Total protein FS*

Order Information

Cat. No.	Kit size	Instrument	Σ
1 2311 99 10 972	R1 3 x 15.8 mL	BX-3010	375 (3 x 125)
		BX-4000	249 (3 x 83)
	R2 3 x 6.5 mL	BX-3010	375 (3 x 125)
		BX-4000	249 (3 x 83)

Intended Use

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

Summary

Measurement of total protein is a useful test in a variety of disorders. Decreased total protein concentrations can be detected in defective protein synthesis in the liver, protein loss due to impaired kidney function, intestinal malabsorption or nutritional deficiency. Elevated protein levels occur in chronic inflammatory disorders, liver cirrhosis and dehydration. [1,2]

Method

Photometric test according to biuret method

Proteins form a violet blue color complex with copper ions 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 and Stability

The reagents are stable up to the date of expiry indicated on the kit, if stored at 2 - 25°C and contamination is avoided. Protect reagents from light.

Warnings and Precautions

1. ⚠ Reagent 1: Warning. H290 May be corrosive to metals. P234 Keep only in original packaging. P390 Absorb spillage to prevent material damage.
2. ⚠ Reagent 2: Warning. Contains: Potassium iodide. H290 May be corrosive to metals. H315 Causes skin irritation. H319 Causes serious eye irritation. H373 May cause damage to organs through prolonged or repeated exposure. H412 Harmful to aquatic life with long lasting effects. P234 Keep only in original packaging. P273 Avoid release to the environment. 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. P314 Get medical advice/attention if you feel unwell.
3. In serum or plasma of 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.
4. In very rare cases, samples of patients with gammopathy might give falsified results [3].
5. 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.
6. For professional use only.

Waste Management

Refer to local legal requirements.

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

Stability [4]:

6 days	at	20 – 25°C
4 weeks	at	4 – 8°C
at least one year	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. TruCal U calibrator values have been made traceable to the biuret method. Use DiaSys TruLab N and P for internal quality control. 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

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 15 g/dL (150 g/L). 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)
Onboard stability	2 weeks
Calibration stability	1 week

Interfering substance	**Interferences ≤ 10% up to**	**Analyte concentration**
Ascorbic acid	30 mg/dL	6.27 g/dL (62.7 g/L)
Hemoglobin	500 mg/dL	6.31 g/dL (63.1 g/L)
Bilirubin (conjugated)	60 mg/dL	6.33 g/dL (63.3 g/L)
Bilirubin (unconjugated)	60 mg/dL	6.34 g/dL (63.4 g/L)
Lipemia (triglycerides)	1000 mg/dL	6.96 g/dL (69.6 g/L)
	1000 mg/dL	9.27 g/dL (92.7 g/L)
For further information on interfering substances refer to Young DS [5,6].		

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
CV [%]	0.406	0.483	0.356
Between day (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
CV [%]	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

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

Reference Range [1]

	[g/dL]	
Adults	6.6 – 8.8	
Children	**Female**	**Male**
1 – 30 day(s)	4.2 – 6.2	4.1 – 6.3
1 – 6 month(s)	4.4 – 6.6	4.7 – 6.7
6 months – 1 year	5.6 – 7.9	5.5 – 7.0
1 – 18 year(s)	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. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 644-7.
2. Johnson Am, Rohlfs 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.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 42-3.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Assocation 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 April 2021. Published by AACC Press and John Wiley and Sons, Inc.

