MEDTEST DX
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# Direct TIBC Reagent Set

## Intended Use
For use in the determination of total iron-binding capacity in serum on the Mindray BS-480 analyzer. For *in vitro* diagnostic use only.

## Introduction
Total iron-binding capacity (TIBC) is the measure of the ability of serum proteins, principally transferrin, to bind iron. It is 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, Serum TIBC is increased in iron deficiency, and decreased in anemia that is due to chronic disease.

## Principle of the Test
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. The iron then forms a colored complex with the dye. The colored complex at the end of this first step represents both the serum iron and excess iron already present in R1.

Step 2: Reagent 2 (R2), a neutral buffer is then added, shifting the pH and resulting in a large increase in affinity of transferrin for iron. The serum transferrin rapidly binds the iron by abstracting it from the dye-iron complex. The observed decrease in absorbance of the colored dye-iron complex is directly proportional to the total iron-binding capacity of the serum sample.

## Reagents
Reagent 1 (R1) contains: 166 µmol/L chromazurol B, 735 µmol/L cetrimide, 16 µmol/L ferric chloride, acetate buffer, stabilizers, and preservatives.
Reagent 2 (R2) contains: 338 mmol/L sodium bicarbonate, buffer, stabilizers, and preservatives.

## Reagent Preparation
The Direct TIBC Reagents, R1 and R2 are ready to use as supplied.

## Reagent Storage and Stability
The reagent is stable until the expiration date shown on the label when stored at 2-8°C. Once placed on board reagent is stable for 30 days.

## Precautions and Hazards
The Direct TIBC Kit is for in-vitro diagnostic use. Normal precautions for handling laboratory reagents should be taken.
1. Do not ingest reagent, do not pipette by mouth.
2. Prevent contact with skin and eyes.
3. Do not mix reagents of different lot numbers.
4. 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.

**Hazards:**

**Signal Word: Warning**

**R1:** Hazard Classifications: Skin Corrosion/Irritation (Category 2), Serious eye damage/eye irritation (Category 2A)
Hazard Statements: H315: Causes skin irritation, H319: Causes serious eye irritation
Precautionary Statements: **Prevention:** P264: Wash skin thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. **Response:** P362: Take off contaminated clothing and wash before reuse. P302 + P352: IF ON SKIN: wash with plenty of soap and water. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332 + P313: IF SKIN irritation occurs: Get medical advice/attention. P337 + P313: IF eye irritation persists: Get medical advice/attention. **Storage:** None **Disposal:** None
**R2:** Hazard Classifications: Not a hazardous substance or mixture.
Pictogram and Signal Word: Not required.
Hazard Statements: Not a hazardous substance or mixture.
Precautionary Statements: Not a hazardous substance or mixture. **Refer to the Safety Data Sheet for this product (MSDS-TIBC480) available at www.medtestdx.com.**

## Specimen Storage and Collection
1. Serum is the specimen of choice. DO NOT USE PLASMA.
2. Samples should be separated from the red cells and analyzed promptly. However, the serum may be stored at 2-8°C, or at -20°C for up to one month. Serum can be stored at room temperature (22-28°C) for two weeks.

## Materials Required but not Provided
Mindray BS-480 Analyzer
Direct TIBC Calibrator Set (Catalog Number: TIBCC480)
Chemistry Controls (Catalog Number: CHEQ480)

## Calibration
The Direct TIBC Calibrator Set is required for calibration; refer to the Calibrator set package insert for directions. Follow the instrument manufacturer's guidelines for calibration performance and frequency, using quality control samples with each run to verify satisfactory calibration. [Results expressed in µg/dL may be converted to µmol/L by multiplying by 0.179]. Calibration stability studies have shown the calibration curve will be stable for at least 14 days.

## Quality Control

Reliability of test results should be monitored by including control sera, with known TIBC concentrations, in each assay run. These controls should be carried through the process and treated in the same manner as the patient's serum samples. The recovery of control values within the established acceptable range should be the criteria used in the evaluation of assay performance.

## Performance

1. Assay Range: 77-694 µg/dL TIBC.
2. Correlation: A study was performed between the Mindray BS-480 and a similar analyzer using this method, resulting in the following:

| Method | TIBC |
|---|---|
| N | 116 |
| Mean TIBC (µg/dL) | 408.27 |
| Range (µg/dL) | 83.0-685.0 |
| Standard Deviation | 168.89 |
| Regression Analysis | y = 0.967 + 7.45 |
| Correlation Coefficient | 0.9535 |

3. Precision: Precision studies were performed following a modification of the guidelines contained in the NCCLS document EP5-T2.[12]

Within Day

| Sample | LOW | MID | HIGH |
|---|---|---|---|
| N | 20 | 20 | 20 |
| Mean | 254.8 | 394.9 | 639.7 |
| Standard Deviation | 2.9 | 2.3 | 1.5 |
| Coefficient of Variation (%) | 1.1% | 0.6% | 0.2% |

Total

| Sample | LOW | MID | HIGH |
|---|---|---|---|
| N | 40 | 40 | 40 |
| Mean | 251.6 | 392.2 | 641.5 |
| Standard Deviation | 9.5 | 13.0 | 4.6 |
| Coefficient of Variation (%) | 3.8% | 3.3% | 0.7% |

