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

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 AMIKACIN standard multipoint Cat. No 3000-2318. The concentrations in µg/mL are indicated on the vial labels. Recalibrate every 7 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 600/650 Operator's 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.[1,5]

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*.[4]

Precision

	Samples/ Runs	Mean (µg/mL)	CV (%)	Mean (µg/mL)	CV (%)
Within run	3/10	4.6	10.0	15.7	2.7
Total	3/10	4.6	9.2	15.7	3.4

Linearity

no rerun 3.0 to 50 µg/mL
With rerun 3.0 to 400 µg/mL

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Instrument Settings

Photometric Test Parameters		***Serum***
Test No.		**
Test Name, Test Code		AMIK, AMIK
Sample Type		Serum
Reporting Unit, Decimal Points		µg/mL, 1
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 20/33
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelenght		700
Sampling Conditions		
Sampling 1	Sample Vol.	3
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	3
	Sample/Diluent Vol.	20/140
Sampling 3	Sample Vol.	6
	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	01991
	Rgt/Dil. Vol. Stirring	250/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	**
R2	Code	01992
	Rgt/Dil. Vol. Stirring	75/10, ON
	Low Vol. Warning Limit	***
	Stability (days)	**

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	**
Normal Range-Female	**
Normal Range-Other	**
Valid Range	0 - 50
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)	7
Calibrator, Concentration	Amikacin Std *
R-Blank Limit (mAbs)	3500
Cal. Reps Range (%)	***
Min Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	***
Reagent Blank	ON
Auto R-Blank by Bottle	ON

* Lot dependent
** operator definable
*** optional
N/A not applicable to this test