quantex CARBAMAZEPINE

CE

Kit Configuration

P/N 3000-2277 2 x 11 mL CARB R1
2 x 3 mL CARB R2

Reagent Preparation

P/N 3000-2277: CARB R1 (Buffer) : Ready to use.
CARB R2 (Reagent) : Ready to use. Invert to mix well before first use. Avoid foam formation
Place the bottles into reagent tray.

In Use Stability

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 CARBAMAZEPINE standard multipoint Cat. No 3000-2318. The concentrations in µg/mL are indicated on the vial labels. Recalibrate every 90 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 4 - 10 µg/mL (17 - 42 µmol/L) and the toxic range is > 15 µg/mL (> 63 µmol/L).
To convert results to µmol/L multiply by 4.23.

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	3.2	3.7	8.5	7.7
Total	4/10	3.2	2.9	8.5	7.7

Linearity

no rerun 1.36 to 20 µg/mL
With rerun 1.36 to 80 µg/mL

Instrumentation Laboratory
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Instrument Settings

Chemistry Parameters				**R1**			
Method				**Reagent Name**	CBZ	**Volume**	220 µL
Name	CBZ			**R2**	enable		
				Reagent Name	CBZ	**Volume**	60 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**	4	10	
		end	26				
Wave Lenght							
Prim	600	**Sec**		**Technical Range (Conc)**	0.0	20	
				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**	CBZ	**Interval**	90 **days**
Calculation	Point to Point				

	Conc	WORK	MASTER	Lot No
S1	0	-172		
S2	2	-2063		
S3	4	-3339		
S4	8	-4661		
S5	12	-5374		
S6	20	-5214		

K N/A

Reagent Registration

Reagent Code	0165								
Reagent Name	CBZ								
			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