4. Sensitivity: 2SD limit of detection (95% Conf) = 2 µg/dL

## Expected Values

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

## Limitations

1. Using normal sera (average TIBC: approx. 400 µg/dL), the following substances were tested for possible interferences by addition and demonstrated less than 10% bias at least the limits given:
   Bilirubin up to 25.6 mg/dL
   Hemoglobin up to 500 mg/dL
   Triglycerides up to 700 mg/dL
   Using normal sera (average TIBC: approx. 350 µg/dL), the following substances were tested for possible interferences by addition and demonstrated less than 5% bias at least the limits given:
   Copper up to 3 mg/dL
   Zinc up to 250 µg/dL
   Nickel up to 500 µg/dL
   Cuprimine up to 250 µg/dL
   Imferon (as iron) up to 1430 µg/dL
   Ascorbate greater than 20 mg/dL of ascorbic acid causes significantly decreased TIBC results.
   Desferal demonstrated less than 5% bias up to 11.5 µg/mL and less than 10% bias up to at least 23 µg/mL
2. Serum is the preferred sample, Do Not Use Plasma.

## References

1. Tietz NW (ed). Textbook of Clinical Chemistry, 3rd ed. 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. Starr RT. Use of an Alumina Column in Estimating Total Iron-Binding Capacity. Clin. Chem. 26: 156-158, 1980.
4. Gambino R., et al. The Relation Between Chemically Measured Total Iron-Binding Capacity Concentrations and Immunologically Measured Transferrin Concentrations in Human Serum. Clin. Chem. 43: 2408-2412, 1997.
5. U.S. Patent Number 6,627,448.

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## CHEMISTRY PARAMETERS

| | | | | | |
|---|---|---|---|---|---|
| Chem: | TIBC | No.: | 228 | Sample Type: | Serum |
| Chemistry: | Direct Total Iron Binding Capacity | | | Print Name: | TIBC |
| Reaction Type: | End Point | | | Reaction Direction: | Negative |
| Pri Wave: | 660 | | | Sec Wave: | |
| Unit: | µg/dL | | | Decimal | 0 |
| Blank Time: | 47 49 | | | Reaction Time: | 80 82 |

| | Sample Vol. | Aspirated | Diluent | Reagent Vol. | Diluent |
|---|---|---|---|---|---|
| Standard: | 9.3 ul | --- ul | --- ul | R1: 120 ul | --- ul |
| Decreased: | --- ul | --- ul | --- ul | R2: 72 ul | -- ul |
| Increased: | --- ul | --- ul | --- ul | R3: --- ul | -- ul |
| | ☐ Sample Blank | ☑ Auto Rerun | | R4: --- ul | --- ul |

**Slope/Offset Adjustment**

Slope: 1 Offset: 0

| | | | | |
|---|---|---|---|---|
| Linearity Range (Standard) | 77 | 694 | Linearity Limit: | |
| Linearity Range (Decreased) | ____ | ____ | Substrate Depletion: | |
| Linearity Range (Increased) | ____ | ____ | Mixed Blank Abs: | |
| R1 Blank Abs: | ____ | ____ | Uncapping Time | |
| Blank Response: | ____ | ____ | Reagent Alarm Limit: | |
| Twin Chemistry: | | | ☐ Enzyme Linear Extension | |

☐ Prozone Check ○ Rate Check ○ Antigen Addition

Q1: Q2: Q3: Q4:

PC: ABS:

5449 Research Dr. • Canton MI 48188 • USA • Phone: 734-487-8300 • Toll Free: 800-445-9853 • Fax: 734-483-1592 • www.medtestdx.com

# Direct TIBC
# Reagent Set

**CALIBRATION PARAMETERS**

**Calibrator Definition**

| | | | |
|---|---|---|---|
| Calibrator: | * | Lot No.: | * |
| Exp Date: | * | | |

| **Carousel** | **Pos** |
|---|---|
| Sample Carousel 1 | * |
| Sample Carousel 2 | |
| Sample Carousel 3 | |

**Reagent/Calibration**

| Calibrator | Pos | Lot No | Exp Date | Chem | Conc | Unit |
|---|---|---|---|---|---|---|
| Water | W | * | * | TIBC | 0 | µg/dL |
| TIBC Cal 1 | * | * | * | TIBC | * | µg/dL |
| TIBC Cal 2 | * | * | * | TIBC | * | µg/dL |

**Calibration Setup**

Chem: TIBC

Calibration Settings

| | | | |
|---|---|---|---|
| Math Model: | Multi-Point Lin | | |
| Factor: | | Replicates: | 2 |

Acceptance Limits

| | | | |
|---|---|---|---|
| Cal Time: | * | Hour | |
| Slope Diff: | --- | SD: | --- |
| Sensitivity : | --- | Repeatability: | --- |
| Deter Coeff: | --- | | |

Auto Calib.

☐ Bottle Changed ☐ Lot Changed ☐ Cal Time

It is recommended that two levels of control material be assayed daily.
* Indicates user defined parameter.

REF TIBC480

Manufactured for MedTest DX
5449 Research Drive Canton, MI 48188

2°C 8°C

IVD

**Symbol Key**

| | | | |
|---|---|---|---|
| Use by (YYYY-MM-DD) | LOT Lot and batch code | REF Catalog number | Manufacturer |
| Temperature limitation | Consult instructions for use | IVD *In vitro* diagnostic medical device | |

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