

Iron FS* Ferene

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

Order information

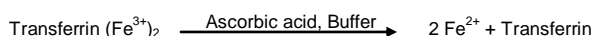
Cat. No.	Kit size	Number of tests
1 1911 99 10 972	R1 3 x 11.8 mL	BX-3010 3 x 90 tests BX-4000 3 x 62 tests
	R2 3 x 5.1 mL	BX-3010 3 x 90 tests BX-4000 3 x 62 tests

Method

Photometric test using Ferene

Principle

Iron bound to transferrin is released in an acidic medium as ferric iron and is then reduced to ferrous iron in the presence of ascorbic acid. Ferrous iron forms a blue complex with Ferene. The absorbance at 595 nm is directly proportional to the iron concentration.



Reagents

Components and Concentrations

R1:	Acetate buffer	pH 4.5	1 mol/L
	Thiourea		120 mmol/L
R2:	Ascorbic acid		240 mmol/L
	Ferene		3 mmol/L
	Thiourea		120 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, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. Reagent 1: Danger. H315 Causes skin irritation. H318 Causes serious eye damage. P264 Wash hands and face thoroughly after handling. 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. Use only disposable material to avoid iron contamination.
3. In very rare cases, samples of patients with gammopathy might give falsified results [8].
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 or heparin plasma

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

Stability [1]:

7 days	at	20 – 25 °C
3 weeks	at	4 – 8 °C
1 year	at	-20 °C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrator have been made traceable to the NIST-SRM®682 reference material. For internal quality control DiaSys TruLab N and P controls 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 10 063	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
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 1000 µg/dL (179 µmol/L) iron (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	2 µg/dL (0.358 µmol/L) iron
On-board stability	6 weeks
Calibration stability	6 weeks

** 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	87.2 µg/dL (15.6 µmol/L)
Hemoglobin	up to 15 mg/dL	17.9 µg/dL (3.21 µmol/L)
	up to 130 mg/dL	169 µg/dL (30.3 µmol/L)
Bilirubin, conjugated	up to 60 mg/dL	87.1 µg/dL (15.6 µmol/L)
Bilirubin, unconjugated	up to 60 mg/dL	87.1 µg/dL (15.6 µmol/L)
Lipemia (triglycerides)	up to 2000 mg/dL	18.0 µg/dL (3.22 µmol/L)
	up to 2000 mg/dL	171 µg/dL (30.6 µmol/L)

For further information on interfering substances refer to Young DS [7].

Precision BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg/dL]	20.2	188	282
Mean [µmol/L]	3.62	33.6	50.4
Coefficient of variation [%]	1.30	0.338	0.448
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg/dL]	20.0	188	274
Mean [µmol/L]	3.58	33.6	49.1
Coefficient of variation [%]	1.33	0.494	0.799

Method comparison (n=110)	
Test x	Iron FS Ferene (BioMajesty 6010C)
Test y	Iron FS Ferene (BX-4000)
Slope	1.02
Intercept	0.473 µg/dL (0.085 µmol/L)
Coefficient of correlation	0.9999

Conversion factor

Iron [µg/dL] x 0.1791 = [µmol/L]

Reference Range [2]

	µg/dL	µmol/L
Children		
2 weeks	63 – 201	11 – 36
6 months	28 – 135	5 – 24
12 months	35 – 155	6 – 28
2 - 12 years	22 – 135	4 – 24
Women		
25 years	37 – 165	6.6 – 29.5
40 years	23 – 134	4.1 – 24.0
60 years	39 – 149	7.0 – 26.7
Pregnant women		
12 th gestational week	42 – 177	7.6 - 31.6
at term	25 – 137	4.5 - 24.5
6 weeks postpartum	16 – 150	2.9 - 26.9
Men		
25 years	40 - 155	7.2 - 27.7
40 years	35 - 168	6.3 - 30.1
60 years	40 - 120	7.2 - 21.5

