PRODUCT SPECIFICATION

Thermo Scientific

QMS Amikacin Immunoassay

QMS liquid-stable reagents offer superior assay performance on general chemistry analyzers

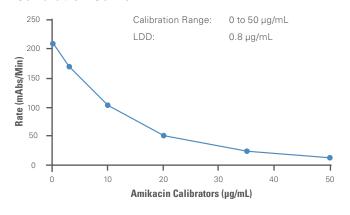
The Thermo ScientificTM QMSTM Amikacin Immunoassay is intended for the quantitative determination of amikacin in human serum or plasma on automated clinical chemistry analyzers. Applications are available on our compact IndikoTM and Indiko Plus clinical and specialty chemistry systems, as well as a wide variety of other laboratory instrumentation. The results obtained are used in the diagnosis and treatment of amikacin overdose and in monitoring levels of amikacin, to help ensure appropriate therapy.

Accuracy

Accuracy by recovery was determined by spiking United States Pharmacopeia (USP) traceable amikacin into human serum, negative for the drug, to achieve concentrations of 18.4 and 9.2 µg/mL. The samples were analyzed in duplicate with the QMS Amikacin assay.

Theoretical Concentration (µg/mL)	Mean Concentration (μg/mL)	Percent Recovery
9.20	8.82	96%
18.40	16.96	92%

Calibration Curve





Precision

A tri-level human serum based commercial control containing amikacin was used in the study. Representative results are shown below.

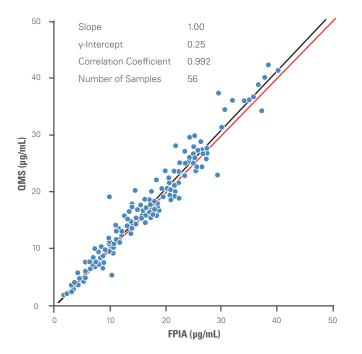
Within Run				
n = 80	Mean (µg/mL)	SD	CV	
Control 1	4.09	0.22	5.37%	
Control 2	12.00	0.21	1.79%	
Control 3	24.37	0.47	1.93%	

Total Run				
n = 80	Mean (µg/mL)	SD	CV	
Control 1	4.09	0.41	9.94%	
Control 2	12.00	0.74	6.22%	
Control 3	24.37	1.54	6.32%	



Method Comparison

Results of serum and plasma samples analyzed for amikacin by the QMS Amikacin Immunoassay were compared with the results obtained using a fluorescence polarization immunoassay (FPIA) system. The amikacin concentrations ranged from 2.38 to 37.58 µg/mL. Representative results are shown below.



Stability

Reagent Open-Vial Stability:

45 days*

Calibration Curve Stability:

Greater than 28 days*

Shelf Life of Reagents and Calibrators:

18 months from date of manufacturing

*Results are typical and might not be achieved on all clinical chemistry analyzers.

Assay Specific Information

Exhibits minimal interference from most common and coadministered drugs. Linear throughout reportable assay range. Application sheets for specific clinical chemistry analyzers available upon request.

Ordering Information: 800-232-3342

Cat #	Product Description	Kit Size
0373910	QMS Amikacin Reagent Kit	2 x 19 mL 2 x 7 mL
0374157	QMS Amikacin Calibrator Set	Levels A-F 1 x 1 mL each

Clinical Diagnostics

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