quantex IgA

CE

Kit Configuration

P/N 3000-2268	1 x 90 mL IgA R1 4 x 16 mL IgA R2

Reagent Preparation

P/N 3000-2268 IgA R1: Ready to use
IgA 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 lot 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 IgA in adults is 70 – 400 mg/dL (0.7 – 40 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 18 mg/dL (307 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	108	1.1	343	0.9
Total	5/6	108	1.6	343	1.5

Method Comparison

Comparison method	Same reagent
Comparison instrument (x)	ILab 900/1800
Slope	1.014
y intercept	-0.39
Range (mg/dl)	2.0 - 5550
Mean X (mg/dl)	244
Mean Y (mg/dl)	243
r	0.9998
Syx	10.5
n	84

Linearity

no rerun 40 - 900 mg/dL ; with rerun 8 - 9000 mg/dL

Instrumentation Laboratory
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Instrument Settings

Photometric Test Parameters		***Serum***
Test No.		**
Test Name, Test Code		IgA, IgA
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 Wavelength
Primary/Secondary Wavelenght		450
Sampling Conditions		
Sampling 1	Sample Vol.	3
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	3
	Sample/Diluent Vol.	15/135
Sampling 3	Sample Vol.	15
	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	01751
	Rgt/Dil. Vol. Stirring	240/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	30
R2	Code	01752
	Rgt/Dil. Vol. Stirring	250/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	30

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	70-400
Normal Range-Female	70-400
Normal Range-Other	**
Valid Range	40** - 900
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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