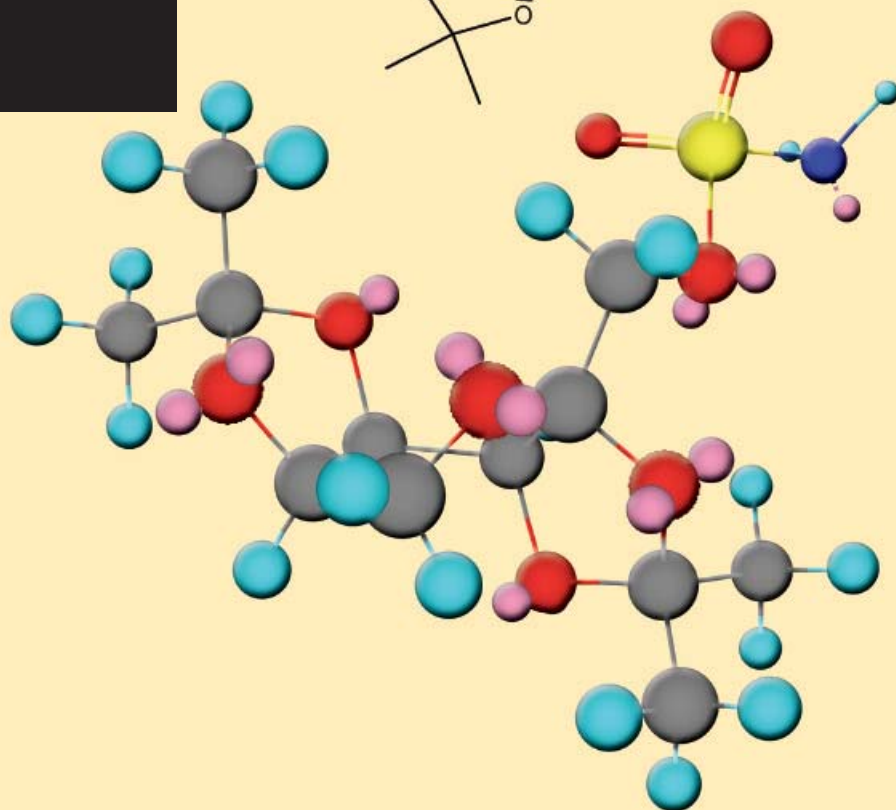
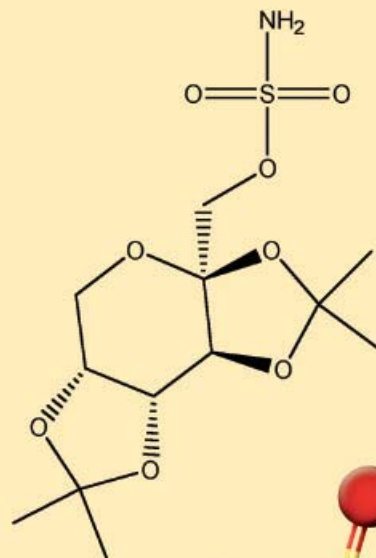
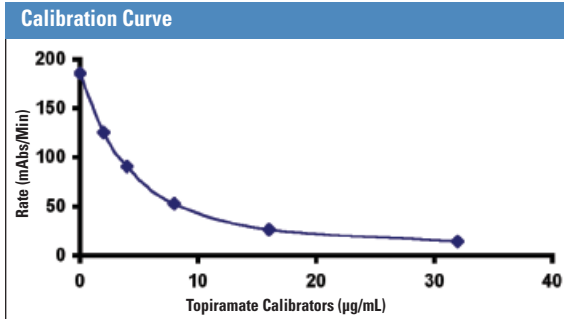


**Thermo Scientific
QMS® Topiramate**



The Thermo Scientific QMS Topiramate Immunoassay is intended for the quantitative determination of topiramate in human serum or plasma on automated clinical chemistry analyzers. The results obtained are used in the diagnosis and treatment of topiramate overdose and in monitoring levels of topiramate 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 32 µg/mL
LDD: 0.15 µg/mL
LOQ: 1.50 µg/mL

Accuracy

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

Theoretical Concentration (µg/mL)	Mean Concentration (µg/mL)	Percent Recovery
32.00	32.48	101%
24.00	24.50	102%
16.00	16.74	105%
8.00	8.35	104%
6.40	6.61	103%
3.20	3.47	108%
2.56	2.67	104%
1.92	2.11	110%
1.60	1.65	103%
1.28	1.33	104%
0.96	1.06	110%

Precision

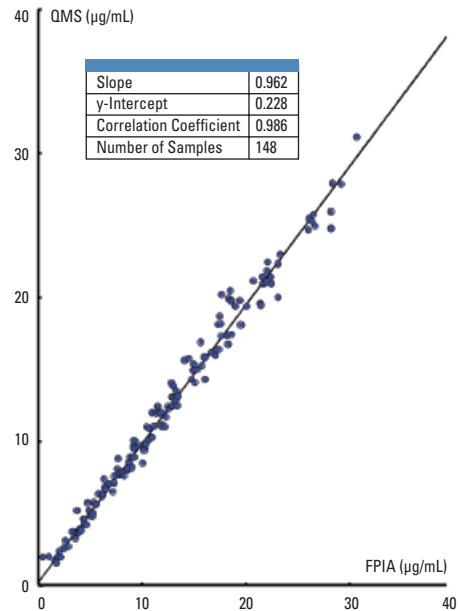
A 20-day study was conducted using commercially available, tri-level, serum-based controls. Results are shown below.

WITHIN RUN			
n = 80	Mean (µg/mL)	SD	CV
Level 1	2.94	0.08	2.77%
Level 2	10.14	0.19	1.83%
Level 3	25.69	0.83	3.23%

TOTAL RUN			
n = 80	Mean (µg/mL)	SD	CV
Level 1	2.94	0.12	4.22%
Level 2	10.14	0.34	3.37%
Level 3	25.69	1.14	4.44%

Method Comparison

Results of patient samples analyzed for topiramate by the QMS Topiramate Immunoassay were compared with the results obtained using a Fluorescence Polarization Immunoassay (FPIA) system. The topiramate concentrations ranged from 1.56 to 30.72 µg/mL. Results are shown below.



Stability

Reagent Open-Vial Stability:

Greater than 25 days*

Calibration Curve Stability:

Greater than 14 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.

Assay Specific Information

Exhibits minimal interference from most common and co-administered drugs.

Ordering Information

QMS Topiramate Reagent Kit.....0374140
 QMS Topiramate Calibrator Set.....0374173
 QMS Topiramate Control Set.....0374181

Application sheets for specific clinical chemistry analyzers available upon request.

UK NEQAS proficiency data is collected and is available upon request.

