

*quantex* CRP (1 point calibration)



**Kit Configuration**

P/N 3000-2209	1 x 80 mL CRP R1
	4 x 10 mL CRP R2

**Reagent Preparation**

P/N 3000-2209	CRP R1: Ready to use
	CRP R2: Ready to use. Invert to mix well before first use. Avoid foam formation.
	Place the bottles into reagent tray.

**In Use Stability**

For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed.

**Specimen**

Serum.

**Calibration**

Use *quantex* CRP Plus standard Cat. No 300-2093. See vial label for lot specific concentration. A reagent blank should be run daily before sample analysis. Recalibrate every 15 days or when a new lot of reagent is used.

**Quality Control**

Use *quantex* ASO-CRP-RF control I Cat. No. 3000-2069. and ASO-CRP-RF control II Cat. No. 3000-2070

**Calculation of Analytical Results**

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 350 Operator Manual.

**Reference Interval**

Concentrations of CRP up to 5 mg/L are considered normal in adults.

**References / Literatur / Bibliografia / Bibliographie / Bibliografía /**

See package insert enclosed in the kit

**Performance Characteristics**

**Limitation/Interfering Substances**

No significant interference from lipemia up to sample absorbance of 3.6/cm at 660 nm (340 mg/dL triglycerides ), bilirubin up to concentrations of 30 mg/dL (510 µmol/L) and hemoglobin up to concentrations of 800 mg/dL (0.48 mmol/L).  
For a comprehensive review of interfering substances, refer to the publication by Young *et al.*<sup>1</sup>

**Precision**

	Samples/Runs	Mean (mg/L)	CV(%)	Mean (mg/L)	CV(%)
Within run	4/10	19.5	1.5	80	2.6
Total	4/10	19.5	0.9	80	1.5

**Method Comparison**

Comparison Method (x)	same reagent
Comparison Instrument (x)	Cobas Mira
Slope	1.11
y intercept	-4.8
Mean X (mg/L)	88.2
Mean Y (mg/L)	83.7
r	0.99
n	39

**Linearity**

no rerun 2.5 - 100 mg/L ; with rerun 2.5 - 1000 mg/L

**Minimun Detection Limit**

0.49mg/L

**Quantification Limit**

2.5 mg/L



**Instrument Settings**

<b>Chemistry Parameters</b>		R1	
Method	<input type="text"/>	Reagent Name	<input type="text" value="CRP"/> Volume <input type="text" value="200 μL"/>
Name	<input type="text" value="CRP"/>	R2	<input type="text" value="enable"/> <input type="text"/>
Unit	<input type="text" value="mg/dL"/>	Reagent Name	<input type="text" value="CRP"/> Volume <input type="text" value="160 μL"/>
Assay Type	<input type="text" value="End"/>	Wash	<input type="text" value="disable"/> Reagent Name <input type="text"/>
		Diluent	<input type="text" value="enable"/> Reagent Type <input type="text"/>
			Reagent Name <input type="text" value="Saline"/>
Measuring Points	1 enable	start	<input type="text" value="12"/>
		end	<input type="text" value="13"/>
	2 enable	start	<input type="text" value="25"/>
		end	<input type="text" value="26"/>
Wave Length		Decimal Points	<input type="text" value="1"/>
Prim	<input type="text" value="570"/> Sec <input type="text"/>	Technical Range (Conc)	<input type="text" value="0.0"/> <input type="text" value="100"/>
		mAbs/10	<input type="text" value="-30000"/> <input type="text" value="30000"/>
Sampling Volume	<input type="text" value="3 μL"/>	RPT Wash (R1)	<input type="text" value="Sys Water"/>
Dilution	<input type="text" value="disable"/>	(R2)	<input type="text" value="Sys Water"/>
Rerun ( High)	<input type="text" value="3 μL"/>	Instrument Factor a	<input type="text" value="1"/> b <input type="text" value="0"/>
Dilution	<input type="text" value="enable"/>	Stirring Speed	R1 <input type="text" value="high"/> R2 <input type="text" value="high"/>
Rerun ( Low)	<input type="text" value="15 μL"/> <input type="text" value="135 μL"/>		
	<input type="text" value="6 μL"/>		

