quantex RUBELLA

CE

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 3000-2188. The calibrator concentration is indicated on the vial label. Instrument will perform autodilution of standard (SS). A reagent blank should be run daily before sample analysis .

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 600/650 Operator's 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(%)	Mean (IU/mL)	CV(%)
Within run	3/10	35.5	1.7	94.2	1.6
Total	3/10	35.5	0.6	94.2	0.96

Linearity

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

Quantification Limit

5 IU/mL

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Instrument Settings

Photometric Test Parameters		***Serum***
Test No.		**
Test Name, Test Code		RUBE, RUBE
Sample Type		Serum
Reporting Unit, Decimal Points		IU/mL, 1
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 20/33
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelenght		570
Sampling Conditions		
Sampling 1	Sample Vol.	15
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	15
	Sample/Diluent Vol.	20/180
Sampling 3	Sample Vol.	30
	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	01611
	Rgt/Dil. Vol. Stirring	100/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	**
R2	Code	01612
	Rgt/Dil. Vol. Stirring	100/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	**

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	**
Normal Range-Female	**
Normal Range-Other	**
Valid Range	0 - 160
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	6 Points, point to point, 2 Reps
Stability (days)	**
Calibrator, Concentration	Std Rubella, * (0 Saline)
R-Blank Limit (mAbs)	2400
Cal. Reps Range (%)	***
Min Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	***
Reagent Blank	ON
Auto R-Blank by Bottle	ON

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

Instrumentation Laboratory

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