

Total protein FS*

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

Order information

Cat. No.	Kit size	Number of tests
1 2311 99 10 972	R1 3 x 15.8 mL	BX-3010 3 x 125 tests BX-4000 3 x 83 tests
	R2 3 x 6.5 mL	BX-3010 3 x 125 tests BX-4000 3 x 83 tests

Method

Photometric test according to biuret method

Principle

Together with copper ions, proteins form a violet blue color complex in alkaline solution. The absorbance of the color is directly proportional to the concentration.

Reagents

Components and Concentrations

R1:	Sodium hydroxide	100 mmol/L
	Potassium sodium tartrate	17 mmol/L
R2:	Sodium hydroxide	500 mmol/L
	Potassium sodium tartrate	80 mmol/L
	Potassium iodide	75 mmol/L
	Copper sulphate	30 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 – 25°C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

- Reagent 1: Warning. H290 May be corrosive to metals. P234 Keep only in original container. P390 Absorb spillage to prevent material damage.
- Reagent 2: Warning. H290 May be corrosive to metals. H315 Causes skin irritation. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects. P234 Keep only in original container. P264 Wash hands and face thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection. P332+P313 If skin irritation occurs: Get medical advice/attention. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
- In very rare cases, samples of patients with gammopathy might give falsified results [5].
- In serum or plasma from patients who have received large intravenous amounts of polydextrans too high values can be measured with the biuret method. In such cases an alternative method (e.g. Kjeldahl) has to be used.
- 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 plasma

Stability [1]:

6 days	at	20 – 25°C
4 weeks	at	4 – 8°C
at least one year	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 are traceable to the Biuret 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 15 g/dL (150 g/L) protein (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	0.01 g/dL (0.1 g/L) protein
On-board stability	2 weeks
Calibration stability	1 week

** 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	6.27 g/dL (62.7 g/L)
Hemoglobin	up to 500 mg/dL	6.31 g/dL (63.1 g/L)
Bilirubin, conjugated	up to 60 mg/dL	6.33 g/dL (63.3 g/L)
Bilirubin, unconjugated	up to 60 mg/dL	6.34 g/dL (63.4 g/L)
Lipemia (triglycerides)	up to 1000 mg/dL	6.96 g/dL (69.6 g/L)
	up to 1000 mg/dL	9.27 g/dL (92.7 g/L)
For further information on interfering substances refer to Young DS [4].		

Precision BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/dL]	3.14	6.21	8.56
Mean [g/L]	31.4	62.1	85.6
Coefficient of variation [%]	0.406	0.483	0.356
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/dL]	3.59	6.12	9.54
Mean [g/L]	35.9	61.2	95.4
Coefficient of variation [%]	0.934	0.680	0.823

Method comparison (n=106)	
Test x	Total protein FS (Biomajesty 6010C)
Test y	Total protein FS (BX-4000)
Slope	1.02
Intercept	-0.018 g/dL (0.181 g/L)
Coefficient of correlation	0.999

Reference Range [2]

	[g/dL]	
	6.6 – 8.8	
Adults	Female	Male
Children	4.2 – 6.2	4.1 – 6.3
1 – 30 day(s)	4.4 – 6.6	4.7 – 6.7
1 – 6 month(s)	5.6 – 7.9	5.5 – 7.0
6 months – 1 year	5.7 – 8.0	5.7 – 8.0

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. 42-3.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 644-7.
3. Johnson Am, Rohlf's EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 477-540.
4. 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.
5. 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.	*	Method Name	TP	Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	Total protein	MethodColor		R1	TP	100																				
Sample Type	Serum			R2	TP	25																				
Unit	g/dL			Diluent	Disable																					
Assay Type	End			Sample Ppt. Wash	Disable																					
Measuring points		Start	End	Stirring Speed R1	Middle	R2 Middle																				
		1	22 - 23																							
		2	45 - 46																							
Wave Length	Prim. 546	Sec.	Disable	<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	*	*
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2	Male-G2	*	*																							
3	Male-G3	*	*																							
4	Female-G1	*	*																							
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range																						
	Low Normal High			(Conc)	0.02	15																				
<input type="checkbox"/> Diluent	0.0 < 2.5 < 0.0			(mAbs/10)	*	*																				
<input type="checkbox"/> Rerun (High/Prozone)				Previous Result Comparison (%)	*	* %																				
<input type="checkbox"/> Diluent	0.0 < 2.5 < 0.0			Abnormal Range	(Conc) *	*																				
<input type="checkbox"/> Rerun (Low)				Panic Range	(Conc) *	*																				
<input type="checkbox"/> Diluent	0.0 < 2.5 < 0.0			Decimal Point	2	Profile SI																				
						Disable																				

