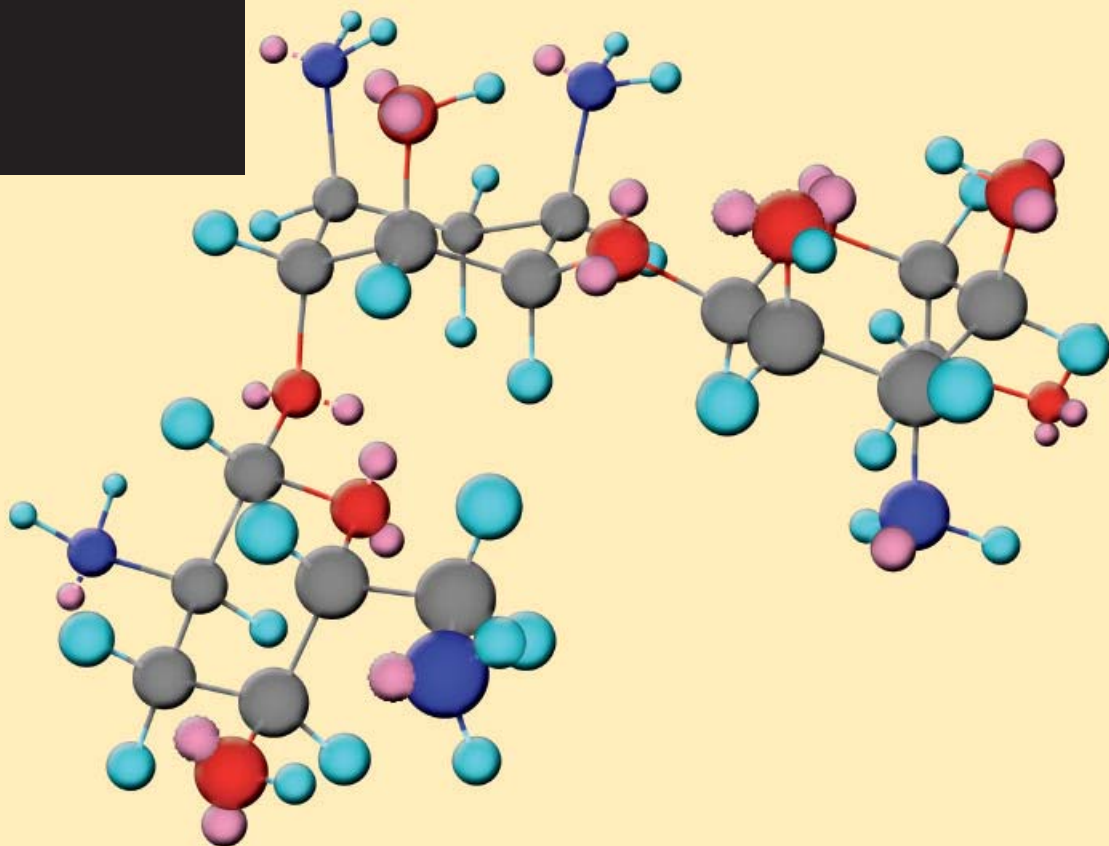
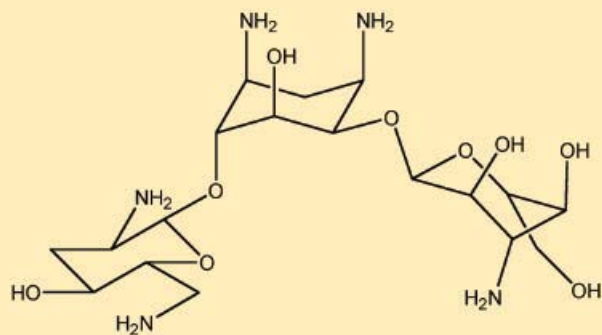
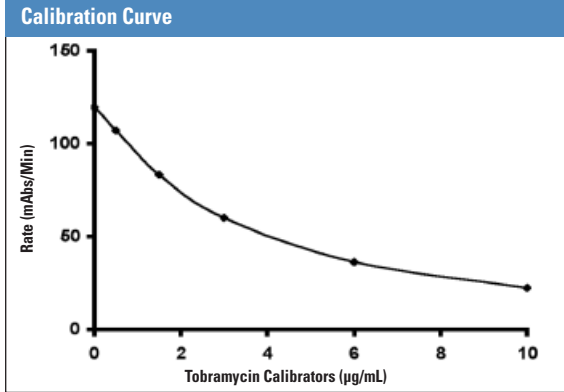


