# Direct Serum Total Iron Binding Capacity (TIBC)

Cat. No.	Pack size	
210 02 050	100 tests Reagent 1 2 x 50 ml Reagent 2 1 x 16 ml Calibrator 1 x 1 ml	

## **Intended Use**

Total iron binding capacity (TIBC) reagent is intended for the in-vitro quantitative, diagnostic determination of total iron binding capacity in human serum.

#### **Background**

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 reflec changes in the body iron stores.

# **Assay Principle**

In the first step, the serum sample is added to reagent 1 (R1). R1 contains iron as ferric ion in sufficient quantity to saturate the highest anticipated TIBC in a complex with an excess of chromazurol B in acetate buffer ar pH 4.8. When the serum sample is added, the serum iron is released from transferrin because of the low pH. The iron from sample then forms a complex with the remaining excess of chromazurol B,increasing the absorbance. In the second step, reagent 2 (R2) which is strongly buffered is added. The affinity of transferrin for iron increases and the transferrin extracts iron from the iron-dye complex, decreasing the absorbance. The decrease in absorbance is directly proportional to TIBC.

# Reagents

## Reagent 1 (R1)

Acetate Buffer pH 4.8	0.4	mol/L
Chromazurol B	300	μmol/L
Surfactant	0.1	%
Non active ingredients		

# Reagent 2 (R2)

MOPs buffer pH 8.0 100 mmol/L

#### Calibrator (C)

Actual concentration is stated on the vial label

# Reagent Preparation, Storage and Stability

Reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2 – 8 °C. Once opened, the reagent is stable for 3 months at the specified temperature.

#### Calibrator:

The calibrator is vacuum sealed; therefore the vial should be reconstituted carefully with distilled water as mentioned on vial label. Close the vial carefully and allow the calibrator to stand for 30 minutes with occasional swirling . Avoid foaming! Do not shake! After reconstitution divide the calibrator into several aliquots. The tightly closed calibrator can be used within 60 days at  $-20^{\circ}$ C. Avoid repeated freeazing and thawing.

#### **Precautions and Warnings**

Do not ingest or inhalate. 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.

## Deterioration

Failure to recover control values within assigned range may indicate reagent deterioration

IVD

# Specimen Collection and Preservation

The recommended specimen is serum. Plasma specimens collected with EDTA, oxalate or citrate as anticoagulants are unsatisfactory since they bind iron, preventing its reaction with the reagent. Morning specimen is preferrable to avoid low result due to diurnal variation. The biological half life of iron in blood is few hours.

Stability: 7 days at 15 –25  $^{\circ}$ C ; 3 weeks at 2 – 8  $^{\circ}$ C; 1 year at -20  $^{\circ}$ C.

#### **Procedure**

Wavelength 630 nm
Optical path 1 cm
Assay type End point
Direction Decrease
Temperature 37 °C

	Calibrator Blank	Calibrator	Sample Blank	Sample
Reagent1	500 μl	500 µl	500 µl	500 µl
Calibrator	· 40 µl	40 µl		
Sample			40 µl	40 µl
Mix and incubate for 5 min, at 37 °C, then add R2				
Reagent	2	150 µl		150 µl
l	<b></b>			

Mix and incubate for 7 minutes then read the absorbance of the Calibrator against Calibrator Blank and absorbance of sample against sample Blank.

Calculation	A <sub>sample</sub>	
Total iron binding capacity =	A <sub>calibrator</sub>	x calibrator Conc

# **Quality Control**

Normal and abnormal commercial control serum of known concentrations should be analyzed with each run.

#### Performance Characteristics

#### Precision

Within run (Repeatability)

	TIBC		
	Level 1	Level 2	
n	20	20	
Mean (μg/dL)	200	299	
SD	2.12	1.36	
CV%	1.06	0.45	

Run to run (Reproducibility)

	TIBC		
	Level 1	Level 2	
n	20	20	
Mean (μg/dL)	203	303	
SD	2.19	1.42	
CV%	1.12	0.51	

# **Methods Comparison**

A comparison between TIBC reagents and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.983 was obtained.

#### Sensitivity

When run as recommended, the sensitivity of this assay is 70  $\mu\text{g}/\text{d}L$ 

#### Linearity

The reaction is linear up to concentration of 700  $\mu g/dl$  .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.

No significant interference up to a bilirubin level of 30 mg/dL.

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.

Pathological albumin levels more than 7 g/dL decrease the TIBC levels

# **Expected values**

TIBC			
1 day	:	134 – 318 μg/dL	(24 - 57 μmol/L)
1 week	:	190 – 324 μg/dL	(34 - 58 µmol/L)
Infants	:	151 – 340 μg/dL	(27 - 61 µmol/L)
3 – 12 months	:	290 – 436 μg/dL	(52 - 78 μmol/L)
1 – 10 years	:	262 – 497 μg/dL	(47 - 89 μmol/L)
11 – 16 years		290 – 441 μg/dL	(49 - 89 μmol/L)
Adults Women	:	274 – 497 μg/dL	(49 - 89 μmol/L)
Men		291 – 430 μg/dL	(52 - 77 μmol/L)

# Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal. \$56: dispose of this material and its container at hazardous or

special waste collection point.

**\$57:** use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety

data sheets.

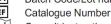
## References

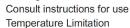
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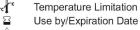
# SYMBOLS IN PRODUCT LABELLING

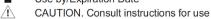
IVD LOT REF

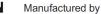
For in-vitro diagnostic use Batch Code/Lot number



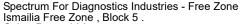












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