UIBC FS*

Diagnostic reagent for quantitative in vitro determination of the unsaturated iron binding capacity in serum and plasma on photometric systems

Order Information

Cat. No.	Kit size					
1 1921 99 10 930	R1	4 x	20 mL	+ R2	2 x	10 mL
1 1920 99 10 046		3 x	1 mL	TruCal UIBC		

Summary [1,2]

The measurement of unsaturated iron binding capacity (UIBC) in combination with serum iron is a useful diagnostic tool in the determination of various iron disorders. The sum of UIBC and serum iron gives a value for the total iron binding capacity (TIBC). TIBC represents the maximum concentration of iron that serum proteins can bind. Serum UIBC levels vary in disorders of iron metabolism where iron capacities are often increased in iron deficiency and decreased in chronic inflammatory disorders or malignancies.

Method

Photometric test using Ferene

Principle

A known ferrous ion concentration incubated with sample, binds specifically with transferrin at unsaturated iron binding sites. Remaining unbound ferrous ions are measured with the ferene reaction.
The difference between the amount of excess iron and the total amount added to the serum is equivalent to the quantity bound to transferrin. This is the UIBC (unsaturated iron binding capacity) of the sample.

$2\ Fe^{2+}$ (known) + Transferrin $\longrightarrow$ Transferrin (Fe^{3+}) + Fe^{2+} (excess)

Fe^{2+}(excess) + 3 Ferene $\longrightarrow$ Ferene (blue complex)

Reagents

Components and Concentrations

R1:	Buffer	pH 8.7	100 mmol/L
	Ammonium iron (II) sulfate		13 µmol/L
	Thiourea		120 mmol/L
R2:	Ascorbic acid		240 mmol/L
	Ferene		6 mmol/L
	Thiourea		125 mmol/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents! Protect reagents from light!

Warnings and Precautions

1. Reagent 1: Danger. H318 Causes serious eye damage. P280 Wear protective gloves/protective clothing/eye protection/face protection. P314 Get medical advice/attention if you feel unwell. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
2. Use only disposable material to avoid iron contamination. Rinse glass material with diluted HCl and copious dist. water.
3. Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
4. In very rare cases, samples of patients with gammopathy might give falsified results [7].
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma
Separate serum/plasma at the latest 2 h after blood collection to avoid hemolysis.

Stability [3]

in serum:		
5 days	at	20 – 25°C
1 month	at	2 – 8°C
1 month	at	–20°C
in plasma:		
1 month	at	2 – 8°C
1 month	at	–20°C

Freeze only once!
Discard contaminated specimens!

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	600 - 620 nm, Hg 578 nm, 623 nm
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or calibrator	-	75 µL
Dist. Water	75 µL	-
Reagent 1	1000 µL	1000 µL
Mix, read absorbance A1 after 5 min., then add:		
Reagent 2	250 µL	250 µL
Mix, read absorbance A2 after exactly 5 min.		

ΔA= (A2 – 0.81 A1) Sample/cal

The factor 0.81 compensates the decrease of the absorbance by addition of reagent 2. The factor is calculated as follows: (Sample + R1)/Total volume. This compensation is necessary as a high sample volume is used.

Calculation

With calibrator

$$UIBC[\mu g/dL] = \frac{\Delta A\,Sample}{\Delta A\,Cal} \times ConcCal\ [\mu g/dL]$$

UIBC [µg/dL] x 0.1791 = UIBC [µmol/L]

TIBC [µg/dL] = UIBC [µg/dL] + Iron [µg/dL]

Transferrin [mg/dL] = 0.7 x TIBC [µg/dL]

* fluid stable

Calibrators and Controls

For calibration of automated photometric systems the DiaSys TruCal UIBC calibrator is recommended. The assigned values of the calibrator have been made traceable to a measurement of transferrin and iron. Thereby, the transferrin value is traceable to ERM®-DA470k/IFCC and the iron value is traceable to NIST SRM 682. For internal quality control DiaSys TruLab N control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range

The test has been developed to determine UIBC within a measuring range from 6 – 750 µg/dL (1 – 135 µmol/L). When values exceed the upper limit samples should be diluted 1 + 2 with NaCl solution (9 g/L) and the result multiplied by 3.

Specificity/Interferences

No interference was observed by ascorbate up to 30 mg/dL, conjugated and free bilirubin up to 60 mg/dL, lipemia up to 2000 mg/dL triglycerides, RF up to 350 IU/mL, copper up to 15 mg/dL and zinc up to 15 mg/dL.
No interference was observed in hemolytic samples with hemoglobin <200 mg/dL. With stronger hemolysis interference occurs as destroyed erythrocytes release iron.
For further information on interfering substances refer to Young DS [6].

Sensitivity/Limit of Detection

The lower limit of detection is 6 µg/dL (1 µmol/L).

Precision

Intra-assay n = 20	Mean [µg/dL]	SD [µg/dL]	CV [%]
Sample 1	65.8	1.27	1.93
Sample 2	264	3.62	1.37
Sample 3	531	8.73	1.64

Inter-assay n = 20	Mean [µg/dL]	SD [µg/dL]	CV [%]
Sample 1	170	4.43	2.61
Sample 2	263	3.61	1.37
Sample 3	475	6.31	1.33

Method Comparison

A comparison of DiaSys UIBC FS (y) with values calculated from transferrin and iron measurement (x) using 98 samples gave following results:
y = 0.985 x – 6.558 µmol/L; r = 0.993

Reference Range [4,5]

Taking into account reference values for iron and transferrin the following reference range results for UIBC: 120 – 470 µg/dL (21 – 84 µmol/L)

Each laboratory should define its own reference range for the relevant population to take into account all affecting factors.

Literature

1. Fairbanks VF, Klee GG. Biochemical aspects of hematology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1642-1710.
2. Wick M, Pingerra W, Lehmann P. Clinical aspects and laboratory. Iron metabolism, anemias. 5th ed. Wien, New York: Springer; 2003.
3. Data on file at DiaSys Diagnostic Systems GmbH.
4. Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Bienvenu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: 517-20.
5. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 273-5.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240-1243.

Manufacturer

IVD CE

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