

quantex IgG

Kit Configuration

P/N 3000-2269	1 x 90 mL IgG R1
	4 x 16 mL IgG R2

Reagent Preparation

P/N 3000-2269	IgG R1: Ready to use.
	IgG R2: Ready to use.
	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 PROTEINS standard multipoint Cat. No 3000-2128. See calibrator insert sheet for specific concentrations. Recalibrate every 60 days or when a new lot of reagent is used.

Quality Control

Use quantex PROTEINS Control I/II Cat. No. 3000-2122.

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

The reported expected range for IgG in adults is 700 - 1600 mg/dL (7.0 – 16.0 g/L).

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No significant interference from lipemia up to sample absorbance of 7.0/cm at 660 nm, triglycerides up to concentrations of 1280 mg/dL (14.5 mmol/L), bilirubin up to concentrations of 20 mg/dL (340 µmol/L) and hemoglobin up to concentrations of 500 mg/dL (0.3 mmol/L). For a comprehensive review of interfering substances, refer to the publication by Young *et al.*¹

Precision

	Samples/Runs	Mean (mg/dL)	CV(%)	Mean(mg/dL)	CV(%)
Within run	5/6	501	0.8	1507	1.1
Total	5/6	501	1.4	1507	1.7

Method Comparison

Comparison Method	Same reagent
Comparison instrument (x)	ILab 900/1800
Slope	1.087
y intercept	-63.8
Range (mg/dL)	168 - 6423
Mean X (mg/dL)	1192
Mean Y (mg/dL)	1219
r	0.9982
Syx	53.0
n	84

Linearity

no rerun 350 - 4100 mg/dL ; with rerun 70 - 41000 mg/dL

Instrument Settings

Photometric Test Parameters		Serum	Ranges and Evaluation Criteria		Serum
Test No.		**	Normal Range-Male		700-1600
Test Name, Test Code		IgG, IgG	Normal Range-Female		700-1600
Sample Type		Serum	Normal Range-Other		**
Reporting Unit, Decimal Points		mg/dL, 0	Valid Range		350** - 4100
Reaction Cycle		Standard	Hemolysis/Icterus/Lipemia Limit		***
Twin Analysis		OFF	Reaction Slope		Positive
Methodology Type, Measuring Point		End Point, 17/33	Absorbance Limit		Above, 3200
Photometric Methodology		1 Wavelength	Prozone Limit		N/A
Primary/Secondary Wavelength		600	Non Linear Limit		N/A
Sampling Conditions			Slope/Intercept Correction		1/0
<i>Sampling 1</i>	Sample Vol.	3	Qualitative Report		OFF
	Sample/Diluent Vol.	0/0	Calibration Conditions		
<i>Sampling 2</i>	Sample Vol.	3	Calibration		5 Points, point to point, 2 Reps
	Sample/Diluent Vol.	15/135	Stability (days)		60
<i>Sampling 3</i>	Sample Vol.	15	Calibrator, Concentration		Proteins Std, *
	Sample/Diluent Vol.	0/0	R-Blank Limit (mAbs)		***
<i>Sampling 4</i>		***	Cal. Reps Range (%)		***
Diluent Code		Saline	Min Cal. Response (mAbs)		***
Diluent Warning Limit		N/A	Cal. Factor Change (%)		***
First Run		Sampling 1	M-Point Curve Fit (%)		N/A
Below/Above Normal Range		***	Reagent Blank		ON
Panic L		Sampling 3	Auto R-Blank by Bottle		ON
Panic H		Sampling 2			
Noise		***			
Prozone		N/A			
High!, ABS!		Sampling 2			
Sample Volume Reduction		**			
Reagent Volumes					
R1	Code	01741			
	Rgt/Dil. Vol. Stirring	240/0, ON			
	Low Vol. Warning Limit	***			
	Stability (days)	30			
R2	Code	01742			
	Rgt/Dil. Vol. Stirring	250/0, ON			
	Low Vol. Warning Limit	***			
	Stability (days)	30			

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