

UIBC FS*

Diagnostic reagent for quantitative in vitro determination of the unsaturated iron binding capacity in serum or plasma on Sysmex BX-Series

Order information

Cat. No.	Kit size	Number of tests
1 1921 99 10 972	R1 3 x 11.8 mL	BX-3010 3 x 90 tests BX-4000 3 x 62 tests
	R2 3 x 5.1 mL	BX-3010 3 x 90 tests BX-4000 3 x 62 tests

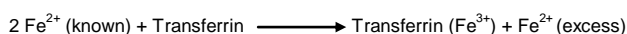
Method

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.



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

- 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.
- In very rare cases, samples of patients with gammopathy might give falsified results [7].
- 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.
- 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 750 µg/dL (134 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**	5 µg/dL (0.9 µmol/L) UIBC
On-board stability	7 days
Calibration stability	7 days

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

Interfering substance	Interferences < 10 %	Analyte concentration
Ascorbate	up to 30 mg/dL	311 µg/dL (55.7 µmol/L)
Hemoglobin	up to 90 mg/dL	144 µg/dL (25.7 µmol/L)
	up to 250 mg/dL	475 µg/dL (85.0 µmol/L)
Bilirubin, conjugated	up to 60 mg/dL	140 µg/dL (25.0 µmol/L)
	up to 60 mg/dL	434 µg/dL (77.8 µmol/L)
Bilirubin, unconjugated	up to 60 mg/dL	139 µg/dL (25.0 µmol/L)
	up to 60 mg/dL	444 µg/dL (79.4 µmol/L)
Lipemia (triglycerides)	up to 2000 mg/dL	141 µg/dL (25.3 µmol/L)
	up to 2000 mg/dL	453 µg/dL (81.2 µmol/L)

For further information on interfering substances refer to Young DS [6].

Precision (BX-3010)			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg/dL]	140	286	617
Mean [µmol/L]	25.1	51.3	110
Coefficient of variation [%]	1.86	1.39	0.69
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg/dL]	156	225	441
Mean [µmol/L]	28.0	40.3	78.9
Coefficient of variation [%]	2.94	1.81	2.02

Method comparison (n=107)	
Test x	DiaSys UIBC FS (BM JCA-BM6010/C)
Test y	DiaSys UIBC FS (BX-3010)
Slope	1.01
Intercept	–8.451 µg/dL (–1.51 µmol/L)
Coefficient of correlation	0.998

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

- 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.
- Wick M, Pingerra W, Lehmann P. Clinical aspects and laboratory. Iron metabolism, anemias. 5th ed. Wien, New York: Springer; 2003.
- Data on file at DiaSys Diagnostic Systems GmbH.
- Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Biennu 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.
- Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 273-5.
- 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.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240-1243.

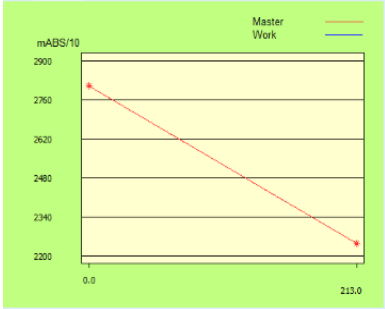
Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters				
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="UIBC"/>	Reagent Name	Reagent (µL)	Water (µL)		
Print Name	<input type="text" value="UIBC"/>	MethodColor	<input type="text" value=""/>	R1	<input type="text" value="UIBC"/>	<input type="text" value="100"/>		
Sample Type	<input type="text" value="Serum"/>			R2	<input type="text" value="UIBC"/>	<input type="text" value="25"/>		
Unit	<input type="text" value="µg/dL"/>			Diluent	<input type="text" value="Disable"/>	<input type="text" value=""/>		
Assay Type	<input type="text" value="End"/>			Sample Ppt. Wash	<input type="text" value="Disable"/>	<input type="text" value=""/>		
Measuring points		Start	End	Stirring Speed R1	<input type="text" value="Middle"/>	R2 <input type="text" value="Middle"/>		
		1	<input type="text" value="22"/> - <input type="text" value="23"/>					
		2	<input type="text" value="45"/> - <input type="text" value="46"/>					
Wave Length				Normal Range				
	Prim. <input type="text" value="600"/>	Sec. <input type="text" value="700"/>		No.	Normal Range Name	Min	Max	
				1	Male-G1	*	*	
				2	Male-G2	*	*	
				3	Male-G3	*	*	
				4	Female-G1	*	*	
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range	(Conc)	<input type="text" value="5"/>	-	<input type="text" value="750"/>
	Low <input type="text" value="0.0"/> < <input type="text" value="8.0"/> < <input type="text" value="0.0"/>	Normal <input type="text" value=""/>	High <input type="text" value=""/>		(mAbs/10)	<input type="text" value="*"/>	-	<input type="text" value="*"/>
<input type="checkbox"/> Diluent								
	Rerun (High/Prozone)							
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="8.0"/> < <input type="text" value="0.0"/>			Previous Result Comparison (%)	<input type="text" value="*"/>			<input type="text" value="*"/> %
	Rerun (Low)							
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="8.0"/> < <input type="text" value="0.0"/>			Abnormal Range	(Conc)	<input type="text" value="*"/>	-	<input type="text" value="*"/>
				Panic Range	(Conc)	<input type="text" value="*"/>	-	<input type="text" value="*"/>
				Decimal Point	<input type="text" value="0"/>	Profile SI	<input type="text" value="Disable"/>	
*Entered by user								

