quantex CRP ULTRA SENSITIVE

CE

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.
On board: 14 days.

Specimen

Serum.

Calibration

Use quantex CRP ULTRA SENSITIVE standard multipoint Cat. No 3000-2298.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 600/650 Operator's Manual.

Reference Interval

Concentrations of CRP up to 300 μg/dL are considered normal in adults.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No interference from triglycerides up to 1500 mg/dL (16.9 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	3/10	157	1.8
Total	3/10	157	3.5

Linearity

no rerun 50 - 2000 μg/dL ; with rerun 50 - 52000 μg/dL

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 US, CRP US
Sample Type		Serum
Reporting Unit, Decimal Points		mg/L, or µg/dL, 0
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 19/33
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelenght		570
Sampling Conditions		
Sampling 1	Sample Vol.	5
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	5
	Sample/Diluent Vol.	15/375
Sampling 3	Sample Vol.	10
	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	01881
	Rgt/Dil. Vol. Stirring	105/10, ON
	Low Vol. Warning Limit	***
	Stability (days)	14
R2	Code	01882
	Rgt/Dil. Vol. Stirring	105/10, ON
	Low Vol. Warning Limit	***
	Stability (days)	14

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	**
Normal Range-Female	**
Normal Range-Other	**
Valid Range	0-2000
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	5 Points, point to point, 2 Reps
Stability (days)	14
Calibrator, Concentration	CRP-US Std, 50, 150,500, 1000,2000*
R-Blank Limit (mAbs)	1200
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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