**Calibration Checks**

** Duplicate Limit	<input type="text"/>	** mAbs/10	<b>Sampling Method for Standards</b>
** Sensitivity Limit	<input type="text"/>	** mAbs/10	<input checked="" type="checkbox"/> Duplicate
			<input type="checkbox"/> Triplicate
** Linearity Limit	<input type="text"/>	** %	<b>Blank measurement</b>
** Prozone Limit	<input type="text" value="upper"/>		<input checked="" type="checkbox"/> Enable Reagent blank
SL1-S	** <input type="text" value="SL1-F"/>	**	<input type="text" value="None"/>
SL2-S	** <input type="text" value="SL2-F"/>	**	<b>Reagent blank measurement at calibration</b>
Sens	<input type="text"/>	mAbs/10	<input checked="" type="checkbox"/> Reagent blank (system water)
<input checked="" type="checkbox"/> Absorbance Limit			<b>Multiplex measurement is the same as standards</b>
Reaction	<input type="text" value="Increase"/>		<b>Reagent Blank Limit Checks</b>
Limit	<input type="text" value="25000"/> mAbs/10		** Duplicate limit <input type="text" value="50"/> mAbs/10

**Calibration**

Method	<input type="text"/>	Name	<input type="text" value="CRP"/>	Interval	<input type="text" value="15"/> days
Calculation	<input type="text" value="Linear"/>				
	Conc	WORK	MASTER	Lot No	
S1	<input type="text" value="0"/>	<input type="text" value="-24"/>	<input type="text"/>	<input type="text"/>	K <input type="text" value="N/A"/>
S2	<input type="text" value="40"/>	<input type="text" value="4032"/>	<input type="text"/>	<input type="text"/>	
S3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
S4	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
S5	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
S6	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	

**Reagent Registration**

Reagent Code	<input type="text" value="0171"/>				
Reagent Name	<input type="text" value="CRP"/>				
R1	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/> mL	Volume (S)	<input type="text" value="**"/> mL
R2	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/> mL	Volume (S)	<input type="text" value="**"/> mL
		Stability Check	<input checked="" type="checkbox"/> enable	Term	<input type="text" value="**"/> days
		Stability Check	<input checked="" type="checkbox"/> enable	Term	<input type="text" value="**"/> days

\*\* Operator definable      N/A not applicable to this test      Calibration curve is only as example

*quantex* CRP (multi point calibration)



**Kit Configuration**

P/N 3000-2209	1 x 80 mL CRP R1
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**Reagent Preparation**

P/N 3000-2209	CRP R1: Ready to use
	CRP R2: Ready to use. Invert to mix well before first use. Avoid foam formation.
	Place the bottles into reagent tray.

**In Use Stability**

For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed.

**Specimen**

Serum.

**Calibration**

Use *quantex* CRP Plus standard multipoint Cat. No 300-2091. See vial label for lot specific concentrations. A reagent blank should be run daily before sample analysis. Recalibrate every 78 days or when a new lot of reagent is used.

**Quality Control**

Use *quantex* ASO-CRP-RF control I Cat. No.3000-2069. and ASO-CRP-RF control II Cat. No. 3000-2070

**Calculation of Analytical Results**

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 350 Operator Manual.

**Reference Interval**

Concentrations of CRP up to 5 mg/L are considered normal in adults.

