

# Bilirubin Auto Direct FS\*

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

## Order information

Cat. No.	Kit size	Number of tests
1 0821 99 10 972	R1 3 x 13.0 mL	BX-3010 3 x 100 tests
		BX-4000 3 x 69 tests
	R2 3 x 5.5 mL	BX-3010 3 x 100 tests
		BX-4000 3 x 69 tests

## Method

Photometric test using 2,4-dichloroaniline (DCA)

## Principle

Direct bilirubin in presence of diazotized 2,4-dichloroaniline forms a red colored azocompound in acidic solution.

## Reagents

### Components and Concentrations

R1:	EDTA-Na <sub>2</sub>	0.1 mmol/L
	NaCl	150 mmol/L
	Sulfamic acid	100 mmol/L
R2:	2,4-Dichlorophenyl-diazonium salt	0.5 mmol/L
	HCl	900 mmol/L
	EDTA-Na <sub>2</sub>	0.13 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

- Reagents: Warning. H290 May be corrosive to metals. P234 Keep only in original container. P390 Absorb spillage to prevent material damage.
- In very rare cases, samples of patients with gammopathy might give falsified results [6].
- Eltrombopag medication leads to falsely low or high results in patient samples.
- 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 or heparin plasma

It is very important to store the samples protected from light!

Stability [1]:

2 days	at	20 – 25°C
7 days	at	4 – 8°C
6 months	at	-20°C

in case of immediate freezing.

Freeze only once! Discard contaminated specimens

### Calibrators and Controls

For calibration the DiaSys TruCal U calibrator is recommended. This method has been standardized against the Jendrassik-Gróf method. 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 9.0 mg/dL (154 µmol/L) bilirubin (in case of higher concentrations re-measure samples after manual dilution with NaCl (9 g/L) or use rerun function)	
Limit of detection**	0.1 mg/dL (1.71 µmol/L) bilirubin
On-board stability	5 weeks
Calibration stability	3 weeks

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	0.248 mg/dL (4.24 µmol/L)
Hemoglobin	up to 10 mg/dL	0.245 mg/dL (4.17 µmol/L)
Lipemia (triglycerides)	up to 800 mg/dL	0.210 mg/dL (3.59 µmol/L)

For further information on interfering substances refer to Young DS [5].

Precision (BX-3010)			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.331	0.809	2.33
Mean [µmol/L]	5.66	13.8	39.8
Coefficient of variation [%]	3.14	1.01	1.05
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.375	0.810	1.22
Mean [µmol/L]	6.41	13.8	20.9
Coefficient of variation [%]	3.15	2.62	3.04

Method comparison (n=92)	
Test x	Bilirubin Auto Direct FS (BioMajesty 6010C)
Test y	Bilirubin Auto Direct FS (BX-3010)
Slope	0.958
Intercept	0.006 mg/dL (0.099 µmol/L)
Coefficient of correlation	0.9996

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

### Conversion factor

Bilirubin [mg/dL] x 17.1 = Bilirubin [µmol/L]

### Reference Range [2]

Adults and children ≤ 0.2 mg/dL (≤ 3.4 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

- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1<sup>st</sup> ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
- Thomas L ed. Clinical Laboratory Diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft, 1998; p. 192-202.
- Tolman KG, Rej R. Liver function. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3<sup>rd</sup> ed. Philadelphia: W.B Saunders Company; 1999. p. 1125-77.
- Rand RN, di Pasqua A. A new diazo method for the determination of bilirubin. Clin Chem 1962; 6: 570-8.
- 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. 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" value="*"/>	Method Name	<input type="text" value="DBIL"/>	Reagent Name	Reagent (μL)	Water (μL)																				
Print Name	<input type="text" value="Bilirubin direct"/>	MethodColor		R1	<input type="text" value="DBIL"/>	<input type="text" value="100"/>																				
Sample Type	<input type="text" value="Serum"/>			R2	<input type="text" value="DBIL"/>	<input type="text" value="25"/>																				
Unit	<input type="text" value="mg/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				Normal Range																						
	Prim. <input type="text" value="546"/>	Sec. <input type="text" value="660"/>		<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	(Conc)	<input type="text" value="1.0"/> - <input type="text" value="10.0"/>																				
	Low	Normal	High		(mAbs/10)	<input type="text" value="*"/> - <input type="text" value="*"/>																				
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> <	<input type="text" value="4.4"/> <	<input type="text" value="0.0"/>																							
	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="4.4"/> <	<input type="text" value="0.0"/>																							
	Rerun (Low)			Abnormal Range	(Conc)	<input type="text" value="*"/> - <input type="text" value="*"/>																				
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> <	<input type="text" value="4.4"/> <	<input type="text" value="0.0"/>																							
				Panic Range	(Conc)	<input type="text" value="*"/> - <input type="text" value="*"/>																				
				Decimal Point	<input type="text" value="2"/>	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="DBIL"/>	Sample	<input type="text" value="Serum"/>	
Limit Checks	Blank measurement					
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="50"/>	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"/>			<input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="20"/> mAbs/10		
	Limit <input type="text" value="25000"/>	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.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

