CRP (Latex), (Normal Application), AU480/AU680

System Reagent: OSR6x99 **Reagent ID: 099**

Specific Test Parameters

General | LIH | ISE | Range

Test Name: CRP1U ▽ < > Type: Serum ▽ Operation: Yes ▽

Sample Volume		1.6 µL	Dilution	0 µL	OD Limit		
Pre-Dilution Rate		1			Min. OD	0.6	Max. OD 2.5
Reagents Volume:	R1(R1-1)	120 µL	Dilution	0 µL	Reagent OD limit:		
					First Low	-0.1	High 2.5
					Last Low	-0.1	High 2.5
	R2 (R2-1)	120 µL	Dilution	10 µL			
					Dynamic Range Low	1.0*	High 480*
					Correlation Factor A	1.0	B 0
Wavelength:	Pri.	570 nm	Sec.	None nm	Factor for Maker A	1.0	B 0
Method:		FIXED ▽					
Reaction slope:		+ ▽			Onboard Stability	90 Day	0 Hour
Measuring Point 1:	First	12	Last	22	LIH Influence Check	# ▽	
Measuring Point 2:	First		Last		Lipemia	+++++ ▽	
Linearity:		%			Icterus	+++++ ▽	
No Lag Time:		▽			Hemolysis	+++++ ▽	

Specific Test Parameters

General | | ISE | Range

Test Name: CRP1U ▽ < > Type: Serum ▽

Value/Flag: # ▽ Level L: # Level H: #

Specific Ranges:

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ▽	#	#	#	#	#	#
☐ 2.	# ▽	#	#	#	#	#	#
☐ 3.	# ▽	#	#	#	#	#	#
☐ 4.	# ▽	#	#	#	#	#	#
☐ 5.	# ▽	#	#	#	#	#	#
☐ 6.	# ▽	#	#	#	#	#	#
7. No demographics						#	#
8. Not within expected values						#	#

Panic Value

Low	High
#	#

Unit mg/L* Decimal Places #

Calibration Specific

General | ISE

Test Name: CRP1U ▽ < > Type Serum ▽ ☐ Use Serum Cal.

Calibration Type: 6AB ▽ Formula: SPLINE ▽ Counts: #

<Calibrator Parameters> Slope Check + ▽

	Calibrator †	OD	Conc*	Factor Range Low	Factor Range High
Point 1:	# ▽		0§	-0.1	2.5
Point 2:	# ▽		10†	-0.1	2.5
Point 3:	# ▽		40†	-0.1	2.5
Point 4:	# ▽		160†	-0.1	2.5
Point 5:	# ▽		320†	-0.1	2.5
Point 6:	# ▽		480†	-0.1	2.5
Point 7:	▽				
Point 8:	▽				
Point 9:	▽				
Point10:	▽				

Allowable Range Check

☐ Reagent Blank

☐ Calibration

Advanced Calibration

Operation Yes ▽

Interval (RB/ACAL) Lot / Lot ▽

<Point Cal. For Master Curve> No. of Correction Points ▽ Use Master Curve ▽ ☐ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point 1:					
Point 2:					

Stability

Reagent Blanks 90 Day 0 Hour

Calibration 90 Day 0 Hour

MB Type Factor: 1-Point Calibration Point None ▽ ☐ With CONC-0

User defined

§ Saline should be used for the Level 1 calibrator

† Beckman Coulter CRP Latex Calibrator Normal Set Cat. No.: ODC0026

* Values set for working in mg/L. To work in mg/dL divide by 10

CRP (Latex), Highly Sensitive (Cardiac/Neonatal), AU480/AU680

System Reagent: OSR6x99 — Reagent ID: 099

Specific Test Parameters — General | LIH | ISE | Range

Test Name: CRP2U ▽ < > Type: Serum ▽ Operation: Yes ▽

Sample Volume		3 µL	Dilution	0 µL	OD Limit		
Pre-Dilution Rate		1			Min. OD	-0.1	Max. OD 2.5
Reagents Volume:	R1(R1-1)	75 µL	Dilution	0 µL	Reagent OD limit:		
					First Low	-0.1	High 2.5
					Last Low	-0.1	High 2.5
	R2 (R2-1)	75 µL	Dilution	10 µL			
					Dynamic Range Low	0.2*	High 160*
					Correlation Factor A	1.0	B 0
Wavelength:	Pri.	570 nm	Sec.	None nm	Factor for Maker A	1.0	B 0
Method:		FIXED ▽					
Reaction slope:		+ ▽			Onboard Stability	90 Day	0 Hour
Measuring Point 1:	First	12	Last	22	LIH Influence Check	# ▽	
Measuring Point 2:	First		Last		Lipemia	+++++ ▽	
Linearity:		%			Icterus	+++++ ▽	
No Lag Time:		▽			Hemolysis	+++++ ▽	