**References / Literatur / Bibliografia / Bibliographie / Bibliografía /**

See package insert enclosed in the kit

**Performance Characteristics**

**Limitation/Interfering Substances**

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**Minimun Detection Limit**

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**Quantification Limit**

2.5 mg/L



**Instrument Settings**

<b>Chemistry Parameters</b>				<b>R1</b>			
Method	<input type="text"/>	Reagent Name	<input type="text" value="CRP"/>	Volume	<input type="text" value="200 μL"/>		
Name	<input type="text" value="CRPmp"/>	R2	<input type="text" value="enable"/>	Reagent Name	<input type="text" value="CRP"/>	Volume	<input type="text" value="160 μL"/>
Unit	<input type="text" value="mg/dL"/>	Wash	<input type="text" value="disable"/>	Reagent Name	<input type="text"/>		
Assay Type	<input type="text" value="End"/>	Diluent	<input type="text" value="enable"/>	Reagent Type	<input type="text"/>		
		Reagent Name	<input type="text" value="Saline"/>				
<b>Measuring Points</b>	1 enable	start	<input type="text" value="12"/>	<b>Decimal Points</b>	<input type="text" value="1"/>		
		end	<input type="text" value="13"/>	<b>Normal Range</b>	<input type="text" value="0"/>	<input type="text" value="5"/>	
	2 enable	start	<input type="text" value="25"/>				
		end	<input type="text" value="26"/>				
<b>Wave Length</b>							
Prim	<input type="text" value="570"/>	Sec	<input type="text"/>	<b>Technical Range (Conc)</b>	<input type="text" value="0.0"/>	<input type="text" value="100"/>	
				mAbs/10	<input type="text" value="-30000 / 30000"/>		
<b>Sampling Volume</b>	<input type="text" value="3 μL"/>						
Dilution	<input type="text" value="disable"/>	RPT Wash	(R1)	<input type="text" value="Sys Water"/>			
	<input type="text" value="μL"/>		(R2)	<input type="text" value="Sys Water"/>			
<b>Rerun ( High)</b>	<input type="text" value="3 μL"/>						
Dilution	<input type="text" value="enable"/>	<b>Instrument Factor a</b>	<input type="text" value="1"/>	<b>b</b>	<input type="text" value="0"/>		
	<input type="text" value="15 μL"/>	<input type="text" value="135 μL"/>	<b>Stirring Speed</b>	R1	<input type="text" value="high"/>		
<b>Rerun ( Low)</b>	<input type="text" value="6 μL"/>			R2	<input type="text" value="high"/>		

**Calibration Checks**

<b>** Duplicate Limit</b>	<input type="text" value="**"/>	mAbs/10	<b>Sampling Method for Standards</b>				
<b>** Sensitivity Limit</b>	<input type="text" value="**"/>	mAbs/10	<input checked="" type="checkbox"/>	Duplicate			
			<input type="checkbox"/>	Triplicate			
<b>** Linearity Limit</b>	<input type="text" value="**"/>	%					
<b>** Prozone Limit</b>	<input type="text" value="**"/>	upper	<b>Blank measurement</b>				
SL1-S	<input type="text" value="**"/>	SL1-F	<input checked="" type="checkbox"/>	Enable Reagent blank			
SL2-S	<input type="text" value="**"/>	SL2-F	<input type="text" value="None"/>				
Sens	<input type="text" value="**"/>	mAbs/10	<b>Reagent blank measurement at calibration</b>				
<b>x Absorbance Limit</b>	<input type="text" value="**"/>		<input checked="" type="checkbox"/>	Reagent blank (system water)			
Reaction	<input type="text" value="Increase"/>		<b>** Multiplex measurement is the same as standards</b>				
Limit	<input type="text" value="25000"/>	mAbs/10	<b>Reagent Blank Limit Checks</b>				
			<input type="text" value="**"/>	Duplicate limit		<input type="text" value="50"/>	mAbs/10

**Calibration**

<b>Method</b>	<input type="text"/>	<b>Name</b>	<input type="text" value="CRP"/>	<b>Interval</b>	<input type="text" value="78"/>	days
<b>Calculation</b>	<input type="text" value="Point to Point"/>					
	Conc	WORK	MASTER	Lot No		
S1	<input type="text" value="0"/>	<input type="text" value="-60"/>	<input type="text"/>	<input type="text"/>	K	<input type="text" value="N/A"/>
S2	<input type="text" value="10"/>	<input type="text" value="915"/>	<input type="text"/>	<input type="text"/>		
S3	<input type="text" value="50"/>	<input type="text" value="5780"/>	<input type="text"/>	<input type="text"/>		
S4	<input type="text" value="100"/>	<input type="text" value="12361"/>	<input type="text"/>	<input type="text"/>		
S5	<input type="text" value="150"/>	<input type="text" value="17511"/>	<input type="text"/>	<input type="text"/>		
S6	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		

**Reagent Registration**

<b>Reagent Code</b>	<input type="text" value="0171"/>							
<b>Reagent Name</b>	<input type="text" value="CRP"/>							
		<b>Volume (L)</b>	<b>Volume (S)</b>	<b>Stability Check</b>	<b>Term</b>			
R1	<input checked="" type="checkbox"/>	enable	<input type="text" value="**"/>	mL	<input checked="" type="checkbox"/>	enable	<input type="text" value="**"/>	days
R2	<input checked="" type="checkbox"/>	enable	<input type="text" value="**"/>	mL	<input checked="" type="checkbox"/>	enable	<input type="text" value="**"/>	days
** Operator definable		N/A	not applicable to this test		Calibration curve is only as example			