CRP FS*

Diagnostic reagent for quantitative in vitro determination of C-reactive protein (CRP) in serum or plasma on Sysmex BX-Series

Order Information

Cat. No.	Kit size		Number of tests	
1 7002 99 10 972	R1	3 x 13.0 mL	BX-3010	3 x 100
			BX-4000	3 x 69
	R2	3 x 5.0 mL	BX-3010	3 x 100
			BX-4000	3 x 69

Method

Immunoturbidimetric test

Principle

Determination of CRP concentration by photometric measurement of antigen-antibody reaction between antibodies against human CRP and CRP present in the sample.

Reagents

Components and Concentrations

R1:	TRIS	pH 7.5	100 mmol/L
R2:	TRIS	pH 8.0	100 mmol/L
	Anti-human CRP antibodies (goat)		< 1%

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: Warning. H319 Causes serious eye irritation. 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. P337+P313 If eye irritation persists: Get medical advice/attention.
2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Reagent 2: contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
4. In very rare cases, samples of patients with gammopathy might give falsified results [8].
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 examination and other findings.
6. 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 or EDTA plasma

Stability [1]:

15 days	at	20 – 25 °C
2 months	at	4 – 8 °C
3 years	at	–20 °C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration the DiaSys TruCal CRP calibrator set is recommended. For internal quality control a DiaSys TruLab CRP or TruLab Protein control should be assayed. The assigned values of the calibrators have been made traceable to the IFCC reference material ERM®-DA474. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal CRP	1 7000 99 10 039	5 x 2 mL
TruLab CRP Level 1	5 9600 99 10 045	3 x 2 mL
TruLab CRP Level 2	5 9610 99 10 045	3 x 2 mL
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

Performance Characteristics

Measuring range up to 250 mg/L CRP, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function)

Limit of detection**	0.5 mg/L CRP
No prozone effect up to 2000 mg/L CRP	
On-board stability	11 weeks
Calibration stability	11 weeks

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	15.8 mg/L
Hemoglobin	up to 500 mg/dL	15.9 mg/L
Bilirubin, conjugated	up to 60 mg/dL	15.9 mg/L
Bilirubin, unconjugated	up to 60 mg/dL	15.6 mg/L
Lipemia (triglycerides)	up to 500 mg/dL	5.45 mg/L
	up to 2000 mg/dL	18.5 mg/L
For further information on interfering substances refer to Young DS [7].		

Precision (BX4000)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	5.93	24.6	61.7
Coefficient of variation [%]	2.57	1.69	1.22
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	6.16	24.6	59.8
Coefficient of variation [%]	3.13	1.58	2.47

Method comparison (n=129)	
Test x	DiaSys CRP FS (BioMajesty 6010/C)
Test y	DiaSys CRP FS (BX 4000)
Slope	1.02
Intercept	0.737 mg/L
Coefficient of correlation	0.996

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

Reference Range [2]

Adults < 5 mg/L

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. 24 -5.
2. Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Bienvenu 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.
3. Thompson D, Milford-Ward A, Whicher JT. The value of acute phase protein measurements in clinical practice. Ann Clin Biochem 1992; 29: 123-31.
4. Gabay C, Kushner I. Acute-phase proteins and other systemic responses to inflammation. N Engl J Med 1999; 340: 448-54.
5. Hansson LO, Lindquist L. C-reactive protein: its role in the diagnosis and follow-up of infectious diseases. Curr Opin Infect Diseases 1997; 10: 196-201.
6. Sipe JD. Acute-phase proteins in osteoarthritis. Semin Arthritis Rheum 1995; 25: 75-86.
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

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Chemistry Parameters 1

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	*	Method Name	CRP FS	Reagent Name	Reagent (µL)	Water (µL)
Print Name	CRP FS	MethodColor		R1 CRP FS	100	
Sample Type	Serum			R2 CRP FS	20	
Unit	mg/L			Diluent Disable		
Assay Type	End			Sample Ppt. Wash Disable		