Thermo Scientific QMS® Tobramycin



The Thermo Scientific QMS Tobramycin Immunoassay is intended for the quantitative determination of tobramycin in human serum or plasma on automated clinical chemistry analyzers. The results obtained are used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to help ensure appropriate therapy.

QMS liquid-stable reagents offer superior assay performance and are widely applicable to general chemistry analyzers.



Assay Range: 0 to 10 µg/mL
LDD: 0.17 µg/mL
LOQ: 0.4 µg/mL

Accuracy

Recovery was determined by spiking tobramycin into human serum negative for the drug to achieve concentrations across the assay range. A mean of triplicates for each sample was determined and percent recovery was calculated. Results are shown below.

Theoretical Concentration (µg/mL)	Mean Concentration (µg/mL)	Percent Recovery
6.00	5.86	98%
4.50	4.30	96%
3.00	2.78	93%
1.50	1.36	91%

Precision

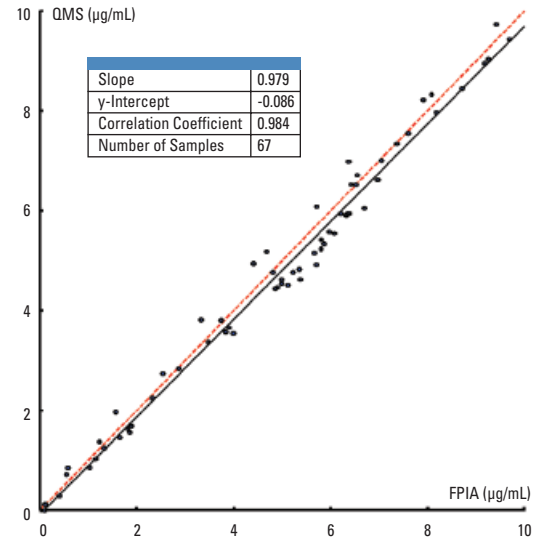
A 20-day study was conducted using commercially available, tri-level, serum-based controls. Results are shown below.

WITHIN RUN			
n = 80	Mean (µg/mL)	SD	CV
Low Control	1.11	0.02	1.98%
Mid Control	3.83	0.05	1.31%
High Control	8.06	0.13	1.63%

TOTAL RUN			
n = 80	Mean (µg/mL)	SD	CV
Low Control	1.11	0.08	7.57%
Mid Control	3.83	0.16	4.23%
High Control	8.06	0.34	4.26%

Method Comparison

Results of serum and plasma samples analyzed for tobramycin by the QMS Tobramycin Immunoassay were compared with the results obtained using a Fluorescence Polarization Immunoassay (FPIA) system. The tobramycin concentrations ranged from 0.08 to 9.69 µg/mL. Results are shown below.



Stability

Reagent Open-Vial Stability:

Greater than 40 days*

Calibration Curve Stability:

Greater than 12 days*

Shelf Life of Reagents, Calibrators and Controls:

12 months from date of manufacturing

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

Ordering Information

QMS Tobramycin Reagent Kit.....0374108
 QMS Tobramycin Calibrator Set.....0374116

Application sheets for specific clinical chemistry analyzers available upon request.

CAP proficiency data is collected and is available upon request.

