UIBC FS*

Diagnostic reagent for quantitative in vitro determination of the unsaturated iron binding capacity in serum or plasma on BioMajesty JCA-BM6010/C

Order information

Cat. No. 1 1921 99 10 964
R1: 6 x 90 tests
R2: 6 x 90 tests

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 ⟶ Transferrin (Fe^{3+}) + Fe^{2+} (excess)

Fe^{2+}(excess) + 3 Ferene ⟶ 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! Reagent 1 and 2 should be protected from light.

Warnings and Precautions

1. Reagent 1: Danger. H318 Causes serious eye damage. P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a poison center or doctor/physician.
2. Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
3. In very rare cases, samples of patients with gammopathy might give falsified results [7].
4. 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.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

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

Discard contaminated specimens! Freeze only once!

Calibrators and Controls

For calibration DiaSys TruCal U 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
TruCal U	5 9100 99 10 064	6 x 3 mL
	5 9100 99 10 063	20 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 625 µg/dL (112 µmol/L) UIBC (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	14 µg/dL (2.5 µmol/L) UIBC
On-board stability	6 weeks
Calibration stability	2 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Bilirubin (conjugated and unconjugated) up to 60 mg/dL
Hemoglobin up to 200 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
For further information on interfering substances refer to Young DS [6].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/dL]	141	232	421
Mean [µmol/L]	25.2	41.5	75.4
Coefficient of variation [%]	1.07	0.81	1.42
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/dL]	143	231	422
Mean [µmol/L]	25.6	41.4	75.7
Coefficient of variation [%]	2.08	1.05	1.36

Method comparison (n=129)	
Test x	DiaSys UIBC FS (Hitachi 917)
Test y	DiaSys UIBC FS (BM JCA-BM6010/C)
Slope	1.01
Intercept	–6.14 µg/dL (–1.1 µmol/L)
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero
mean + 3 SD (n = 20) of an analyte free specimen

Conversion factor

UIBC [µg/dL] x 0.1791 = UIBC [µmol/L]

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 check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

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

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

BioMajesty

UIBC FS

Chemistry code 10 192

Application for serum, plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	6
Sample vol (U)	6
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	UIBC
Digits	1
M-wave L.	596
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	6	6
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9,999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9,9990
STD H	9.999
STD L	-9.999