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

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 34-5.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 273-5.
3. Wick M. Iron metabolism and its disorders. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 268-73.
4. 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.
5. Higgins T. Novel chromogen for serum iron determinations. Clin Chem 1981; 27: 1619.
6. Artiss JD, Vinogradov S, Zak B. Spectrophotometric study of several sensitive reagents for serum iron. Clin Biochem 1981; 14: 311-15.
7. 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.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 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"/>	Method Name	<input type="text" value="FE"/>	Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	<input type="text" value="Iron"/>	MethodColor		R1	<input type="text" value="FE"/>	<input type="text" value="100"/>																				
Sample Type	<input type="text" value="Serum"/>			R2	<input type="text" value="FE"/>	<input type="text" value="25"/>																				
Unit	<input type="text" value="µg/dL"/>			Diluent	<input type="text" value="Disable"/>																					
Assay Type	<input type="text" value="End"/>			Sample Ppt. Wash	<input type="text" value="Disable"/>																					
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	Prim. <input type="text" value="600"/>	Sec. <input type="text" value="700"/>		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>			No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
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																						
	Low Normal High			(Conc)	<input type="text" value="2"/>	- <input type="text" value="1000"/>																				
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="6.3"/> < <input type="text" value="0.0"/>	<input type="text"/>	<input type="text"/>	(mAbs/10)	*	- *																				
<input type="checkbox"/> Rerun (High/Prozone)				Previous Result Comparison (%)	<input type="text" value="*"/>	<input type="text" value="*"/> %																				
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="6.3"/> < <input type="text" value="0.0"/>	<input type="text"/>	<input type="text"/>	Abnormal Range	(Conc) <input type="text" value="*"/>	- <input type="text" value="*"/>																				
<input type="checkbox"/> Rerun (Low)				Panic Range	(Conc) <input type="text" value="*"/>	- <input type="text" value="*"/>																				
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="6.3"/> < <input type="text" value="0.0"/>	<input type="text"/>	<input type="text"/>	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"/>	Method Name	<input type="text" value="FE"/>	Sample	<input type="text" value="Serum"/>	
Limit Checks				Blank measurement		
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="20"/>	mAbs/10		Blank measurement:		
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="400"/>	mAbs/10		<input type="text" value="Disable reagent blank and C1 blank"/>		
<input checked="" type="checkbox"/> Linearity Limit	<input type="text"/>	%		Measurement of Reagent Blank during Run:		
	<input type="text"/>	(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"/>			<input type="text" value="Reagent blank (No sample)"/>		
				The number of measurement:		
				<input type="text" value="Duplicate"/>		
	SL1-S <input type="text"/>	-	SL1-F <input type="text"/>	Reagent blank limit checks:		
	SL2-S <input type="text"/>	-	SL2-F <input type="text"/>	<input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="20"/> mAbs/10		
	Sensitivity <input type="text"/>	mAbs/10		Instrument Factor		
<input checked="" type="checkbox"/> Absorbance Limit	Abs. in reaction <input type="text" value="Increase"/>	Limit <input type="text" value="25000"/> mAbs/10		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.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

Reagent Lot

Calibrator Name

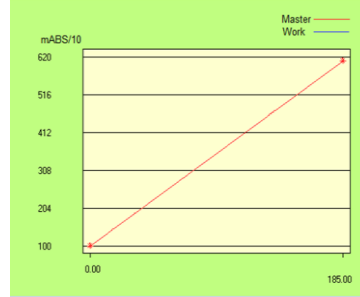
	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K C1 Blank
 Reagent Blank for C1

Reagent Lot No.

(R1)
(R2)

Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																							
Method	* <input type="text"/>	Name	<input type="text" value="FE"/>																						
Print Name	<input type="text" value="Iron"/>	R1	Reagent Name	Reagent (μL)	Water (μL)																				
Sample	<input type="text" value="Serum"/>	R2	<input type="text" value="FE"/>	<input type="text" value="150"/>	<input type="text"/>																				
Unit	<input type="text" value="μg/dL"/>	<input checked="" type="checkbox"/> Enable	<input type="text" value="FE"/>	<input type="text" value="38"/>	<input type="text"/>																				
Assay Type	<input type="text" value="End"/>	Diluent	<input type="checkbox"/> Enable	<input type="text"/>	<input type="text"/>																				
Measuring points	Start	End	Decimal Points	<input type="text" value="0"/>																					
	1	<input type="text" value="33"/> - <input type="text" value="34"/>																							
<input type="checkbox"/> Enable	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"/>																					
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No.	Normal Range Name	Min	Max																						
1	Male-G1	*	*																						
2	Male-G2	*	*																						
3	Male-G3	*	*																						
4	Female-G1	*	*																						
<input type="checkbox"/> Dilution	Normal Sampling	Sample (μL)	Diluent (μL)	Technical Range	(Conc) <input type="text" value="2"/> - <input type="text" value="1000"/>																				
<input type="checkbox"/> Dilution	<input type="text" value="9.5"/>	<input type="text"/>	<input type="text"/>	(mAbs/10)	<input type="text"/>																				
<input type="checkbox"/> Dilution	<input type="text" value="9.5"/>	<input type="text"/>	<input type="text"/>																						
<input type="checkbox"/> Dilution	<input type="text" value="9.5"/>	<input type="text"/>	<input type="text"/>																						
	SPT Wash	<input type="checkbox"/> Enable	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"/>	Name	<input type="text" value="FE"/>	Sample	<input type="text" value="Serum"/>
Limit Checks	<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="20"/>	mAbs/10		
	<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="400"/>	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="20"/>	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 Name

R Lot No. R1 Last
R2

Sample

Sampling

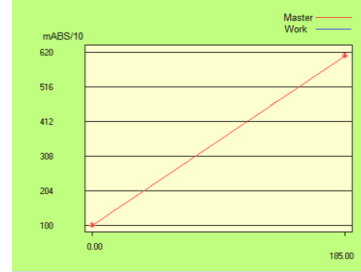
Check Interval days

Auto

Auto Interval hours

Type Lot

Material Name



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Type Conc.

Absorbance mAbs/10

	Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All
S1	<input type="text" value="0"/>	Automatic entry	Automatic entry	
S2	<input type="text" value="*"/>	Automatic entry	Automatic entry	
S3	<input type="text" value="*"/>			
S4	<input type="text" value="*"/>			
S5	<input type="text" value="*"/>			
S6	<input type="text" value="*"/>			
S7	<input type="text" value="*"/>			

K S1 Blank Reagent Blank for S1

*Entered by user