

quantex CRP ULTRA SENSITIVE



Kit Configuration

P/N 3000-2297	1 x 13 mL CRP-US R1
	1 x 13 mL CRP-US R2

Reagent Preparation

P/N 3000-2297 CRP-US R1: Ready to use
 CRP-US 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 ULTRA SENSITIVE standard multipoint Cat. No 300-2298. See vial label for lot specific concentrations. A reagent blank should be run daily before sample analysis. Recalibrate every 14 days or when a new lot of reagent is used.

Quality Control

Use quantex CRP ULTRA SENSITIVE control Cat. No.3000-2299.

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 300 µg/dL are considered normal in adults.

References / Literatur / Bibliografia / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No interference from triglycerides up to 1500 mg/dL (17 mmol/L), bilirubin up to concentrations of 30 mg/dL (510 µmol/L), hemoglobin up to concentrations of 500 mg/dL (0.3 mmol/L), and Rheumatoid factor up to 500 IU/mL.

For a comprehensive review of interfering substances, refer to the publication by Young *et al.*¹

Precision

	Samples/Runs	Mean (µg/dL)	CV(%)
Within run	4/10	172.7	4.0
Total	4/10	172.7	4.9

Method Comparison

Comparison Method and Instrument (x)	Latex assay
Slope	1.003
y intercept	0.018
Mean X (µg/dL)	24.63
Mean Y (µg/dL)	34.58
r	0.999
n	156

Linearity

no rerun 40 - 2000 µg/dL ; with rerun 40 - 40000 µg/dL

Minimum Detection Limit

28.6 µg/dL

Quantification Limit

40 µg/dL



Instrument Settings

Chemistry Parameters				R1			
Method	<input type="text"/>	Reagent Name	<input type="text" value="CRPus"/>	Volume	<input type="text" value="105 μL"/>		
Name	<input type="text" value="CRPus"/>	R2	<input type="text" value="enable"/>				
Unit	<input type="text" value="μg/dL"/>	Reagent Name	<input type="text" value="CRPus"/>	Volume	<input type="text" value="105 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" value="Saline"/>
Measuring Points	1 enable	start	<input type="text" value="14"/>	Decimal Points	<input type="text" value="2"/>		
		end	<input type="text" value="15"/>	Normal Range	<input type="text" value="0"/>	<input type="text" value="300"/>	
	2 enable	start	<input type="text" value="25"/>				
		end	<input type="text" value="26"/>				
Wave Length				Technical Range (Conc)	<input type="text" value="0.0"/>	<input type="text" value="2000"/>	
Prim	<input type="text" value="570"/>	Sec	<input type="text"/>	mAbs/10	<input type="text" value="-30000 / 30000"/>		
Sampling Volume	<input type="text" value="5 μL"/>			RPT Wash (R1)	<input type="text" value="Sys Water"/>		
Dilution	<input type="text" value="disable"/>	μL	<input type="text"/>	(R2)	<input type="text" value="Sys Water"/>		
Rerun (High)	<input type="text" value="5 μL"/>			Instrument Factor a	<input type="text" value="1"/>	b	<input type="text" value="0"/>
Dilution	<input type="text" value="enable"/>	10 μL	<input type="text" value="190 μL"/>	Stirring Speed	R1 <input type="text" value="high"/>	R2	<input type="text" value="high"/>
Rerun (Low)	<input type="text" value="10 μL"/>						

Calibration Checks

** Duplicate Limit	<input type="text" value="**"/>	mAbs/10	Sampling Method for Standards				
** Sensitivity Limit	<input type="text" value="**"/>	mAbs/10	<input checked="" type="checkbox"/> Duplicate				
			<input type="checkbox"/> Triplicate				
** Linearity Limit	<input type="text" value="**"/>	%	Blank measurement				
** 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	Reagent blank measurement at calibration				
Sens	<input type="text" value="**"/>	mAbs/10	<input checked="" type="checkbox"/> Reagent blank (system water)				
<input checked="" type="checkbox"/> Absorbance Limit			Multiplex measurement is the same as standards				
Reaction	<input type="text" value="Increase"/>						
Limit	<input type="text" value="25000"/>	mAbs/10	Reagent Blank Limit Checks				
				<input type="text" value="**"/>	Duplicate limit	<input type="text" value="50"/>	mAbs/10

Calibration

Method	<input type="text"/>	Name	<input type="text" value="CRPus"/>	Interval	<input type="text" value="14"/>	days
Calculation	<input type="text" value="Point to Point"/>					
	Conc	WORK	MASTER	Lot No		
S1	<input type="text" value="0"/>	<input type="text" value="12"/>	<input type="text"/>	<input type="text"/>	K	<input type="text" value="N/A"/>
S2	<input type="text" value="50"/>	<input type="text" value="110"/>	<input type="text"/>	<input type="text"/>		
S3	<input type="text" value="150"/>	<input type="text" value="306"/>	<input type="text"/>	<input type="text"/>		
S4	<input type="text" value="500"/>	<input type="text" value="1152"/>	<input type="text"/>	<input type="text"/>		
S5	<input type="text" value="1000"/>	<input type="text" value="2719"/>	<input type="text"/>	<input type="text"/>		
S6	<input type="text" value="2000"/>	<input type="text" value="6635"/>	<input type="text"/>	<input type="text"/>		

Reagent Registration

Reagent Code	<input type="text" value="0188"/>						
Reagent Name	<input type="text" value="CRPus"/>						
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		