

## UIBC FS\*

### Order Information

**Cat. No.**

1 1921 99 10 964

**Kit size**



540 (R1: 6 x 90, R2: 6 x 90)

### Intended Use

Diagnostic reagent for quantitative in vitro determination of UIBC (unsaturated iron binding capacity) in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

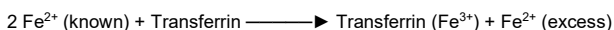
### Summary

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 [1]. 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 [2].

### Method

Photometric test using Ferene

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 of the sample.



### Reagents

#### Components and Concentrations

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

### Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

### Warnings and Precautions

- Components contained in UIBC FS are classified according to EC regulation 1272/2008 (CLP) as follows:



**⚠ Reagent 1: Danger.** Contains Dodecan-1-ol, ethoxylated and Alcohols, C9-11-iso-, C10-rich, ethoxylated. H318 Causes serious eye damage. P280 Wear protective gloves/protective clothing/eye 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/doctor.

- Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- In patients with iron supplementation, the supplement-bound iron may physiologically reduce UIBC values, limiting result interpretability.
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.

- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) 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.
- For professional use only.

### Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

### Reagent Preparation

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

### Materials Required

General laboratory equipment

### Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Separate serum/plasma at the latest 2 h after blood collection to minimize hemolysis.

Stability in serum [4]:

5 days	at	20 – 25°C
1 month	at	2 – 8°C
1 month	at	-20°C

Stability in plasma [4]:

1 month	at	2 – 8°C
1 month	at	-20°C

Only freeze once. Discard contaminated specimens.

### Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to a measurement of transferrin and iron. The transferrin value is traceable to ERM®-DA470k/IFCC and the iron value is traceable to NIST SRM 682. Use DiaSys TruLab N for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 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, linearity is given within ± 5%. 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
Onboard stability	6 weeks
Calibration stability	2 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [µg/dL]
<b>Ascorbic acid</b>	30 mg/dL	304
<b>Bilirubin</b> (conjugated)	60 mg/dL	303
<b>Bilirubin</b> (unconjugated)	60 mg/dL	303
<b>Hemolysis</b>	200 mg/dL	303
<b>Lipemia</b> (triglycerides)	2000 mg/dL	293
For further information on interfering substances, refer to the literature [5,6].		

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg/dL]	141	232	421
CV [%]	1.07	0.809	1.42
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg/dL]	143	231	422
CV [%]	2.08	1.05	1.36

Method comparison (n=129)	
Test x	DiaSys UIBC FS (Hitachi 917)
Test y	DiaSys UIBC FS (BioMajesty® JCA-BM6010/C)
Slope	1.01
Intercept	-6.14 µg/dL
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]

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

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

#### Reference Range

Taking into account reference values for iron and transferrin the following reference range results for UIBC [7,8]:

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 et al, Clinical Aspects and Lab Iron Metabolism, Anemias. Novel concepts, Springer, 5th ed. Wien New York 2003 p. 141–147.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240-1243.
4. Data on file at DiaSys Diagnostic Systems GmbH.
5. 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.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinfx.wiley.com/aaccweb/aacc/>, accessed in June 2024. Published by AACC Press and John Wiley and Sons, Inc.
7. 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.
8. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 273-5.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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\* Fluid Stable

## 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

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

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.l.	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

# entered by user