

quantex Lp(a)

**Kit Configuration**

P/N 3000-2292	1 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 300-2293. 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 350 Operator 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.*<sup>8</sup> For a comprehensive review of interfering substances, refer to the publication by Young *et al.*<sup>1</sup>

**Precision**

	Samples/Runs	Mean (mg/dL)	CV(%)	Mean (mg/dL)	CV(%)
Within run	4/10	17	1.7	62	3.1
Total	4/10	17	0.8	62	1.1

**Method Comparison**

Comparison Method (x)	Turbidimetric assay
Slope	1.08
y intercept	-4.61
Mean X (mg/dL)	38
Mean Y (mg/dL)	37
r	0.92
n	90

**Linearity**

no rerun 7.5 - 80 mg/dL ; with rerun 7,5 - 640 mg/dL

**Minimum Detection Limit**

1.5 mg/dL

**Quantification Limit**

7.5 mg/dL

### Instrument Settings

<b>Chemistry Parameters</b>				R1				
Method	<input type="text"/>			Reagent Name	<input type="text" value="Lpa"/>	Volume	<input type="text" value="140 μL"/>	
Name	<input type="text" value="Lpa"/>			R2	<input type="text" value="enable"/>			
Unit	<input type="text" value="mg/dL"/>			Reagent Name	<input type="text" value="Lpa"/>	Volume	<input type="text" value="65 μL"/>	
Assay Type	<input type="text" value="End"/>			Wash	<input type="text" value="disable"/>	Reagent Name	<input type="text"/>	
				Diluent		Reagent Type	<input type="text"/>	
				enable		Reagent Name	<input type="text" value="Saline"/>	
<b>Measuring Points</b>		1 enable	start	<input type="text" value="14"/>	<b>Decimal Points</b>			<input type="text" value="0"/>
			end	<input type="text" value="15"/>				
		2 enable	start	<input type="text" value="25"/>	<b>Normal Range</b>			<input type="text" value="0"/> <input type="text" value="30"/>
			end	<input type="text" value="26"/>				
<b>Wave Length</b>				Technical Range (Conc)				
Prim	<input type="text" value="700"/>	Sec	<input type="text"/>	mAbs/10		<input type="text" value="0.0"/>	<input type="text" value="85"/>	
				<input type="text" value="-30000 / 30000"/>				
<b>Sampling Volume</b>				<b>RPT Wash</b>				
Dilution	<input type="text" value="4 μL"/>			(R1)	<input type="text" value="Sys Water"/>			
				(R2)	<input type="text" value="Sys Water"/>			
<b>Rerun ( High )</b>				<b>Instrument Factor a</b>				
Dilution	<input type="text" value="4 μL"/>			enable	<input type="text" value="1"/>	b	<input type="text" value="0"/>	
				<b>Stirring Speed</b>	R1	<input type="text" value="high"/>	R2	<input type="text" value="high"/>
<b>Rerun ( Low )</b>								

### Calibration Checks

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

### Calibration

<b>Method</b>	<input type="text"/>	<b>Name</b>	<input type="text" value="Lpa"/>	<b>Interval</b>	<input type="text" value="14"/> days
<b>Calculation</b>	<input type="text" value="Point to Point"/>				
	Conc	WORK	MASTER	Lot No	
S1	0	-46			K <input type="text" value="N/A"/>
S2	6	83			
S3	10.7	264			
S4	27.6	957			
S5	53.1	2682			
S6	80	4830			

### Reagent Registration

Reagent Code	<input type="text" value="0185"/>							
Reagent Name	<input type="text" value="Lpa"/>							
		Volume (L)		Volume (S)		Stability Check		Term
R1	<input checked="" type="checkbox"/> enable	**	mL	**	mL	<input checked="" type="checkbox"/> enable	**	days
R2	<input checked="" type="checkbox"/> enable	**	mL	**	mL	<input checked="" type="checkbox"/> enable	**	days

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