quantex AMIKACIN

CE

Kit Configuration

P/N 3000-2317	2 x 12.5 mL AMIK R1
	2 x 3.8 mL AMIK R2

Reagent Preparation

P/N 3000-2317: AMIK R1: Ready to use.
AMIK 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 AMIKACIN standard multipoint Cat. No 3000-2318. The concentrations in µg/mL are indicated on the vial labels. Recalibrate every 36 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 automaticallycalculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 350 Operator Manual.

Therapeutic Range

Recommended "trough" levels are: 5 - 8 µg/mL (8.5 - 14 µmol/L).
Recommended "peak" levels are: 20 - 30 µg/mL (34 - 51 µmol/L).
"Trough" concentrations above 10 µg/mL (> 17 µmol/L) and "peak" concentrations above 35 µg/mL (> 60 µmol/L) are often associated with renal impairment and ototoxicity.
To convert results to µmol/L multiply by 1.71.

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	5.1	7.1	16.6	2.6
Total	4/10	5.1	8.3	16.6	3.0

Linearity

no rerun 1.5 to 50 µg/mL
With rerun 1.5 to 75 µg/mL

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

Chemistry Parameters				**R1**			
Method				**Reagent Name**	AMIK	**Volume**	250 µL
Name	AMIK			**R2**	enable		
				Reagent Name	AMIK	**Volume**	75 µL
				Wash	disable	**Reagent Name**	
Unit	µg/mL					**Reagent Type**	
Assay Type	End			**Diluent**	disable	**Reagent Name**	
Measuring Points	**1** enable	start	14	**Decimal Points**	1		
		end	15				
	2 enable	start	25	**Normal Range**	0	50	
		end	26				
Wave Lenght							
Prim	700	**Sec**		**Technical Range (Conc)**	0.0	60	
				mAbs/10	-30000 / 30000		
Sampling Volume	3 µL						
Dilution	disable			**RPT Wash**	(R1)	Sys Water	
	µL	µL			(R2)	Sys Water	
Rerun (High)	2 µL						
Dilution	disable			**Instrument Factor a**	1	**b**	0
	µL	µL		**Stirring Speed**	R1 mid	R2	mid
Rerun (Low)	6 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**	AMIK	**Interval**	36	**days**
Calculation	Point to Point					

	Conc	WORK	MASTER	Lot No
S1	0	54		
S2	3	-896		
S3	10	-2557		
S4	20	-4090		
S5	35	-5045		
S6	50	-5377		

K N/A

Reagent Registration

Reagent Code	199
Reagent Name	AMIK

			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

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