Specific Test Parameters — General | | ISE | Range

Test Name: CRP2U ▽ < > Type: Serum ▽

Value/Flag: # ▽ Level L: # Level H: #

Specific Ranges:

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ▽	#	#	#	#	#	#
☐ 2.	# ▽	#	#	#	#	#	#
☐ 3.	# ▽	#	#	#	#	#	#
☐ 4.	# ▽	#	#	#	#	#	#
☐ 5.	# ▽	#	#	#	#	#	#
☐ 6.	# ▽	#	#	#	#	#	#
7. No demographics						#	#
8. Not within expected values						#	#

Panic Value — Low: # High: #

Unit: mg/L* Decimal Places: #

Calibration Specific — General | ISE

Test Name: CRP2U ▽ < > Type: Serum ▽ ☐ Use Serum Cal.

Calibration Type: 6AB ▽ Formula: SPLINE ▽ Counts: #

<Calibrator Parameters> Slope Check: + ▽

	Calibrator †	OD	Conc*	Factor Range Low	Factor Range High
Point 1:	# ▽		0§	-0.1	2.5
Point 2:	# ▽		2.5†	-0.1	2.5
Point 3:	# ▽		10†	-0.1	2.5
Point 4:	# ▽		20†	-0.1	2.5
Point 5:	# ▽		80†	-0.1	2.5
Point 6:	# ▽		160†	-0.1	2.5
Point 7:	▽				
Point 8:	▽				
Point 9:	▽				
Point10:	▽				

Allowable Range Check: ☐ Reagent Blank ☐ Calibration

Advanced Calibration: Operation: Yes ▽ Interval (RB/ACAL): Lot / Lot ▽

<Point Cal. For Master Curve> No. of Correction Points: ▽ Use Master Curve: ▽ ☐ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point 1:					
Point 2:					

Stability: Reagent Blanks 90 Day 0 Hour; Calibration 90 Day 0 Hour

MB Type Factor: 1-Point Calibration Point: None ▽ ☐ With CONC-0

User defined
§ Saline should be used for Level 1 calibrator
† Beckman Coulter CRP Latex Calibrator Highly Sensitive Set Cat. No.: ODC0027
* Values set for working in mg/L. To work in mg/dL divide by 10

CRP (Latex), (Normal Application) AU5800

System Reagent: OSR6x99 **Reagent ID: 099**

Parameters | Specific Test Parameters

General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: CRP1U ∇ < > Type: Serum ∇ Operation Yes ∇

Sample Volume		1.2 µL	Dilution	0 µL	OD Limit				
Pre-Dilution Rate		1 ∇	Diluent Bottle	# ∇		Min OD	0.6	Max.OD	2.5
Rgt. Volume	R1(R1-1)	90 µL	Dilution	0 µL	Reagent OD Limit				
	R1-2	µL	Dilution	µL	1st	Low	-0.1	High	2.5
					Last	Low	-0.1	High	2.5
	R2(R2-1)	90 µL	Dilution	10 µL					
					Dynamic Range	Low	1.0*	High	480*
Common Rgt. Type		None		None	Correlation Factor	A	1	B	0
Wavelength	Pri	570 ∇nm	Sec.	None ∇nm	Factor for Maker	A	1	B	0
Method		FIXED ∇							
Reaction Slope		+ ∇			Onboard Stability Period		90 Day	0 Hour	
Measuring Point1	1st	12	Last	22	LIH Influence Check		# ∇		
Measuring Point2	1st		Last		Lipemia		+++++ ∇		
Linearity Limit		%			Icterus		+++++ ∇		
Lag Time Check		∇			Hemolysis		+++++ ∇		

