

BIOLABO www.biolabo.fr

MANUFACTURER: **BIOLABO SAS** Les Hautes Rives 02160, Maizy, France **U.I.B.C.** Unsaturated Iron Binding Capacity

Reagent for quantitative determination of Unsaturated Iron Binding Capacity in human serum and plasma



CE

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# **CLINICAL SIGNIFICANCE (1)**

Transport of iron from one organ to another is accomplished by a plasma transport protein called apotransferrin ( $\beta_1$ -Globulin). The **apotransferrin-Fe**<sup>3+</sup> **complex is called transferrin**. Because normally only about one third of apotransferrin is occupied by Fe<sup>3+</sup>, serum apotransferrin has considerable reserve iron binding capacity. This is called the serum Unsaturated Iron Binding Capacity (U.I.B.C.). U.I.B.C. may be used to calculate T.I.B.C. (Total Iron Binding Capacity) as follows: (T.I.B.C. = Serum Iron + U.I.B.C.).

The serum T.I.B.C. varies in disorders of iron metabolism. It is often increased in iron deficiency and decreased in chronic inflammatory disorders or malignancies, and it is often decreased also in hematochromatosis.

# **PRINCIPLE (4)**

A known quantity of Fe<sup>3+</sup> is added to saturate all iron binding sites of apotransferrin. Free iron is measured by formation of a coloured compound with Ferene in alkaline solution. The decrease in absorbance of this complex measured at 600 nm (580-620) is directly proportional to the amount of unsaturated sites of apotransferrin.

# **REAGENTS COMPOSITION**

Vial R1	UIBC BUFFER	
Tris pH 8.6	500	m
Thiourea	26	m
Surfactant	0.2	%
Preservative		
		TIC

500 mmol/L 26 mmol/L 0.2 %

#### **IRON SOLUTION** (500 µg/dl) Vial R2

Iron (89 umol/L) Hydroxylamine HCl Preservative

500 µg/dl 719 mmol/L

Dangerous for environment

R43 May cause sensitisation by skin contact Toxic to aquatic organisms R51

Avoid release to the environment. Refer to instruction/Safety Data Sheet S61 S37/39 Wear suitable gloves and eyes/face protection



CHROMOGEN

Ferene Preservative 36.8 mmol/l

# SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

IVD IN VITRO DIAGNOSTIC USE

- · Verify the integrity of the contents before use
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- . In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

#### **REAGENTS PREPARATION**

Reagents are ready for use

#### STABILITY AND STORAGE

Store at 18-25°C, well recap in the original vial and away from light.

- Iron solution (vial R2): Transfer the requested quantity, recap and store at 18-25°C.
- · When used and stored as described in the technical sheet, reagents are stable until expiry date stated on the label.
- Don't use reagents after expiry date stated on the label.

Discard reagents if cloudy or if reagent blank at 600 nm > 0.100.

## **SPECIMEN COLLECTION AND HANDLING (2)**

Serum or heparinised plasma. Analyse fresh or store at 2-8°C less than 72 h. Discard lipemic or hemolysed specimens.

Transferrin is stable in specimen for:

- 6 months at –20°C.
- indefinitely at –70°C.

## **INTERFERENCES (3)**

	(-)
Hemoglobin:	No interference.
EDTA:	Negative interference.
Total Bilirubin:	No interference.
Triglycerides:	No interference.
Lise carefully clear	ned material with HCL01 N and w

material with HCI 0.1 N and well rinsed with demineralised water. Give a special care to quality of water, reagents and/or specimens.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.

2. Normal and pathological control sera

Σ Manufacturer Use by





Ē LOT See insert Batch number



# **CALIBRATION (6)**

• Use the Iron Solution enclosed in the kit (vial R2) traceable to SRM 3126a

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

- It is recommended to calibrate in the following cases:
- 1. When using a new batch of reagent.
- 2. After maintenance operations on the instrument.
- 3. When control values obtained are out of ranges, even after using a new vial of fresh serum.

