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.

Specimen

Serum.

Calibration

Use quantex RF Plus standard Cat. No 300-2252. 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 90 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 350 Operator 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	4/10	50	1.2	131	2.3
Total	4/10	50	2.6	131	3.1

Method Comparison

Comparison Method (x)	Quantex RF Plus
Comparison Instrument (x)	Cobas Mira
Slope	1.00
y intercept	0.0629
Mean X (IU/mL)	172
Mean Y (IU/mL)	171
r	0.99
n	40

Linearity

no rerun 21 - 200 IU/mL ; with rerun 21 - 2000 IU/mL

Minimun Detection Limit

2 IU/mL

Quantification Limit

21 IU/mL

Instrumentation Laboratory

Instrumentation Laboratory SpA – V.le Monza 338 – 20128 Milano (Italy)
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Instrument Settings

Chemistry Parameters				**R1**			
Method				**Reagent Name**	RF	**Volume**	190 µL
Name	RF			**R2**	enable		
				Reagent Name	RF	**Volume**	40 µL
				Wash	disable	**Reagent Name**	
Unit	IU/mL					**Reagent Type**	
Assay Type	End			**Diluent**	enable	**Reagent Name**	Saline

Measuring Points	**1** enable	start	12	**Decimal Points**	1	
		end	13			
	2 enable	start	25	**Normal Range**	0	30
		end	26			

Wave Lenght							
Prim	570	**Sec**		**Technical Range (Conc)**	0.0	200	
				mAbs/10	-30000 / 30000		
Sampling Volume	6 µL						
Dilution	disable			**RPT Wash**	(R1)	Sys Water	
	µL	µL			(R2)	Sys Water	
Rerun (High)	6 µL						
Dilution	enable			**Instrument Factor a**	1	**b**	0
	15 µL	135 µL		**Stirring Speed**	R1 high	R2	high
Rerun (Low)	12 µL						

Calibration Checks

**	**Duplicate Limit**	**	mAbs/10	**Sampling Method for Standards**	
**	**Sensitivity Limit**	**	mAbs/10	x	Duplicate
					Tripicate
**	**Linearity Limit**	**	%		
				Blank measurement	
**	**Prozone Limit**	** upper		x	Enable Reagent blank
	SL1-S	** SL1-F **		None	
	SL2-S	** SL2-F **		**Reagent blank measurement at calibration**	
	Sens	**	mAbs/10	x	Reagent blank (system water)
x	**Absorbance Limit**			**	**Multiplex measurement is the same as standards**
	Reaction	Increase			
	Limit	25000	mAbs/10	**Reagent Blank Limit Checks**	
				**	Duplicate limit 50 mAbs/10

Calibration

Method		**Name**	RF	**Interval**	90	**days**	
Calculation	Point to Point						

	Conc	WORK	MASTER	Lot No
S1	0	8		
S2	25	838		
S3	50	3687		
S4	87.5	7471		
S5	200	16027		
S6				

K N/A

Calibtation (2/2) Autodilution

Serial Dilution x enable disable **Claculation** Point to Point

	Conc	**Post Sampling (µL)**	**Pre Sampling (µL)**	**Diluent(µL)**
S1	0	6	0	80
S2	25	6	10	70
S3	50	6	20	60
S4	87.5	6	35	45
S5	200	6	0	0
S6				

Reagent Registration

Reagent Code 0173

Reagent Name RF

			Volume (L)		Volume (S)		Stability Check		Term	
R1	x	enable	**	mL	**	mL	x	enable	**	days
R2	x	enable	**	mL	**	mL	x	enable	**	days

** Operator definable N/A not applicable to this test Calibration curve is only as example

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