*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	*	Method Name	TP	Sample	Serum	
Limit Checks <input checked="" type="checkbox"/> Duplicate Limit 50 mAbs/10 <input checked="" type="checkbox"/> Sensitivity Limit 2000 mAbs/10 <input checked="" type="checkbox"/> Linearity Limit % (mAbs/10)/min <input type="checkbox"/> Prozone Limit Higher % SL1-S - SL1-F SL2-S - SL2-F Sensitivity mAbs/10 <input checked="" type="checkbox"/> Absorbance Limit Abs. in reaction Increase Limit 25000 mAbs/10				Blank measurement Blank measurement: Disable reagent blank and C1 blank Measurement of Reagent Blank during Run: None Reagent blank measurement at calibration: Reagent blank (No sample) The number of measurement: Duplicate Reagent blank limit checks: <input checked="" type="checkbox"/> Duplicate Limit 20 mAbs/10		
				Instrument Factor a 1.00 b 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

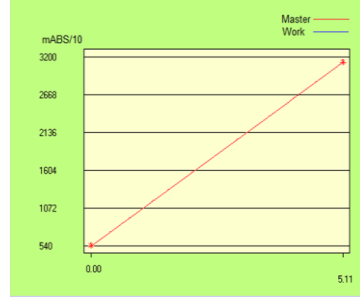
	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

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="TP"/>																																																								
Print Name	<input type="text" value="Total protein"/>		R1	<input type="text" value="TP"/>	<input type="text" value="158"/>																																																						
Sample	<input type="text" value="Serum"/>		R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="TP"/> <input type="text" value="38"/>																																																						
Unit	<input type="text" value="g/dL"/>																																																										
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="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	Prim. <input type="text" value="546"/>	Sec <input type="checkbox"/> Disable	<input type="text"/>																																																								
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				SPT Wash	<input type="checkbox"/> Enable	<input type="text" value="Reagent Name"/>																																																					
				Stirring Speed	R1	<input type="text" value="Middle"/>	R2	<input type="text" value="Middle"/>																																																			

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Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters			
Method No.	* <input type="text"/>	Name	<input type="text" value="TP"/>	Sample	<input type="text" value="Serum"/>
Limit Checks					
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="50"/>	mAbs/10			
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="2000"/>	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 <input type="text" value="*"/> Name <input type="text" value="TP"/>	R Lot No. R1 <input type="text" value="*"/> Last <input type="text"/>																																
Sample <input type="text" value="Serum"/>	R2 <input type="text" value="*"/>																																
Sampling <input type="text" value="Duplicate"/>																																	
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Material Name <input type="text" value="TruCal U"/>	The calibration curve is lot dependent																																
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Conc.</th> <th>WORK</th> <th>MASTER</th> <th>Lot No. (S) <input type="checkbox"/> All</th> </tr> </thead> <tbody> <tr> <td>S1</td> <td><input type="text" value="0"/> Automatic entry</td> <td><input type="text" value="Automatic entry"/></td> <td></td> </tr> <tr> <td>S2</td> <td><input type="text" value="*"/> Automatic entry</td> <td><input type="text" value="Automatic entry"/></td> <td></td> </tr> <tr> <td>S3</td> <td><input type="text" value="*"/></td> <td></td> <td></td> </tr> <tr> <td>S4</td> <td><input type="text" value="*"/></td> <td></td> <td></td> </tr> <tr> <td>S5</td> <td><input type="text" value="*"/></td> <td></td> <td></td> </tr> <tr> <td>S6</td> <td><input type="text" value="*"/></td> <td></td> <td></td> </tr> <tr> <td>S7</td> <td><input type="text" value="*"/></td> <td></td> <td></td> </tr> </tbody> </table>	Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All	S1	<input type="text" value="0"/> Automatic entry	<input type="text" value="Automatic entry"/>		S2	<input type="text" value="*"/> Automatic entry	<input type="text" value="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="*"/>			Reagent blank <input type="text"/> mAbs/10 Last <input type="text"/>
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