Parameters | Calibration Parameters

Calibrators | Calibration Specific

General | ISE

Test Name: CRP1U ∇ < > Type Serum ∇ Cuvette ∇

Calibration Type: 6AB ∇ Formula: SPLINE ∇ Counts: # ∇

<Calibrator Parameters>

	Calibrator	OD	Conc	Range Low	Range High
Point 1:	# ∇		0§	-0.1	2.5
Point 2:	# ∇		10†	-0.1	2.5
Point 3:	# ∇		40†	-0.1	2.5
Point 4:	# ∇		160†	-0.1	2.5
Point 5:	# ∇		320†	-0.1	2.5
Point 6:	# ∇		480†	-0.1	2.5
Point 7:	∇				
Point 8:	∇				
Point 9:	∇				
Point 10:	∇				

Slope Check + ∇

Allowance Range Check

□ Reagent Blank

□ Calibration

Advanced Calibration Operation Yes ∇

Interval (RB/ACAL) Lot/Lot ∇

<Point Cal. For Master Curve> No. of Correction Points ∇ Use Master Curve ∇ □ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point-1	∇				
Point-2	∇				

Stability: Reagent Blank 90 Day 0 Hour; Calibration 90 Day 0 Hour

MB Type Factor: 1-Point Calibration Point None ∇ o with Conc-0

Parameters | Misc

Checked Tests | Contamination Parameters | Data Check Parameters

Test Name: CRP1U ∇ < > Type: Serum ∇

Logic Check 1		Logic Check 2		Logic Check 3	
Check Point 1		Check Point 1		Check Point 1	
Check Point 2		Check Point Interval		Check Point Interval	
Check Point 3					
Decision Value 1		Decision Value 1		Decision Value 1	
Decision Value 2		Decision Value 2		Decision Value 2	
Decision Value 3					
Limit Point 1		Limit Point 1		Limit Point 1	
Limit Point 2:		Limit Point 2		Limit Point 2	
Check Pattern	∇				

User defined.

§ Saline should be used for the Level 1 calibrator

† Beckman Coulter CRP Latex calibrator Normal Set Cat. No.: ODC0026

* Values set for working in mg/L. To work in mg/dL divide by 10

CRP (Latex), Highly Sensitive (Cardiac/Neonatal)), AU5800

System Reagent: OSR6x99 **Reagent ID: 099**

Parameters | Specific Test Parameters

General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: CRP2U ∇ < > Type: Serum ∇ Operation Yes ∇

Sample Volume		2.2 µL	Dilution	0 µL	OD Limit				
Pre-Dilution Rate		1 ∇	Diluent Bottle	# ∇	Min OD	-0.1	Max.OD	2.5	
Rgt. Volume	R1(R1-1)	55 µL	Dilution	0 µL	Reagent OD Limit				
	R1-2	µ	Dilution	µL	1st	Low -0.1	High	2.5	
					Last	Low -0.1	High	2.5	
	R2(R2-1)	55 µL	Dilution	0 µL					
					Dynamic Range	Low 0.2*	High	80*	
Common Rgt. Type		None		None	Correlation Factor	A 1	B	0	
Wavelength	Pri	570 ∇nm	Sec.	None ∇nm	Factor for Maker	A 1	B	0	
Method		FIXED ∇							
Reaction Slope		+ ∇			Onboard Stability Period	90 Day	0 Hour		
Measuring Point1 1st		12	Last	22	LIH Influence Check	# ∇			
Measuring Point2 1st			Last		Lipemia	+++++ ∇			
Linearity Limit		%			Icterus	+++++ ∇			
Lag Time Check		∇			Hemolysis	+++++ ∇			

Parameters | Calibration Parameters

Calibrators | Calibration Specific

General | ISE

Test Name: CRP2U ∇ < > Type Serum ∇ Cuvette ∇

Calibration Type: 6AB ∇ Formula: SPLINE ∇ Counts: # ∇

<Calibrator Parameters>

	Calibrator	OD	Conc	Range Low	Range High
Point 1:	# ∇		0§	-0.1	2.5
Point 2:	# ∇		2.5†	-0.1	2.5
Point 3:	# ∇		10†	-0.1	2.5
Point 4:	# ∇		20†	-0.1	2.5
Point 5:	# ∇		80†	-0.1	2.5
Point 6:	# ∇		160†	-0.1	2.5
Point 7:	∇				
Point 8:	∇				
Point 9:	∇				
Point 10:	∇				

