

quantex IgM



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.

Specimen

Serum.

Calibration

Use quantex PROTEINS standard multipoint Cat. No 300-2128. See calibrator insert sheet for specific concentrations. Recalibrate every 90 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 350 Operator 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 (15 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	60	4.0	204	2.5
Total	4/10	60	4.1	204	3.4

Method Comparison

Comparison Method (x)	same reagent
Comparison Instrument (x)	ILab 600
Slope	1.04
y intercept	-7.47
Mean X (mg/dL)	117
Mean Y (mg/dL)	115
r	0.99
n	48

Linearity

no rerun 6 - 400 mg/dL ; with rerun 1,5 - 3200 mg/dL

Minimum Detection Limit

1.2 mg/dL

Quantification Limit

6 mg/dL



Instrument Settings

Chemistry Parameters				R1			
Method	<input type="text"/>	Reagent Name	<input type="text" value="IgM"/>	Volume	<input type="text" value="190 μL"/>		
Name	<input type="text" value="IgM"/>	R2	<input type="text" value="enable"/>				
Unit	<input type="text" value="mg/dL"/>	Reagent Name	<input type="text" value="IgM"/>	Volume	<input type="text" value="200 μL"/>		
Assay Type	<input type="text" value="End"/>	Wash	<input type="text" value="disable"/>	Reagent Name			
		Diluent	<input type="text" value="enable"/>	Reagent Type			
				Reagent Name	<input type="text" value="Saline"/>		
Measuring Points	1 enable	start	<input type="text" value="12"/>	Decimal Points	<input type="text" value="0"/>		
		end	<input type="text" value="13"/>				
	2 enable	start	<input type="text" value="25"/>	Normal Range	<input type="text" value="40"/>	<input type="text" value="230"/>	
		end	<input type="text" value="26"/>				
Wave Length				Technical Range (Conc)	<input type="text" value="6.0"/>	<input type="text" value="400"/>	
Prim	<input type="text" value="340"/>	Sec	<input type="text"/>	mAbs/10	<input type="text" value="-30000 / 30000"/>		
Sampling Volume	<input type="text" value="4 μL"/>			RPT Wash (R1)	<input type="text" value="Sys Water"/>		
Dilution	<input type="text" value="disable"/>			(R2)	<input type="text" value="Sys Water"/>		
Rerun (High)	<input type="text" value="4 μL"/>			Instrument Factor a	<input type="text" value="1"/>	b	<input type="text" value="0"/>
Dilution	<input type="text" value="enable"/>			Stirring Speed	R1 <input type="text" value="high"/>	R2	<input type="text" value="high"/>
Rerun (Low)	<input type="text" value="20 μL"/>	<input type="text" value="140 μL"/>					
	<input type="text" value="16 μL"/>						

Calibration Checks

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

Calibration

Method	<input type="text"/>	Name	<input type="text" value="IgM"/>	Interval	<input type="text" value="90"/> days
Calculation	<input type="text" value="Point to Point"/>				
	Conc	WORK	MASTER	Lot No	
S1	0	21			K <input type="text" value="N/A"/>
S2	31	717			
S3	78	1912			
S4	156	3892			
S5	234	5706			
S6	312	6933			

Reagent Registration

Reagent Code	<input type="text" value="0176"/>											
Reagent Name	<input type="text" value="IgM"/>											
R1	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text"/>	mL	Volume (S)	<input type="text"/>	mL	Stability Check	<input checked="" type="checkbox"/> enable	Term	<input type="text"/>	days
R2	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text"/>	mL	Volume (S)	<input type="text"/>	mL	Stability Check	<input checked="" type="checkbox"/> enable	Term	<input type="text"/>	days

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