## QUALITY CONTROL

- BIOLABO EXATROL-N Level I REF 95010.
- BIOLABO EXATROL-P Level II REF 95011.
- Assayed control sera referring to the same method.
- External quality control program.
- It is recommended to control in the following cases:
- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.
- If control is out of range, apply following actions:
- Repeat the test with the same control. 1.
- If control is still out of range, prepare a fresh control serum and 2. repeat the test.
- 3 If control is still out of range, use a new vial of Iron solution R2 and repeat the test.
- If control is still out of range, calibrate with new vials of reagent 4. (vial R1, R3).
- If control is still out of range, please contact BIOLABO technical 5 support or your local Agent.

## EXPECTED VALUES (1) (2)

T.I.B.C.	μg/dL	[µmol/L]
0-4 days	186-393	[33.3-70.4]
3 months-16 years	290-515	[52.0-92.3]
16-60 years, male	307-522	[55.0-93.5]
16-60 years, femal	358-543	[64.1-97.3]
60-90 years	272-536	[48.7-96.1]
> 90 years	266-496	[47.7-88.9]

1 mg transferin binds 1.25 µg of iron.

As a screening, according to following formula:

Serum transferin (g/L) = 0.008 T.I.B.C. (µg/dL).

Confirm transferin concentration by immunochemical procedure.

Each laboratory should establish its own normal ranges for the population that it serves.

## PERFORMANCES CHARACTERISTICS

Within run N = 20	Level I	Level II	Between run N = 20	Level I	Level II
Mean µg/dL	154	149	Mean µg/dL	190	211
S.D. µg/dL	3.1	1.2	S.D.m µg/dL	8.6	5.3
C.V. %	2.02	0.79	C.V. %	4.51	2.51

approximately 10 µg/dL (1.79 µmol/L) Detection limit: Sensitivity for 200 µg/dL: approximately 0.160 Abs. at 600 nm.

## LINEARITY

U.I.B.C. measurement is linear up to 450 µg/dl (80.5 µmol/L).

Above dilute specimen with iron-free demineralised water and reassay taking into account dilution factor to calculate the result. Linearity limit depends on the reagent/specimen ratio.

## MANUAL PROCEDURE

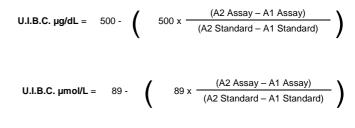
Let stand reagents and specimens at room temperature.

Pipette into well identified test tubes:	Blank	Standard	Assay	
R1: U.I.B.C. Buffer	1 mL	1 mL	1 mL	
Demineralised water	400 µL	200µL		
R2: Iron Solution		200 µL	200 µL	
Specimen			200 µL	
Mix. Read Abs. A1 at 600 nm (580-620 nm, Hg 578 nm) against reagent blank.				
R3: Chromogen	20 µL	20 µL	20 µL	
Mix. Incubate at least 6 minutes at 37°C, 8 minutes at 30°C or 20 minutes at room temperature.				
Read Abs. A2 at 600 nm (580-620 nm, Hg 578) against reagent blank.				

Specific procedures are available upon request for automated Note: instruments. Please contact BIOLABO technical support.

## CALCULATION

#### T.I.B.C. = Serum Iron + U.I.B.C.



Serum iron may be measured with BIOLABO REF 92108 (direct method) or REF 80008 (with deproteinization).

#### REFERENCES

- TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. (1) Ashwood, W.B. Saunders (1999) p. 1699-1703. Clinical Guide to Laboratory Test, 4<sup>th</sup> Ed., N.W. TIETZ (2006) p. 634-639,
- (2)
- YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4<sup>th</sup> Ed. (1995) p. (3) 3-572
- Persijn JP, Van der Silk W and Riethorst A Determination of serum Iron (4) and latent Iron-binding capacity (L.I.B.C) Clin. Chim. Acta 35, 91, 1971.
- (5) International Commitee for standardization in Haematology: the measurement of total and unsaturated iron binding capacity in serum. Br. J. Haematol., (1978), 38, p.281-294.
- SRM: Standard Reference Material ® (6)