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 :	**Fixed Time**
Wavelength:	**630 nm(600-700 nms)**
Temperature:	**37^{o}C**
Direction:	**Increasing**
Delay	**5 Seconds**
Measuring	**120 Seconds**
Reagent 1	**500 µl**
Reagent 2	**100 µl**
Sample volume	**5 µl**
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:

	Calibrator	Sample
R1	**500 µL**	**500 µL**
Calibrator	**5 µL**	**----**
Sample	**----**	**5 µL**
R2	**100 µL**	**100 µL**

Mix well and immediately aspirate in to the analyzer. After 5 Sec delay, measure the change of optical density during 120 seconds against distilled water at 630 nms as follows for Calibrator and Serum Samples

Delay - Exactily after 5 Seconds.
Measuring - Exactily after 120 seconds.

Calculations:

$$\text{TIBC in µg/dl} = \frac{\Delta AT}{\Delta AS} \times \text{Calibrator Concentration (On the label)}$$

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

The Direct TIBC method demonstrated linearity up to 700 µg/dL TIBC.

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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

Precautions:

- The Direct TIBC Reagent is for in vitro diagnostic use. Normal precautions for handling laboratory reagents should be taken.
- Do not ingest, do not pipette by mouth. Prevent contact with skin and eyes.
- Do not mix reagents of different lot numbers.
- All specimens and controls being tested should be considered potentially infectious. Universal precautions, as they apply to your facility, should be used for handling and disposal of materials during and after testing.

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.

5. Serum is the preferred sample. Do Not Use Plasma.

eIFU Indicator

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Manufactured in India by :
Pariksha Biotech Pvt Ltd,
Plot no.1/B-14, SVICE,
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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
- 2 Minutes Fixed Time 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
- In vitro diagnostic medical device
- Do not freeze
- Use-by date
- Keep dry
- Consult instructions for use
- Consult electronic instructions for use
- Catalogue number
- Caution
- Manufactured by
- Keep away from sunlight
- This way up
- Do not use if package is damaged
- Batch Code
- Reagent
- Calibrator Material

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