

quantex RUBELLA



Kit Configuration

P/N 3000-2180	2 x 5 mL RUBE R1
	2 x 4 mL RUBE R2

Reagent Preparation

P/N 3000-2180 RUBE R1: Ready to use.
 RUBE R2: Reconstitute with 4 mL of NCCLS Type II water. Allow the reconstituted reagent to stand for 30 minutes 30 minutes. Invert to mix before use. Transfer the reagent in an empty vial.
 Place the bottles into reagent tray.

In Use Stability

RUBE R1: Until Expiration date. RUBE R2: 30 days stored at 2-8°C
 For optimal stability remove reagents from the system immediately after use, and store them at 2-8°C in the original vial securely closed.

Specimen

Serum.

Calibration

Use quantex RUBELLA standard Cat. No 300-2188. The calibrator concentration is indicated on the vial label. Instrument will perform autodilution of standard (SS). Recalibrate every 90 days or when a new lot of reagent is used.

Quality Control

Use quantex RUBELLA Control Cat. No. 3000-2189.

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.

Interpretation of results

Result	Interpretation
< 6 IU/mL	Negative
6-10 IU/mL	Doubtful
> 10 IU/mL	Positive

Concentrations of rubella antibodies:

- Under 6 IU/mL: Should be interpreted as absence of antibodies to rubella virus. In this case, the individual can be infected or reinfected by the virus. If the serum corresponds to a pregnant woman it is recommended to repeat the test monthly, specially within the first trimester, in order to detect a possible seroconversion.
- Between 6 and 10 IU/mL: Should be interpreted as presence of antibodies to RUBELLA virus but at too weak level to confirm their protection against re-infection.
- Over 10 IU/mL: Should be interpreted as presence of antibodies to rubella virus in the serum. This indicates previous exposure to the virus and the immunization of the individual against it. The diagnosis of acute rubella infection should be confirmed serologically by the presence of specific IgM antibody.

Reference Interval

See Package insert enclosed in the kit.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No interference has been observed in hemolyzed or icteric serum. Very lipemic or turbid samples should be clarified by high speed centrifugation before running the assay. To study possible interferences, samples with potential risk of producing cross reaction were tested, including sera positive for rheumatoid factor (RF), anti-nuclear antibodies (ANA) and from pregnant women. No evidences of interference were observed. For a comprehensive review of interfering substances, refer to the publication by Young *et al.*¹

Precision

	Samples/Runs	Mean (IU/mL)	CV(IU/mL)
Within run	4/10	37	2.5
Total	4/10	37	3.9

Method Comparison

Comparison Method (x)	Quantex Rubella
Comparison Instrument (x)	Cobas Mira
Slope	0.942
y intercept	9.89
Mean X (IU/mL)	161
Mean Y (IU/mL)	161
r	0.975
n	134

Linearity

no rerun 5- 160 IU/mL ; with rerun5- 1600 IU/mL

Minimun Detection Limit

5 IU/mL

Quantification Limit

5 IU/mL



Instrument Settings

Chemistry Parameters		R1	
Method	<input type="text"/>	Reagent Name	<input type="text" value="RUBE"/> Volume <input type="text" value="120 μL"/>
Name	<input type="text" value="RUBE"/>	R2	<input type="text" value="enable"/>
Unit	<input type="text" value="IU/mL"/>	Reagent Name	<input type="text" value="RUBE"/> Volume <input type="text" value="80 μL"/>
Assay Type	<input type="text" value="End"/>	Wash	disable Reagent Name <input type="text"/>
			Reagent Type <input type="text"/>
		Diluent	enable Reagent Name <input type="text" value="Saline"/>
Measuring Points	1 enable start <input type="text" value="14"/> end <input type="text" value="15"/>	Decimal Points	<input type="text" value="1"/>
	2 enable start <input type="text" value="25"/> end <input type="text" value="26"/>	Normal Range	<input type="text" value="0"/> <input type="text" value="10"/>
Wave Length		Technical Range (Conc)	<input type="text" value="0.0"/> <input type="text" value="160"/>
Prim	<input type="text" value="570"/> Sec <input type="text"/>	mAbs/10	<input type="text" value="-30000"/> <input type="text" value="30000"/>
Sampling Volume	<input type="text" value="16 μL"/>	RPT Wash (R1)	<input type="text" value="Sys Water"/>
Dilution	disable <input type="text" value="μL"/> <input type="text" value="μL"/>	(R2)	<input type="text" value="Sys Water"/>
Rerun (High)	<input type="text" value="16 μL"/>	Instrument Factor a	<input type="text" value="1"/> b <input type="text" value="0"/>
Dilution	enable <input type="text" value="15 μL"/> <input type="text" value="135 μL"/>	Stirring Speed	R1 <input type="text" value="mid"/> R2 <input type="text" value="high"/>
Rerun (Low)	<input type="text" value="30 μL"/>		

Calibration Checks

** Duplicate Limit	** <input type="text"/> mAbs/10	Sampling Method for Standards	<input checked="" type="checkbox"/> Duplicate
** Sensitivity Limit	** <input type="text"/> mAbs/10		<input type="checkbox"/> Triplicate
** Linearity Limit	** <input type="text"/> %	Blank measurement	<input checked="" type="checkbox"/> Enable Reagent blank
** Prozone Limit	** upper <input type="text"/>		<input type="text" value="None"/>
SL1-S	** <input type="text" value="SL1-F"/> **	Reagent blank measurement at calibration	<input checked="" type="checkbox"/> Reagent blank (system water)
SL2-S	** <input type="text" value="SL2-F"/> **		
Sens	** <input type="text"/> mAbs/10	Multiplex measurement is the same as standards	<input checked="" type="checkbox"/>
x Absorbance Limit	Reaction <input type="text" value="Increase"/>	Reagent Blank Limit Checks	** Duplicate limit <input type="text" value="50"/> mAbs/10
	Limit <input type="text" value="25000"/> mAbs/10		

Calibration

Method	<input type="text"/>	Name	<input type="text" value="RUBE"/>	Interval	<input type="text" value="90"/> days
Calculation	<input type="text" value="Point to Point"/>				
	Conc	WORK	MASTER	Lot No	
S1	0	-46			K <input type="text" value="N/A"/>
S2	10	272			
S3	20	521			
S4	40	1016			
S5	70	1726			
S6	160	3860			

Calibration (2/2) Autodilution

Serial Dilution	<input checked="" type="checkbox"/> enable	<input type="checkbox"/> disable	Claculation	<input type="text" value="Point to Point"/>
	Conc	Post Sampling (μL)	Pre Sampling (μL)	Diluent(μL)
S1	0	16	0	80
S2	10	16	5	75
S3	20	16	10	70
S4	40	16	20	60
S5	70	16	35	45
S6	160	16	0	0

Reagent Registration

Reagent Code	<input type="text" value="0161"/>
Reagent Name	<input type="text" value="RUBE"/>
R1	<input checked="" type="checkbox"/> enable <input type="text" value="**"/> mL <input type="text" value="**"/> mL <input checked="" type="checkbox"/> enable <input type="text" value="**"/> days
R2	<input checked="" type="checkbox"/> enable <input type="text" value="**"/> mL <input type="text" value="**"/> mL <input checked="" type="checkbox"/> enable <input type="text" value="**"/> days

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