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="UIBC"/>	Sample	<input type="text" value="Serum"/>	
Limit Checks				Blank measurement		
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="150"/>	mAbs/10		Blank measurement:		
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="500"/>	mAbs/10		<input type="text" value="Disable reagent blank and C1 blank"/>		
<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value=""/>	%		Measurement of Reagent Blank during Run:		
	<input type="text" value=""/>	(mAbs/10)/min		<input type="text" value="None"/>		
<input type="checkbox"/> Prozone Limit	<input type="text" value="Higher"/>	%		Reagent blank measurement at calibration:		
	<input type="text" value=""/>			<input type="text" value="Reagent blank (No sample)"/>		
	SL1-S <input type="text" value=""/>	-	SL1-F <input type="text" value=""/>	The number of measurement:		
	SL2-S <input type="text" value=""/>	-	SL2-F <input type="text" value=""/>	<input type="text" value="Duplicate"/>		
	Sensitivity <input type="text" value=""/>	mAbs/10		Reagent blank limit checks:		
<input checked="" type="checkbox"/> Absorbance Limit	Abs. in reaction <input type="text" value="Increase"/>	Limit <input type="text" value="25000"/>		<input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="100"/> mAbs/10		
				Instrument Factor		
				a	<input type="text" value="1.00"/>	b <input type="text" value="0.00"/>

Calibration Registration	Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																																																
Method No. <input style="width: 80px;" type="text" value="*"/> Method Name <input style="width: 80px;" type="text" value="UIBC"/> Sample Type <input style="width: 80px;" type="text" value="Serum"/> Replication <input style="width: 80px;" type="text" value="Duplicate"/> Check Interval <input style="width: 60px;" type="text" value="10"/> Test without calibration <input style="width: 80px;" type="text" value="Disable"/> Calibration Type <input style="width: 150px;" type="text" value="Linear"/> Reagent Lot <input style="width: 60px;" type="text" value="New"/> <input style="width: 50px;" type="button" value="Add"/> Calibrator Name <input style="width: 100px;" type="text" value="TruCal UIBC"/>	Reagent Lot No. (R1) <input style="width: 80px;" type="text" value="*"/> (R2) <input style="width: 80px;" type="text" value="*"/> Last <input style="width: 100px;" type="text"/> <div style="text-align: center;">  <p>The calibration curve is lot dependent</p> </div>																																																
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 15%;">Conc.</th> <th style="width: 20%;">WORK</th> <th style="width: 20%;">MASTER</th> <th style="width: 15%;">Calibr. Lot No.</th> <th style="width: 35%;"></th> </tr> </thead> <tbody> <tr> <td>C1</td> <td>0</td> <td>Automatic entry</td> <td>Automatic entry</td> <td>*</td> <td><input type="checkbox"/> All</td> </tr> <tr> <td>C2</td> <td>*</td> <td>Automatic entry</td> <td>Automatic entry</td> <td>*</td> <td></td> </tr> <tr> <td>C3</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>C4</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>C5</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>C6</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>C7</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>K <input style="width: 60px;" type="text" value="Automatic entry"/> <input type="checkbox"/> C1 Blank <input type="checkbox"/> Reagent Blank for C1</p>		Conc.	WORK	MASTER	Calibr. Lot No.		C1	0	Automatic entry	Automatic entry	*	<input type="checkbox"/> All	C2	*	Automatic entry	Automatic entry	*		C3	*					C4	*					C5	*					C6	*					C7	*					Reagent blank <input style="width: 80px;" type="text"/> mAbs/10 Last <input style="width: 80px;" type="text"/> Blank <input style="width: 80px;" type="text" value="Automatic entry"/> mAbs/10 Last <input style="width: 80px;" type="text"/> Calibration Curve <input style="width: 80px;" type="text"/> Conc. <input style="width: 80px;" type="text"/> Absorbance <input style="width: 80px;" type="text"/> mAbs/10 <input style="width: 100px;" type="button" value="Recalculation"/>
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Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters						
Method	<input type="text" value="*"/>	Name	<input type="text" value="UIBC"/>	Reagent Name	Reagent (µL)	Water (µL)		
Print Name	<input type="text" value="UIBC"/>	R1	<input type="text" value="UIBC"/>	<input type="text" value="150"/>	<input type="text"/>	<input type="text"/>		
Sample	<input type="text" value="Serum"/>	R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="UIBC"/>	<input type="text" value="38"/>	<input type="text"/>		
Unit	<input type="text" value="µg/dL"/>							
Assay Type	<input type="text" value="End"/>	Diluent	<input type="checkbox"/> Enable	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Measuring points		Start	End	Decimal Points	<input type="text" value="0"/>			
	<input type="checkbox"/> Enable	1	<input type="text" value="33"/> - <input type="text" value="34"/>					
		2	<input type="text" value="67"/> - <input type="text" value="68"/>					
Wave Length	Prim. <input type="text" value="600"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="700"/>				
				Normal Range				
				No.	Normal Range Name	Min	Max	
				1	Male-G1	*	*	
				2	Male-G2	*	*	
				3	Male-G3	*	*	
				4	Female-G1	*	*	
Normal	Sampling	Sample (µL)	Diluent (µL)	Technical Range	(Conc)	<input type="text" value="5"/>	-	<input type="text" value="750"/>
<input type="checkbox"/>	Dilution	<input type="text" value="11.3"/>	<input type="text"/>		(mAbs/10)	<input type="text"/>	-	<input type="text"/>
<input type="checkbox"/>	Rerun (High/Prozone)	<input type="text"/>	<input type="text"/>					
<input type="checkbox"/>	Dilution	<input type="text" value="11.3"/>	<input type="text"/>					
<input type="checkbox"/>	Rerun (Low)	<input type="text"/>	<input type="text"/>					
<input type="checkbox"/>	Dilution	<input type="text" value="11.3"/>	<input type="text"/>					
				SPT Wash	<input type="checkbox"/> Enable	<input type="text"/>		
				Reagent Name	<input type="text"/>			
				Stirring Speed	R1	<input type="text" value="Middle"/>	R2	<input type="text" value="Middle"/>

