quantex Valproic Acid

CE

Kit Configuration

P/N 3000-2280	2 x 15 mL VALP R1 2 x 3.8 mL VALP R2

Reagent Preparation

P/N 3000-2280: VALP R1: Ready to use.
VALP R2: Ready to use. Invert to mix well before first use. Avoid foam formation
Place the bottles into reagent tray.

In Use Stability

Stable until the expiration date shown on the vial when stored at 2-8°C. 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 VALPROIC ACID standard multipoint Cat. No 3000-2288. The concentrations in µg/mL are indicated on the vial labels. Recalibrate every 60 days, when a new lot of reagents is used, when control recovery falls out of the expected range or when adjustments are made to the instrument. A reagent blank should be run daily before sample analysis.

Quality Control

Use quantex TDM control I/II Cat. No 3000-2303.

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.

Therapeutic Range

The typical therapeutic range is 50 - 100 µg/mL (347 - 693 µmol/L) and the toxic range is > 100 µg/mL(> 693 µmol/L).
Some patients achieve the desired therapeutic response at levels outside this range; therefore, individual clinical evaluation should be considered when interpreting assay results.
To convert results to µmol/l multiply by 6.93.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No significant interference from bilirubin up to concentrations of 20 mg/dL, hemoglobin up to concentrations of 1000 mg/dL and lipemia up to concentrations of 20 g/L. For a comprehensive review of interfering substances, refer to the publication by Young *et al*.[1]

Precision

	Samples/ Runs	Mean (µg/mL)	CV (%)	Mean (µg/mL)	CV (%)
Within run	4/10	37.8	2.7	88.8	1.1
Total	4/10	37.8	6.4	88.8	5.1

Linearity

no rerun 11 to 150 µg/mL
With rerun 11 to 600 µg/mL

Instrumentation Laboratory
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Instrument Settings

Chemistry Parameters				**R1**			
Method				**Reagent Name**	VLP	**Volume**	200 µL
Name	VLP			**R2**	enable		
				Reagent Name	VLP	**Volume**	50 µL
				Wash	disable	**Reagent Name**	
Unit	µg/mL					**Reagent Type**	
Assay Type	End			**Diluent**	enable	**Reagent Name**	Saline
Measuring Points	**1** enable	start	14	**Decimal Points**	1		
		end	15				
	2 enable	start	25	**Normal Range**	50	100	
		end	26				
Wave Lenght							
Prim	600	**Sec**		**Technical Range (Conc)**	0.0	150	
				mAbs/10	-30000 / 30000		
Sampling Volume	2 µL						
Dilution	disable			**RPT Wash**	(R1)	Sys Water	
	µL	µL			(R2)	Sys Water	
Rerun (High)	2 µL						
Dilution	enable			**Instrument Factor a**	1	**b**	0
	35 µL	105 µL		**Stirring Speed**	R1 high	R2	high
Rerun (Low)	4 µL						

Calibration Checks

**	**Duplicate Limit**	**	mAbs/10	**Sampling Method for Standards**	
**	**Sensitivity Limit**	**	mAbs/10	x	Duplicate
					Tripicate
**	**Linearity Limit**	**	**%**		
				Blank measurement	
**	**Prozone Limit**	** upper		x	Enable Reagent blank
	SL1-S	** SL1-F **		None	
	SL2-S	** SL2-F **		**Reagent blank measurement at calibration**	
	Sens	**	mAbs/10	x	Reagent blank (system water)
x	**Absorbance Limit**			**	**Multiplex measurement is the same as standards**
	Reaction	Increase			
	Limit	25000	mAbs/10	**Reagent Blank Limit Checks**	
				**	Duplicate limit 50 mAbs/10

Calibration

Method		**Name**	VLP	**Interval**	60	**days**
Calculation	Point to Point					

	Conc	WORK	MASTER	Lot No
S1	0	-632		
S2	12.5	-1833		
S3	25	-3240		
S4	50	-5544		
S5	100	-7241		
S6	150	-7506		

K N/A

Reagent Registration

Reagent Code	0150								
Reagent Name	VLP								
			Volume (L)		Volume (S)		Stability Check		Term	
R1	x	enable	**	mL	**	mL	x	enable	**	days
R2	x	enable	**	mL	**	mL	x	enable	**	days

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