Reagent Lot

Calibrator Name

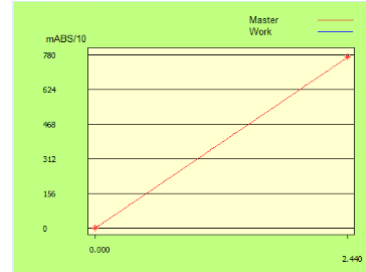
	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	<input type="text" value="0"/>	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

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

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# Bilirubin Auto Direct FS\*

Chemistry Code 100 14

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters		
Method	* <input type="text"/>	Name	<input type="text" value="DBIL"/>	
Print Name	<input type="text" value="Bilirubin direct"/>	Reagent Name	<input type="text" value="DBIL"/>	Reagent (µL)
Sample	<input type="text" value="Serum"/>	R1	<input type="text" value="150"/>	Water (µL)
Unit	<input type="text" value="mg/dL"/>	R2	<input type="text" value="38"/>	
Assay Type	<input type="text" value="End"/>	✓ Enable		
Measuring points		Diluent	<input type="text"/>	<input type="text"/>
	Start	End	Decimal Points	<input type="text" value="2"/>
	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		Normal Range		
Prim. <input type="text" value="546"/>	Sec <input type="checkbox"/> Disable <input type="text" value="660"/>	No.	Normal Range Name	Min
		1	Male-G1	*
		2	Male-G2	*
		3	Male-G3	*
		4	Female-G1	*
Normal	Sampling	Sample (µL)	Diluent (µL)	Technical Range
<input type="checkbox"/> Dilution	<input type="text" value="6.6"/>	<input type="text"/>	<input type="text"/>	(Conc) <input type="text" value="1.0"/> - <input type="text" value="10.0"/>
	Rerun (High/Prozone)			(mAbs/10) <input type="text"/> - <input type="text"/>
<input type="checkbox"/> Dilution	<input type="text" value="6.6"/>	<input type="text"/>	<input type="text"/>	
	Rerun (Low)			
<input type="checkbox"/> Dilution	<input type="text" value="6.6"/>	<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="DBIL"/>
Sample	<input type="text" value="Serum"/>		
Limit Checks	Blank measurement		
✓ Duplicate Limit	<input type="text" value="50"/> mAbs/10	Blank measurement:	
✓ Sensitivity Limit	<input type="text" value="500"/> mAbs/10	<input type="text" value="Disable reagent blank and S1 blank"/>	
✓ Linearity Limit	<input type="text"/> % <input type="text"/> (mAbs/10)/min	Measurement of Reagent Blank during Run:	
<input type="checkbox"/> Prozone Limit	<input type="text"/> % <input type="text" value="Upper"/>	<input type="text" value="None"/>	
SL1-S <input type="text"/>	-	SL1-F <input type="text"/>	Reagent blank measurement at calibration:
SL2-S <input type="text"/>	-	SL2-F <input type="text"/>	<input type="text" value="Reagent blank (No sample)"/>
Sensitivity	<input type="text"/> mAbs/10	The number of measurement:	
✓ Absorbance Limit		<input type="text" value="Duplicate"/>	
Reaction	<input type="text" value="Increase"/>	Reagent blank limit checks:	
Limit	<input type="text" value="25000"/> mAbs/10	✓ 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"/>

# Bilirubin Auto Direct FS\*

Chemistry Code 100 14

## Registration Calibration

## Sysmex BX-4000 Chemistry Analyzer Analytical Parameters

Method  Name

R Lot No. R1  Last   
R2

Sample

Sampling

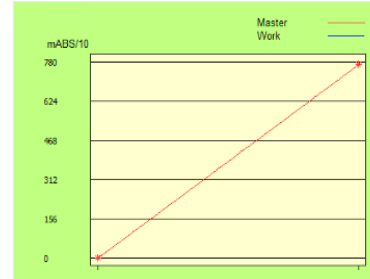
Check Interval  days

Auto

Auto Interval  hours

Type  Lot

Material Name



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

Reagent blank  mAbs/10 Last

Blank  mAbs/10 Last

Type  Conc.

Absorbance  mAbs/10

K   S1 Blank  Reagent Blank for S1

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