



Therapeutic  
Drug Monitoring



SERUM PLASMA

# QMS<sup>®</sup> Amikacin Assay (AMKX)

Utilization on Beckman Coulter's UniCel<sup>®</sup> Dx<sub>C</sub> and Synchron<sup>®</sup> CX and LX Clinical Systems

## Simplified Reagent Handling

### Introduction

Amikacin is a semi-synthetic aminoglycoside antibiotic used to treat different types of bacterial infections. Aminoglycoside concentrations are measured to guide and monitor dosing regimens and to evaluate toxicity and efficacy.<sup>1</sup>

The QMS<sup>®</sup> Amikacin assay is intended for the quantitative determination of amikacin in human serum or plasma on automated clinical chemistry analyzers. The results obtained are used in the diagnosis and treatment of amikacin overdose and in monitoring levels of amikacin to help ensure appropriate therapy.

QMS Amikacin is a homogeneous particle-enhanced turbidimetric immunoassay. The assay is based on competition between drug in the sample and drug coated onto a microparticle for antibody binding sites of the amikacin antibody reagent. The amikacin-coated microparticle reagent is rapidly agglutinated in the presence of the anti-amikacin antibody reagent and in the absence of any competing drug in the sample. The rate of absorbance

change is measured photometrically. When a sample containing amikacin is added, the agglutination reaction is partially inhibited, slowing down the rate of absorbance change. A concentration-dependent classic agglutination inhibition curve can be obtained with maximum rate of agglutination at the lowest amikacin concentration and the lowest agglutination rate at the highest amikacin concentration.

### Features of the QMS Amikacin assay include:

- Sensitivity of 0.8 µg/mL
- Analytical range of 1.5 to 50 µg/mL
- 35-day onboard reagent stability
- Typical Total Imprecision of <5% CV





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## Performance Characteristics

### Analytical Sensitivity

The analytical sensitivity of the QMS Amikacin assay, defined as the lowest measurable concentration that can be distinguished from zero with 95% confidence, is 0.8 µg/mL.

### Linearity

Each level of QMS Amikacin calibrator was diluted with equal volume of the next higher level calibrator to achieve samples at 1.5, 6.5, 15.0, 27.5 and 42.5 µg/mL. The samples were analyzed in duplicate using the QMS Amikacin assay. A mean of the replicates for each sample was determined and a percent recovery calculated. Results are shown below:

Theoretical Concentration (µg/mL)	Percent Recovery
1.5	111.3
6.5	99.7
15.0	97.8
27.5	95.7
42.5	97.5
Mean percent recovery: 100.4	

### Method Comparison

A total of 59 clinical samples were tested on the UniCel and Synchron systems and the results compared with the Hitachi™ 717 analyzer method. The data were analyzed and are presented in the tables below.

CX		DxC		LX	
Slope	0.963	Slope	0.978	Slope	0.959
y-intercept	0.230	y-intercept	0.339	y-intercept	-0.104
R	0.996	R	0.996	R	0.998

Beckman Coulter Reorder Number	Item
A45384	QMS Amikacin Reagent Kit (2 x 19 mL – R1, 2 x 7 mL – R2)
A45385	QMS Amikacin Calibrator Kit (6 levels x 1.0 mL)*
442835	User Defined Reagent Cartridges (pkg. of 12)*
A45386	Instructions for Use**

\* Sold separately  
\*\* Ordered Separately

### References

1. NACB Standards of Laboratory Practice. Guidelines for Therapeutic Drug Monitoring Services, 1999.

QMS<sup>®</sup> is a registered trademark of Thermo Fisher Scientific Corporation.

Distributed by: Beckman Coulter, Inc. for UniCel DxC and SYNCHRON CX and LX Clinical Systems

Manufactured by: Thermo Fisher Scientific  
Diagnostic Division, Seradyn Products  
7998 Georgetown Road, Suite 100  
Indianapolis, IN 46268  
U.S.A.

**Thermo**  
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Australia, Gladesville (61) 2 9844 6000 Canada, Mississauga (1) 905 819 1234 China, Beijing (86) 10 6515 6028  
Czech Republic, Prague (420) 267 00 83 66 Eastern Europe, Middle East, North Africa, South West Asia: Switzerland, Nyon (41) 22 365 3707  
France, Villepinte (33) 1 49 90 90 00 Germany, Krefeld (49) 2151 33 35 Hong Kong (852) 2814 7431 India, Mumbai (91) 22 3080 5101  
Italy, Cassina de' Pecchi, Milan (39) 02 953921 Japan, Tokyo (81) 3 5530 8500 Latin America (1) (305) 380 4709  
Mexico, Mexico City (001) 52 55 9183 2800 Netherlands, Mijdrecht (31) 297 230630 Puerto Rico (787) 747 3335 Singapore (65) 6339 3633  
South Africa/Sub-Saharan Africa, Johannesburg (27) 11 805 2014 Spain, Madrid (34) 91 3836080 Sweden, Bromma (46) 8 564 85 900  
Switzerland, Nyon (41) 0800 850 810 Taiwan, Taipei (886) 2 2378 3456 Turkey, Istanbul (90) 216 309 1900 UK, High Wycombe (44) 01494 441181  
USA, Brea, CA (1) 800 352 3433, (1) 714 993 5321