Slope Check + ∇

Allowance Range Check

□ Reagent Blank

□ Calibration

Advanced Calibration Operation Yes ∇

Interval (RB/ACAL) Lot/Lot ∇

<Point Cal. For No. of Correction Points ∇ Use Master Curve ∇ □ Lot Calibration

Master Curve>

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point-1	∇				
Point-2	∇				

Stability: Reagent Blank 90 Day 0 Hour; Calibration 90 Day 0 Hour

MB Type Factor: 1-Point Calibration Point None ∇ o with Conc-0

Parameters | Misc

Checked Tests | Contamination Parameters | Data Check Parameters

Test Name: CRP2U ∇ < > Type: Serum ∇

	Logic Check 1	Logic Check 2	Logic Check 3
	Check Point 1	Check Point 1	Check Point 1
	Check Point 2	Check Point Interval	Check Point Interval
	Check Point 3		
	Decision Value 1	Decision Value 1	Decision Value 1
	Decision Value 2	Decision Value 2	Decision Value 2
	Decision Value 3		
	Limit Point 1	Limit Point 1	Limit Point 1
	Limit Point 2:	Limit Point 2	Limit Point 2
	Check Pattern ∇		

User defined.

§ Saline should be used for the Level 1 calibrator

† Beckman Coulter CRP Latex calibrator Highly Sensitive Set Cat. No.: ODC0027

* Values set for working in mg/L. To work in mg/dL divide by 10

Name: CRP Latex (Normal), DxC 700 AU Serum Application

System Reagent: OSR6x99
Test name: CRP1U
Reagent ID: 099

General	LIH	ISE	Calculated Test	Range

Test Name: CRP1U ▼ | Test No | **Type:** Serum ▼ | Operation Yes ▼

Sample Volume		1.2 µL	Dilution	0 ▼ µL	OD Limit				
Pre-Dilution Rate		1 ▼					Min. OD	0.6000	Max OD 2.5000
Reagent Volume	R1 (R1-1)	90 µL	Dilution	0 µL	Reagent OD Limit 1st		Low	-0.1000	High 2.5000
	R1-2	µL	Dilution	µL		Last	Low	-0.1000	High 2.5000
	R2 (R2-1)	90 µL	Dilution	10 µL	Analytical Measuring Range		Low	1.0*	High 480*
Common Reagent	Type	None	Name	None	Correlation Factor		A	1	B 0
Wavelength	Pri	570 ▼ nm	Sec	None ▼ nm	Manufacturer Factor		A	1	B 0
Method		FIXED ▼							
Reaction Slope		+ ▼			Onboard Stability Period		90 Day		0 Hour
Measuring Point-1	1st	12	Last	22	LIH Influence Check		# ▼		
Measuring Point-2	1st		Last		Lipemia		+++++ ▼		
Linearity Limit		%			Icterus		+++++ ▼		
Lag Time Check		▼			Hemolysis		+++++ ▼		

General	LIH	ISE	Calculated Test	Range

Test Name: CRP1U ▼ | Test No | **Type:** Serum ▼

Value /Flag: # | Level Low: # | High: #

Specific Ranges

	Sex	From Year	From Month	To Year	To Month	Other Type	Low	High
☐ 1:	# ▼	#	#	#	#	None	#	#
☐ 2:	# ▼	#	#	#	#	None	#	#
☐ 3:	# ▼	#	#	#	#	None	#	#
☐ 4	# ▼	#	#	#	#	None	#	#
☐ 5:	# ▼	#	#	#	#	None	#	#
☐ 6:	# ▼	#	#	#	#	None	#	#
7:	Standard demographics						#	#
8:	Not within expected values						#	#

Critical Limits: Low # | High # | Unit mg/L* | Select | Decimal Places #

Calibrators	General	ISE

Test Name: CRP1U ▼ | **Type:** Serum ▼

☐ Use Serum Cal.