*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters			
Method No.	<input type="text" value="*"/>	Name	<input type="text" value="UIBC"/>	Sample	<input type="text" value="Serum"/>
Limit Checks					
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="150"/>	mAbs/10			
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="500"/>	mAbs/10			
<input checked="" type="checkbox"/> Linearity Limit	<input type="text"/>	%	<input type="text"/>	(mAbs/10)/min	
<input type="checkbox"/> Prozone Limit	<input type="text"/>	%	<input type="text" value="Upper"/>		
	SL1-S	<input type="text"/>	-	SL1-F	<input type="text"/>
	SL2-S	<input type="text"/>	-	SL2-F	<input type="text"/>
	Sensitivity	<input type="text"/>	mAbs/10		
<input checked="" type="checkbox"/> Absorbance Limit					
	Reaction	<input type="text" value="Increase"/>			
	Limit	<input type="text" value="25000"/>	mAbs/10		
Blank measurement					
Blank measurement:					
<input type="text" value="Disable reagent blank and S1 blank"/>					
Measurement of Reagent Blank during Run:					
<input type="text" value="None"/>					
Reagent blank measurement at calibration:					
<input type="text" value="Reagent blank (No sample)"/>					
The number of measurement:					
<input type="text" value="Duplicate"/>					
Reagent blank limit checks:					
<input checked="" type="checkbox"/>	Duplicate Limit	<input type="text" value="100"/>	mAbs/10		
Instrument Factor					
	a	<input type="text" value="1.00"/>	b	<input type="text" value="0.00"/>	

Registration Calibration		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																																	
Method <input type="text" value="*"/>	Name <input type="text" value="UIBC"/>	R Lot No. R1 <input type="text" value="*"/>	Last <input type="text"/>																																
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Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All																																
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S3	*																																		
S4	*																																		
S5	*																																		
S6	*																																		
S7	*																																		
K <input type="text" value="Automatic entry"/>	<input type="checkbox"/> S1 Blank	<input type="checkbox"/> Reagent Blank for S1																																	

The calibration curve is lot dependent

Reagent blank <input type="text"/>	mAbs/10	Last <input type="text"/>
Blank <input type="text" value="Automatic entry"/>	mAbs/10	Last <input type="text"/>
Type <input type="text"/>		Conc. <input type="text"/>
Absorbance <input type="text"/>	mAbs/10	<input type="button" value="Recalculation"/>

*Entered by user