

quantex GENTAMICIN



Kit Configuration

P/N 3000-2281	2 x 12.5 mL GENT R1
	2 x 3.8 mL GENT R2

Reagent Preparation

P/N 3000-2275: GENT R1: Ready to use.
 GENT 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 GENTAMICIN standard multipoint Cat. No 3000-2289. 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 therapeutic ranges for gentamicin are a function of the severity of infection.

Recommended "trough" levels are: < 2 - 4 µg/mL (< 4.2 - 8.4 µmol/L) for severe infections.

< 2 µg/mL (< 4.2 µmol/L) for moderate infections.

< 1 µg/mL (< 2.1 µmol/L) for less severe infections.

Recommended "peak" levels are: 8 - 10 µg/mL (16.7 - 20.9 µmol/L) for severe infections.

5 - 8 µg/mL (10.4 - 16.7 µmol/L) for less severe infections.

"Trough" concentrations above 2 - 4 µg/mL (> 4 - 8 µmol/L) and "peak" concentrations above 10 - 12 µg/mL (> 21 - 25 µmol/L) are often associated with renal impairment and ototoxicity.

To convert results to µmol/l multiply by 2.09.

References / Literatur / Bibliografia / 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	2.1	4.3	7.4	4.0
Total	4/10	1.9	9.4	7.4	8.2

Linearity

no rerun 0.37 to 10 µg/mL

With rerun 0.37 to 40 µg/mL



Instrument Settings

Chemistry Parameters				R1			
Method	<input type="text"/>	Reagent Name	<input type="text" value="GTM"/>	Volume	<input type="text" value="250 μL"/>		
Name	<input type="text" value="GENT"/>	R2	<input type="text" value="enable"/>				
Unit	<input type="text" value="μg/mL"/>	Reagent Name	<input type="text" value="GTM"/>	Volume	<input type="text" value="75 μL"/>		
Assay Type	<input type="text" value="End"/>	Wash	<input type="text" value="disable"/>	Reagent Name	<input type="text"/>		
				Diluent	<input type="text" value="enable"/>	Reagent Type	<input type="text"/>
				Reagent Name	<input type="text" value="Saline"/>		
Measuring Points	1 enable	start	<input type="text" value="14"/>	Decimal Points	<input type="text" value="1"/>		
		end	<input type="text" value="15"/>	Normal Range	<input type="text" value="0.0"/>	<input type="text" value="2.0"/>	
	2 enable	start	<input type="text" value="25"/>				
		end	<input type="text" value="26"/>				
Wave Length							
Prim	<input type="text" value="700"/>	Sec	<input type="text"/>	Technical Range (Conc)	<input type="text" value="0.0"/>	<input type="text" value="10"/>	
					mAbs/10	<input type="text" value="-30000 / 30000"/>	
Sampling Volume	<input type="text" value="2 μL"/>						
Dilution	<input type="text" value="disable"/>		RPT Wash	(R1)	<input type="text" value="Sys Water"/>		
	<input type="text"/>	<input type="text"/>	(R2)	<input type="text" value="Sys Water"/>			
Rerun (High)	<input type="text" value="2 μL"/>						
Dilution	<input type="text" value="disable"/>		Instrument Factor a	<input type="text" value="1"/>	b	<input type="text" value="0"/>	
	<input type="text"/>	<input type="text"/>	Stirring Speed	R1	<input type="text" value="high"/>	R2	<input type="text" value="high"/>
Rerun (Low)	<input type="text" value="4 μL"/>						

Calibration Checks

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

Calibration

Method	<input type="text"/>	Name	<input type="text" value="GENT"/>	Interval	<input type="text" value="60"/>	days
Calculation	<input type="text" value="Point to Point"/>					
	Conc	WORK	MASTER	Lot No		
S1	<input type="text" value="0"/>	<input type="text" value="-145"/>	<input type="text"/>	<input type="text"/>	K	<input type="text" value="N/A"/>
S2	<input type="text" value="0.5"/>	<input type="text" value="-1675"/>	<input type="text"/>	<input type="text"/>		
S3	<input type="text" value="1.5"/>	<input type="text" value="-4607"/>	<input type="text"/>	<input type="text"/>		
S4	<input type="text" value="3"/>	<input type="text" value="-6862"/>	<input type="text"/>	<input type="text"/>		
S5	<input type="text" value="6"/>	<input type="text" value="-7961"/>	<input type="text"/>	<input type="text"/>		
S6	<input type="text" value="10"/>	<input type="text" value="-8276"/>	<input type="text"/>	<input type="text"/>		

Reagent Registration

Reagent Code	<input type="text" value="0167"/>													
Reagent Name	<input type="text" value="GENT"/>													
R1	<input checked="" type="checkbox"/>	enable	Volume (L)	<input type="text"/>	mL	Volume (S)	<input type="text"/>	mL	Stability Check	<input checked="" type="checkbox"/>	enable	Term	<input type="text"/>	days
R2	<input checked="" type="checkbox"/>	enable	Volume (L)	<input type="text"/>	mL	Volume (S)	<input type="text"/>	mL	Stability Check	<input checked="" type="checkbox"/>	enable	Term	<input type="text"/>	days
**	Operator definable		N/A		not applicable to this test			Calibration curve is only as example						