quantex RF plus

CE

Kit Configuration

P/N 3000-2255	1 x 75 mL RF R1 2 x 6 mL RF R2

Reagent Preparation

P/N 3000-2255 RF R1: Ready to use.
RF 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: 30 days.

Specimen

Serum.

Calibration

Use quantex RF Plus standard Cat. No 3000-2252. The calibrator contains 200 IU/mL of RF. Serial dilution of standard with saline automatically by instrument as follows: 0 IU/mL (saline) 25, 50, 100 and 200 IU/mL (undiluted standard). A reagent blank should be run dasily before sample analisys. Recalibrate every 7 days or when a new lot of reagent is used.

Quality Control

Use quantex ASO/CRP/RF Control I Cat. No. 3000-2069 and quantex 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

Results of RF lower than 30 IU/mL are considered normal.[/] Results between 30 to 50 IU/mL are considered weakly positive.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No significant interference from lipemia up to a sample absorbance of 1.0/cm at 660 nm or 300 mg/dL triglycerides (3.39 mmol/L) bilirubin up to concentrations of 33 mg/dL (560 μmol/L) , hemoglobin up to concentrations of 150 mg/dL (0.09 mmol/L). For a comprehensive review of interfering substances, refer to the publication by Young *et al.*[1]

Precision

	Samples/Runs	Mean (IU/mL)	CV(%)	Mean (IU/mL)	CV(%)
Within run	5/6	40.2	1.2	143.3	1.0
Total	5/6	40.2	1.9	143.3	1.6

Method Comparison

Comparison Method	Same reagent
Comparison Instrument (x)	ILab 900/1800
Slope	0.97
y intercept	-8.5
Range x	1-1073
Mean x (IU/mL)	170
Mean y (IU/mL)	156
r	0.975
Syx	55.3
n	56

Linearity

no rerun 25 - 200 IU/mL ; with rerun 25 - 1600 IU/mL

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		RF, RF
Sample Type		Serum
Reporting Unit, Decimal Points		IU/mL, 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.	6
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	8
	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	01731
	Rgt/Dil. Vol. Stirring	190/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	30
R2	Code	01732
	Rgt/Dil. Vol. Stirring	40/10, ON
	Low Vol. Warning Limit	***
	Stability (days)	30

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	0 - 30 **
Normal Range-Female	0 - 30 **
Normal Range-Other	0 - 30 **
Valid Range	0** - 200
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)	7
Calibrator, Concentration	Std RF, *
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