Calibration Type: 6AB ▼ | Formula: SPLINE ▼ | Counts: #

<Calibrator Parameters>

Slope Check: + ▼

	Calibrator	OD	Conc	Range Low	Range High
Point-1	# ▼		0§*	-0.1	2.5
Point-2	# ▼		10†*	-0.1	2.5
Point-3	# ▼		40†*	-0.1	2.5
Point-4	# ▼		160†*	-0.1	2.5
Point-5	# ▼		320†*	-0.1	2.5
Point-6	# ▼		480†*	-0.1	2.5
Point-7	▼				

Allowable Range Check
☐ Reagent Blank
☐ Calibration
Advanced Calibration Operation: Yes ▼

Interval (RB): Lot ▼

MB Type Factor | 1-Point Calibration Point: None ▼ | ☐ with Conc-0 | Interval (ACAL): Lot ▼

Stability
Reagent Blank: 90 Day 0 Hour
Calibration: 90 Day 0 Hour

User defined
§ Saline should be used for the Level 1 calibrator
† Beckman Coulter CRP Latex Calibrator Normal Set Cat. No.: ODC0026
* Values set for working mg/L. To work in mg/dL divide by 10

Name: CRP Latex (HS), DxC 700 AU Serum Application

System Reagent: OSR6x99
Test name: CRP2U
Reagent ID: 099

General | LIH | ISE | Calculated Test | Range

Test Name: CRP2U ▼ Test No **Type:** Serum ▼ Operation Yes ▼

Sample Volume		3 µL	Dilution	0 ▼ µL	OD Limit					
Pre-Dilution Rate		1 ▼						Min. OD	-0.1000	Max OD 2.5000
					Reagent OD Limit					
Reagent Volume	R1 (R1-1)	75 µL	Dilution	0 µL		1st	Low	-0.1000	High	2.5000
	R1-2	µL	Dilution	µL		Last	Low	-0.1000	High	2.5000
	R2 (R2-1)	75 µL	Dilution	10 µL	Analytical Measuring Range		Low	0.2*	High	80*
Common Reagent	Type	None	Name	None	Correlation Factor		A	1	B	0
Wavelength	Pri	570 ▼ nm	Sec	None ▼ nm	Manufacturer Factor		A	1	B	0
Method		FIXED ▼								
Reaction Slope		+ ▼			Onboard Stability Period		90	Day	0	Hour
Measuring Point-1	1st	12	Last	22	LIH Influence Check		# ▼			
Measuring Point-2	1st		Last		Lipemia		+++++ ▼			
Linearity Limit		%			Icterus		+++++ ▼			
Lag Time Check		▼			Hemolysis		+++++ ▼			

General | LIH | **ISE** | Calculated Test | **Range**

Test Name: CRP2U ▼ Test No **Type:** Serum ▼

Value /Flag # Level Low # High #

Specific Ranges

	Sex	From Year	From Month	To Year	To Month	Other Type	Low	High
☐ 1:	# ▼	#	#	#	#	None	#	#
☐ 2:	# ▼	#	#	#	#	None	#	#
☐ 3:	# ▼	#	#	#	#	None	#	#
☐ 4	# ▼	#	#	#	#	None	#	#
☐ 5:	# ▼	#	#	#	#	None	#	#
☐ 6:	# ▼	#	#	#	#	None	#	#
7:	Standard demographics						#	#
8:	Not within expected values						#	#

Critical Limits Low # High # Unit mg/L* Select Decimal Places #

Calibrators | **General** | **ISE**

Test Name: CRP2U ▼ **Type:** Serum ▼

☐ Use Serum Cal.

Calibration Type: 6AB ▼ Formula: SPLINE ▼ Counts: #

<Calibrator Parameters>

Slope Check + ▼

	Calibrator	OD	Conc	Range Low	Range High
Point-1	# ▼		0§*	-0.1	2.5
Point-2	# ▼		2.5†*	-0.1	2.5
Point-3	# ▼		10†*	-0.1	2.5
Point-4	# ▼		20†*	-0.1	2.5
Point-5	# ▼		80†*	-0.1	2.5
Point-6	# ▼		160†*	-0.1	2.5
Point-7	▼				

Allowable Range Check
□ Reagent Blank
□ Calibration
Advanced Calibration Operation Yes ▼
Interval (RB) Lot ▼

MB Type Factor 1-Point Calibration Point None ▼ □ with Conc-0 Interval (ACAL) Lot ▼

Stability
Reagent Blank 90 Day 0 Hour
Calibration 90 Day 0 Hour

User Defined
§ Saline should be used for the Level 1 calibrator
† Beckman Coulter CRP Latex Calibrator Highly Sensitive Set Cat. No: ODC0027
* Values set for working in mg/L. To work in mg/dL divide by 10