quantex Lp(a)

CE

Kit Configuration

P/N 3000-2292	2 x 11 mL Lp(a) R1 2 x 4 mL Lp(a) R2

Reagent Preparation

P/N 3000-2292 Lp(a) R1: Ready to use.
Lp(a) R2: Ready to use. Invert to mix well before first use. Avoid foam formation.
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 Lp(a) standard multipoint Cat. No 3000-2293. See calibrator insert sheet for specific concentrations. Recalibrate every 14 days or when a new lot of reagent is used.

Quality Control

Use quantex Lp(a) Control I/II Cat. No. 3000-2294.

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

Plasma Lp(a) concentrations have been reported to be independent of body mass, age and sex. Concentrations of Lp(a) up to 30 mg/dL (64 nmol/L) are considered normal.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No significant interference from triglycerides up to concentrations 900 mg/dL (10 mmol/L), bilirubin up to concentrations of 9 mg/dL (150 µmol/L), hemoglobin up to concentrations of 10 g/L (0.6 mmol/L), apolipoprotein B up to 2 g/L and plasminogen up to 50 mg/dL. No cross-reactivity and/or non-specific aggregation from paraproteinemia (IgG, IgM and IgA) following the methodology described by Simó JM *et al*. For a comprehensive review of interfering substances, refer to the publication by Young *et al*.[1]

Linearity

no rerun 3.1 - 96 mg/dL (4.8 to 220 nmol/L); with rerun 3.1 - 960 mg/dL (4.8 to 2200 nmol/L)

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		Lp(a), Lp(a)
Sample Type		Serum
Reporting Unit, Decimal Points		mg/dL, 1
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 19/33
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelenght		700
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.	***
	Sample/Diluent Vol.	0/0
Sampling 4		***
Diluent Code		Saline
Diluent Warning Limit		***
First Run		Sampling 1
Below/Above Normal Range		***
Panic L		***
Panic H		Sampling 2
Noise		***
Prozone		N/A
High!, ABS!		Sampling 2
Sample Volume Reduction		**
Reagent Volumes		
R1	Code	01851
	Rgt/Dil. Vol. Stirring	140/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	**
R2	Code	01852
	Rgt/Dil. Vol. Stirring	65/10, ON
	Low Vol. Warning Limit	***
	Stability (days)	**

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	**
Normal Range-Female	**
Normal Range-Other	**
Valid Range	0 - 90
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	6 Points, point to point, 2 Reps
Stability (days)	**
Calibrator, Concentration	Std Lp(a), * 0 (saline)
R-Blank Limit (mAbs)	1000
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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