LiquiMAX TIBC-DIRECT
Chromozurol-B Method

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVITB - 30	30 ml	Two Liquid Reagents with Calibrator
AVITB - 60	60 ml	

INTENDED USE :
Kit is use for the determination of Total Iron-Binding Capacity in human serum.

PRODUCT FEATURE

1. Two liquid reagents and Calibrator
2. 10 Minutes End Point Assay
3. Linearity : 700 µg/dL
4. No need to estimate UIBC
5. Serum is the specimen
6. Can be used on semi and fully auto analyzers

CLINICAL SIGNIFICANCE :
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.

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

When stored at 2-8°c the regents are stable until the expiration date stated on the bottle and kit box labels .
It is recommended that when the reagent is not in use for prolonged periods of the reagent be capped and stored at 2-8°c.

KIT COMPONENTS

1. TIBC Reagent R1
2. TIBC Reagent R2
3. TIBC Calibrator : Concentration as stated on the label

COMPOSITION

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

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

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

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°C for extended use up to 3 months. Reconstituted Calibrator at 2-8 °C can be used for 30 days

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

- Discard any turbid reagent if reagent absorbance less than 0.8 at 630 nm against distilled water.
- Keep the standard vial plugged after use, in order to avoid deterioration.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP guidelines.

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.

SYSTEM PARAMETERS:

Mode :	End Point
Wavelength:	630 nm (600-700 nms)
Temperature:	37°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
Low Normal	250 µg/dl

TEST PROCEDURE
Pipette in a test tube or cuvette labeled As:

Reagent	Calibrator	Sample
Reagent-1	500 µL	500 µL
Calibrator	5 µl	-
Sample	-	5 µl
Reagent-2	100 µL	100 µL

Mix well and Incubate at 37°C 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.

QUALITY CONTROL & CALIBRATION
It is recommend to perform internal quality control to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended calibrator (Avecon) included, calibrate the assay:
a) When using a new reagent or lot.
b) When QC values are out of range.

PERFORMANCE CHARACTERISTICS
1. Linearity
Linearity : 700 µg/dl

2. Sensitivity/ Limit of Detection (LOD)
The lower limit of detection is 5 µg/dl

3. Interferences
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.

4. Precision

Intra-assay precision	mean	SD	CV
N=25	(µg/dl)	(µg/dl)	(%)
Sample 1	250	9.0	3.6
Sample 2	446	8.2	1.8

Inter-assay precision	mean	SD	CV
N=25	(µg/dl)	(µg/dl)	(%)
Sample 1	247	9.5	3.8
Sample 2	451	10.4	2.3

5. Method Comparison:
A comparison of the LiquiMAX TIBC (y) with a commercial obtainable assay (x) gave the following result : $y = 1.113\,x - 0.278$; $r = 0.990$

LIMITATIONS
Measuring range: 5-700 µg/dl. Determine samples having higher concentrations manually dilute with
0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

NOTES
- 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.

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

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.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
Σ	Contains sufficient no. of test		

ISO 13485 Certified Company

5 Schedule MDR 2017

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