Measuring points

	Start	End
1	22	23
2	45	46

Stirring Speed R1 Middle R2 Middle

Wave Length Prim. 340 Sec. 700

Normal Range

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

	Normal Sample Volume (µL) Low	Normal	High	Diluted Sample (µL)	Diluent (µL)
☐ Diluent	0.0 <	6.0 <	0.0		
Rerun (High/Prozone) ☐ Diluent	0.0 <	6.0 <	0.0		
Rerun (Low) ☐ Diluent	0.0 <	6.0 <	0.0		

Technical Range (Conc) 0.00 – 250.00 (mAbs/10) * – *

Previous Result Comparison (%) * * %

Abnormal Range (Conc) * – *

Panic Range (Conc) * – *

Decimal Point 2 Profile SI Disable

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Chemistry Parameters 2

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * Method Name CRP FS Sample Serum

Limit Checks

- ✓ Duplicate Limit 100 mAbs/10
- ✓ Sensitivity Limit 5000 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

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name CRP FS

Sample Type Serum

Replication Duplicate

Check Interval 77

Test without calibration
Disable

Calibration Type Spline

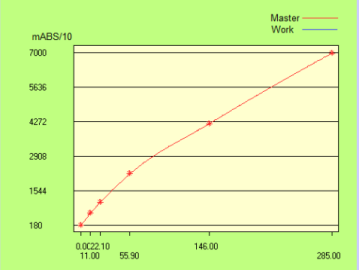
Reagent Lot New Add

Calibrator Name TruCal CRP

	Conc.	WORK	MASTER	Calibr. Lot No. ☐ All
C1	0.00	Automatic entry	Automatic entry	
C2	Enter conc Level 1			*
C3	Enter conc Level 2			*
C4	Enter conc Level 3			*
C5	Enter conc Level 4			*
C6	Enter conc Level 5			*
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

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CRP FS

Chemistry Code 100 29

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * | Name: CRP FS

Print Name: CRP FS

Sample: Serum

Unit: mg/L

Assay Type: End

	Reagent Name	Reagent (µL)	Water (µL)
R1	CRP FS	150	
R2 ✓ Enable	CRP FS	30	
Diluent ☐ Enable			

Measuring points: Start – End; Decimal Points: 2

		Start	End
	1	33	34
☐ Enable	2	67	68

Wave Length: Prim. 340 Sec ☐ Disable 700

Normal Range

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

	Sampling	Sample (µL)	Diluent (µL)
Normal ☐ Dilution	9.0		
Rerun (High/Prozone) ☐ Dilution	9.0		
Rerun (Low) ☐ Dilution	9.0		

Technical Range: (Conc) 0.00 – 250.00; (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: CRP FS | Sample: Serum

Limit Checks

- ✓ Duplicate Limit: 100 mAbs/10
- ✓ Sensitivity Limit: 5000 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

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * Name: CRP FS

Sample: Serum

Sampling: Duplicate

Check Interval: 77 days

Auto: Change Lot Full Calibration

Auto Interval: hours

Type: Spline Lot: New

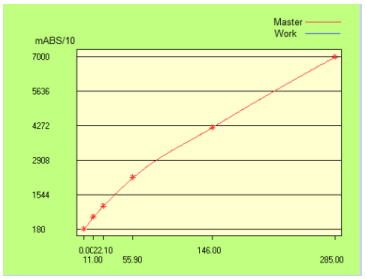
Material Name: TruCal CRP

	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0.00			
S2	Enter conc Level 1			
S3	Enter conc Level 2			
S4	Enter conc Level 3			
S5	Enter conc Level 4			
S6	Enter conc Level 5*			
S7	*			

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

***Entered by user**

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



The calibration curve is lot dependent

Reagent blank: mAbs/10 Last:

Blank: Automatic entry mAbs/10 Last:

Type: Conc.:

Absorbance: mAbs/10 Recalculation