

## quantex CRP

### Kit Configuration

P/N 3000-2321	4 x 13 mL CRP R1
	4 x 6.5 mL CRP R2

### Reagent Preparation

P/N 3000-2321	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 rack.

### 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 3000-2093 or 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 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 300 Plus Operator's Manual.

### Reference Interval

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

### References / Literatur / Bibliografia / Bibliographie / Bibliografia /

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 or 3.8 mmol/L 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	20.5	3.8	79.3	1.8
Total	4/10	20.5	6.0	79.3	4.2

### Method Comparison

Comparison Method (x)	same reagent	same reagent
Comparison Instrument (x)	Cobas Mira	ILab 350
Slope	1.003	0.957
y intercept	0.393	1.283
Range (mg/dL)	0.0 – 182.8	2.1 – 198.8
Mean x (mg/dL)	56.6	63.2
Mean y (mg/dL)	57.2	61.7
r	0.997	0.991
Syx	4.16	7.49
n	40	27

### Linearity

3 to 100 mg/L (one-point calibration).

3 to 150 mg/L (multipoint calibration).

### Instrument Settings

Description: CRP  
 Unit: mg/dL  
 Decimals: 1  
 LIS Code: \*\*  
 Unit Factor: 1.0  
 Slope: 1.00  
 Intercept: 0.00

	Reference Range							
	LOW VALUES				HIGH VALUES			
Male:	3.0	3.0	3.0	3.0	5.0	50.0	100.0	100.0
Female:	3.0	3.0	3.0	3.0	5.0	50.0	100.0	100.0
Children:	3.0	3.0	3.0	3.0	5.0	50.0	100.0	100.0
	Low Alert	Very Low	Low	Normal Values	High	Very High	High Alert	
Rerun:	No	No				No	No	No

Reaction Type: End Point  
 Direction: None  
 E.P. Limit (abs): 1.0000  
 Depl Limit (abs): N/A  
 First Limit (abs): N/A  
 Linear Factor: N/A  
 Fit: N/A

	Parameter				
	Predilut.->	S.+R. 1->	Reag. 2 ->	Reag. 3 ->	Incubation ->
Times (sec):		0	0	0	296
Dil./Rgt. Code:		CRP R1	CRP R2		*) = kinetic
Lot Number:					Filter 1 (nm): 340
Ratio/Vol. (ul):	1/1	300	160	0	Filter 2 (nm): (none)
Rinse (ul):		0	0	0	Bicr. Factor: 1.00
Sample (ul):		3			

Lin Limit. Low: 3  
 High: 100.0  
 Rerun when Over: No

RBL Min (abs): -0.2000  
 Max (abs): 2.5000

Calculation Model: Standard  
 Factor: N/A  
 Sample Blank: Yes

RBL Stability (days): 15  
 Calibration Stab. (days): 15  
 Dynamic Controls (min): None

\*\* Operator definable  
 N/A Not applicable to this test