quantex CRP (1 point calibration)

CE

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.
On Board: 14 days

Specimen

Serum.

Calibration

Use quantex CRP Plus standard Cat. No 3000-2093.See vial label for lot specific concentration. 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 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 600/650 Operator's Manual.

Reference Interval

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

References / Literatur / Bibliografía / 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.*[1]

Precision

	Samples/Runs	Mean (mg/L)	CV(%)	Mean (mg/L)	CV(%)
Within run	5/6	18.0	2.5	71.4	0.8
Total	5/6	18.0	1.7	71.4	1.4

Method Comparison

Comparison method	Same reagent
Comparison instrument (x)	ILab 900/1800
Slope	0.975
y intercept	-0.95
Range (mg/L)	0 - 400
Mean X (mg/L)	83.8
Mean Y (mg/L)	80.8
r	0.997
Syx	8.41
n	59

Linearity

no rerun 3 - 100 mg/L ; with rerun 3 - 600 mg/L

Instrumentation Laboratory
Instrumentation Laboratory SpA – V.le Monza 338 – 20128 Milano (Italy))
Instrumentation Laboratory Company - Lexington, MA 02421-3125 (USA)

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Instrument Settings

Photometric Test Parameters		***Serum***
Test No.		**
Test Name, Test Code		CRP, CRP
Sample Type		Serum
Reporting Unit, Decimal Points		mg/L, 1
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 17/33
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelenght		570
Sampling Conditions		
Sampling 1	Sample Vol.	3
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	3
	Sample/Diluent Vol.	10/90
Sampling 3	Sample Vol.	***
	Sample/Diluent Vol.	0/0
Sampling 4		***
Diluent Code		Saline
Diluent Warning Limit		***
First Run		Sampling 1
Below/Above Normal Range		***
Panic L		***
Panic H		Sampling 2
Noise		***
Prozone		N/A
High!, ABS!		Sampling 2
Sample Volume Reduction		**
Reagent Volumes		
R1	Code	01711
	Rgt/Dil. Vol. Stirring	200/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	14
R2	Code	01712
	Rgt/Dil. Vol. Stirring	160/10, ON
	Low Vol. Warning Limit	***
	Stability (days)	14

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	0 - 5**
Normal Range-Female	0 - 5**
Normal Range-Other	0 - 5**
Valid Range	0 - 100
Hemolysis/Icterus/Lipemia Limit	***
Reaction Slope	Positive
Absorbance Limit	Above, 3200
Prozone Limit	N/A
Non Linear Limit	N/A
Slope/Intercept Correction	1/0
Qualitative Report	OFF
Calibration Conditions	
Calibration	1 Point, Linear, 2 Reps
Stability (days)	14
Calibrator, Concentration	Std. CRP, 40
R-Blank Limit (mAbs)	900
Cal. Reps Range (%)	***
Min Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	N/A
Reagent Blank	ON
Auto R-Blank by Bottle	ON

*	Lot dependent
**	operator definable
***	optional
N/A	not applicable to this test

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