

quantex IgM

Kit Configuration

P/N 3000-2324	1 x 30 mL IgM R1
	4 x 5 mL IgM R2

Reagent Preparation

P/N 3000-2324	IgM R1: Ready to use.
	IgM R2: Ready to use.
	Place the bottles into reagent rack.

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 PROTEINS standard multipoint Cat. No 3000-2128. See calibrator insert sheet for specific concentrations. Recalibrate every 30 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 300 Plus Operator's Manual.

Reference Interval

The reported expected range for IgM in adults is 40 -230 mg/dL (0.4 – 2.3 g/L).⁶

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	4/10	62.5	2.3	206.5	1.6
Total	4/10	62.5	2.4	206.5	2.1

Method Comparison

	ILab 350	ILab 600
Comparison Method (x)	same reagent	same reagent
Comparison Instrument (x)	ILab 350	ILab 600
Slope	1.104	1.115
y intercept	-1.07	-4.78
Range (mg/dL)	3.5 – 389.2	5 - 380
Mean X (mg/dL)	131.4	133.4
Mean Y (mg/dL)	144.0	144.0
r	0.995	0.994
Syx	12.9	14.9
n	30	30

Linearity

30 -400 mg/dL

Quantification Limit

30 mg/dL

Instrument Settings

Description: IgM
 Unit: mg/dL
 Decimals: 1
 LIS Code: **
 Unit Factor: 1.0
 Slope: 1.00
 Intercept: 0.00

	Reference Range							
	LOW VALUES				HIGH VALUES			
Male:	30.0	30.0	30.0	40.0	230.0	400.0	400.0	400.0
Female:	30.0	30.0	30.0	40.0	230.0	400.0	400.0	400.0
Children:	30.0	30.0	30.0	40.0	230.0	400.0	400.0	400.0
	Low Alert	Very Low	Low	Normal Values	High	Very High	High Alert	
Rerun:	No	No				No	No	No

Reaction Type: End Point
 Direction: None
 E.P. Limit (abs): 1.0000
 Depl Limit (abs): 0
 First Limit (abs): 0
 Linear Factor: 0
 Fit: 0

	Parameter					
	Predilut.->	S.+R. 1->	Reag. 2 ->	Reag. 3 ->	Incubation ->	Read
Times (sec):		0	90	0	296	0
Dil./Rgt. Code:		IgM 1	IgM 2			*) = kinetic
Lot Number:					Filter 1 (nm): 340 Filter 2 (nm): (none) Bicr. Factor: 1.00	
Ratio/Vol. (ul):	1/1	300	200	0		
Rinse (ul):		0	0	0		
Sample (ul):		4				

Lin Limit. Low: 30.0
 High: 400.0
 Rerun when Over: No

RBL Min (abs): -0.5000
 Max (abs): 2.5000

Calculation Model: Point to Point
 Factor: 0.00
 Sample Blank: Yes

RBL Stability (days): 15
 Calibration Stab. (days): 30
 Dinamic Controls (min): None

** Operator definable
 N/A Not applicable to this test