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany
www.diasys-diagnostics.com

* Fluid Stable

Total protein FS

Chemistry Code 100 71

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

	Start		End
1	22	–	23
2	45	–	46

Wave Length — Prim. 546 — Sec. Disable

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Sample Volume (µL) Low	Normal	High	Diluted Sample (µL)	Diluent (µL)
☐ Diluent	0.0 <	2.5 <	0.0		
Rerun (High/Prozone) ☐ Diluent	0.0 <	2.5 <	0.0		
Rerun (Low) ☐ Diluent	0.0 <	2.5 <	0.0		

Technical Range — (Conc) 0.02 – 15 — (mAbs/10) * – *

Previous Result Comparison (%) * – * %

Abnormal Range (Conc) * – *

Panic Range (Conc) * – *

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

- ✓ Duplicate Limit 50 mAbs/10
- ✓ Sensitivity Limit 2000 mAbs/10
- ✓ Linearity Limit %
- (mAbs/10)/min
- ☐ Prozone Limit Higher %

SL1-S – SL1-F

SL2-S – SL2-F

Sensitivity mAbs/10

- ✓ 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:
✓ Duplicate Limit 20 mAbs/10

Instrument Factor

a 1.00 — b 0.00

Total protein FS

Chemistry Code 100 71

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name TP

Sample Type Serum

Replication Duplicate

Check Interval 7

Test without calibration
Disable

Calibration Type Linear

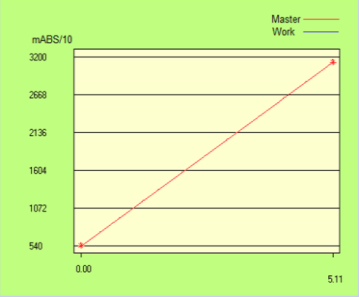
Reagent Lot New Add

Calibrator Name TruCal U

	Conc.	WORK	MASTER	Calibr. Lot No.	☐ All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K Automatic entry
☐ C1 Blank
☐ Reagent Blank for C1

Reagent Lot No.
(R1) *
(R2) *
Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10 Recalculation

***Entered by user**

Total protein FS

Chemistry Code 100 71

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method	*	Name	TP		Reagent Name	Reagent (µL)	Water (µL)
Print Name	Total protein			R1	TP	150	
Sample	Serum			R2 ✓ Enable	TP	38	
Unit	g/dL						
Assay Type	End			Diluent ☐ Enable			

Measuring points

		Start		End
	1	33	–	34
☐ Enable	2	67	–	68

Decimal Points: 2

Wave Length
Prim. 546 Sec ✓ Disable

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)
☐	Dilution	3.8		
	Rerun (High/Prozone)			
☐	Dilution	3.8		
	Rerun (Low)			
☐	Dilution	3.8		

Technical Range
(Conc) 0.02 – 15
(mAbs/10) –

SPT Wash ☐ Enable — Reagent Name

Stirring Speed R1 Middle R2 Middle

***Entered by user**

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method No. * Name TP Sample Serum

Limit Checks

✓ Duplicate Limit	50	mAbs/10	
✓ Sensitivity Limit	2000	mAbs/10	
✓ Linearity Limit		%	(mAbs/10)/min
☐ Prozone Limit		%	Upper
SL1-S		– SL1-F	
SL2-S		– SL2-F	
Sensitivity		mAbs/10	
✓ Absorbance Limit			
Reaction	Increase		
Limit	25000	mAbs/10	

Blank measurement

Blank measurement:
Disable reagent blank and S1 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:
✓ Duplicate Limit 20 mAbs/10

Instrument Factor
a 1.00 b 0.00

Total protein FS

Chemistry Code 100 71

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * Name: TP

Sample: Serum

Sampling: Duplicate

Check Interval: 7 days

Auto: Change Lot | Full Calibration

Auto Interval: hours

Type: Linear Lot: New

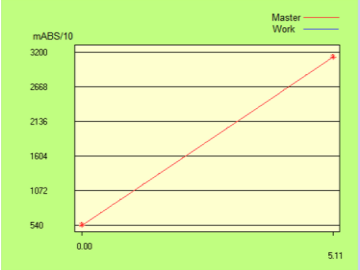
Material Name: TruCal U

	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K: Automatic entry ☐ S1 Blank ☐ Reagent Blank for S1

***Entered by user**

R Lot No. R1: * Last:
R2: *



The calibration curve is lot dependent

Reagent blank: mAbs/10 Last:

Blank: Automatic entry mAbs/10 Last:

Type: Conc.:

Absorbance: mAbs/10 Recalculation