quantex IgM

CE

Kit Configuration

P/N 3000-2270	1 x 90 mL IgM R1 4 x 16 mL IgM R2

Reagent Preparation

P/N 3000-2270	IgM R1: Ready to use. IgM 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 quantexPROTEINS 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 IgM in adults is 40 -230 mg/dL (0.4 – 2.3 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	46	0.4	171	0.8
Total	5/6	46	1.9	171	1.7

Method Comparison

Comparison Method	Same reagent
Comparison instrument (x)	ILab 900/1800
Slope	1.043
y intercept	-1.03
Range (mg/dL)	8.0 - 2550
Mean X (mg/dL)	134
Mean Y (mg/dL)	134
r	0.9995
Syx	8.1
n	84

Linearity

no rerun 30 -400 mg/dL ; with rerun 10- 4000 mg/dL

Instrumentation Laboratory

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

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Instrument Settings

Photometric Test Parameters		***Serum***
Test No.		**
Test Name, Test Code		IgM, IgM
Sample Type		Serum
Reporting Unit, Decimal Points		mg/dL, 0
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 17/33
Photometric Methodology		1 Wavelenght
Primary/Secondary Wavelenght		340
Sampling Conditions		
Sampling 1	Sample Vol.	4
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	4
	Sample/Diluent Vol.	15/135
Sampling 3	Sample Vol.	12
	Sample/Diluent Vol.	0/0
Sampling 4		***
Diluent Code		Saline
Diluent Warning Limit		N/A
First Run		Sampling 1
Below/Above Normal Range		***
Panic L		Sampling 3
Panic H		Sampling 2
Noise		***
Prozone		N/A
High!, ABS!		Sampling 2
Sample Volume Reduction		**
Reagent Volumes		
R1	Code	01761
	Rgt/Dil. Vol. Stirring	190/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	30
R2	Code	01762
	Rgt/Dil. Vol. Stirring	200/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	30

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	40 - 230
Normal Range-Female	40 - 230
Normal Range-Other	**
Valid Range	30** - 400
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	5 Points, point to point, 2 Reps
Stability (days)	60
Calibrator, Concentration	Proteins Std, *
R-Blank Limit (mAbs)	***
Cal. Reps Range (%)	***
Min Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	N/A
Reagent Blank	ON
Auto R-Blank by Bottle	ON

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

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