measured Transferring Concentrations in Human Serum. Clin. Chem. 43: 2408-2412, 1997.

Ordering Information:

Ref./Cat.	Pack Size	Presentation
P-TIBC(D)50	50 Tests	(25 ml R1 + 5 ml R2 with Calibrator)
P-TIBC(D)100	100 Tests	(2 x 25 ml R1 + 2 x 5 ml R2 with Calibrator)

Product Features

- Two liquid reagents and Calibrator
- 5 Minutes End Point Assay
- Linearity : 700 µg/dL
- No need to estimate UIBC
- Serum is the specimen
- Can be used on semi and fully auto analyzers

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		

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AN ISO 13485 Certified Company

Rev # 2