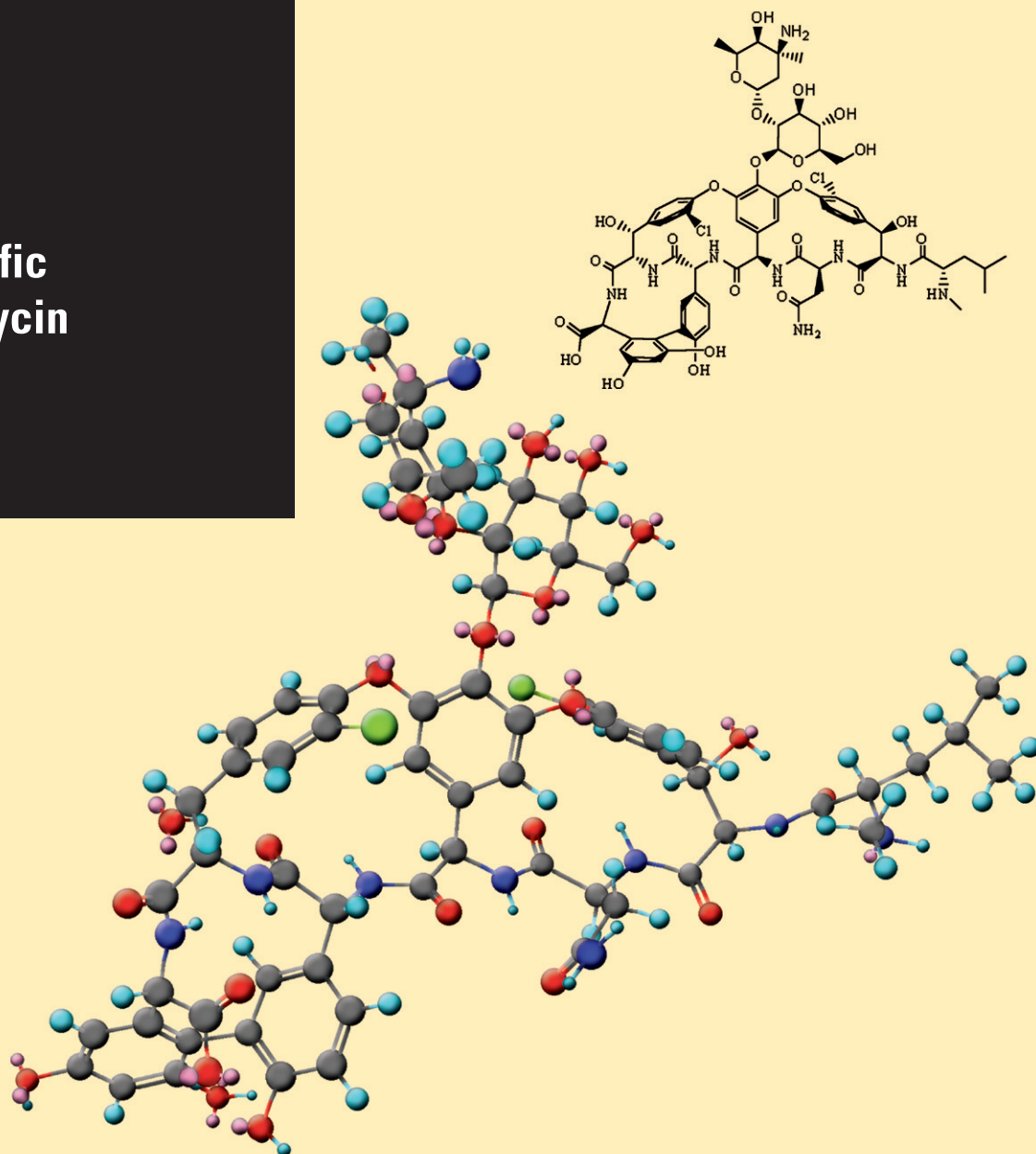


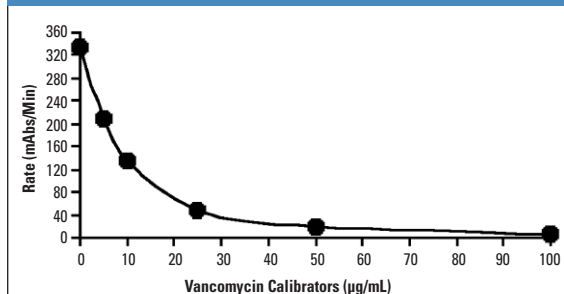
Thermo Scientific QMS® Vancomycin



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

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

Calibration Curve



LDD: 0.55 µg/mL

LOQ: 2.0 µg/mL

Accuracy

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

Theoretical Concentration (µg/mL)	Mean Concentration (µg/mL)	Percent Recovery
100.00	95.02	95%
75.00	73.24	98%
50.00	52.25	105%
37.50	39.70	106%
25.00	27.65	111%
17.50	17.45	100%
10.00	9.27	93%
7.50	6.83	91%
5.00	4.97	99%

Precision

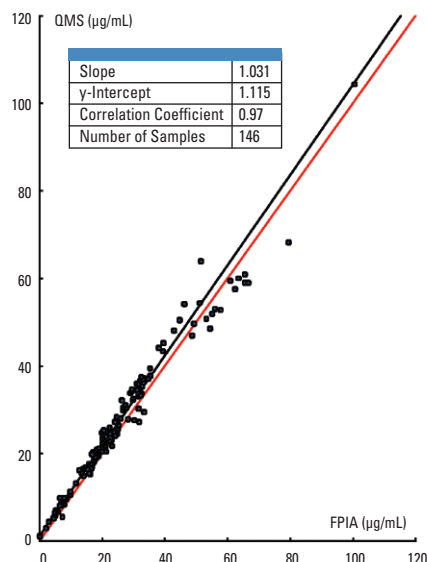
A tri-level human serum based commercial control containing vancomycin was used in the study. Representative results are shown below.

WITHIN RUN			
n = 80	Mean (µg/mL)	SD	CV
1	7.57	0.27	3.59%
2	20.79	0.51	2.44%
3	33.65	0.80	2.37%

TOTAL RUN			
n = 80	Mean (µg/mL)	SD	CV
1	7.57	0.67	8.84%
2	20.79	1.29	6.21%
3	33.65	1.72	5.12%

Method Comparison

Results of serum and plasma samples analyzed for vancomycin by the QMS Vancomycin Immunoassay were compared with the results obtained using a Fluorescence Polarization Immunoassay system. The vancomycin concentrations ranged from 0.04 to 100.0 µg/mL. Representative results are shown below.



Stability

Reagent Open-Vial Stability:

Up to 62 days*

Calibration Curve Stability:

Up to 31 days*

Shelf Life of Reagents and Calibrators:

12 months from date of manufacturing

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

Assay Specific Information

The vancomycin metabolite, Crystalline Degradation Product-I, exhibits less than 5% cross-reactivity.

Teicoplanin, a structurally similar compound to Vancomycin, shows less than 1% cross-reactivity.

The assay exhibits minimal interference from most common and co-administered drugs.

Ordering Information

QMS Vancomycin Reagent Kit.....0373589
QMS Vancomycin Calibrator Set.....0373597

Application sheets for specific clinical chemistry analyzers available upon request.

CAP and New York Department of Health proficiency data are collected and available upon request.