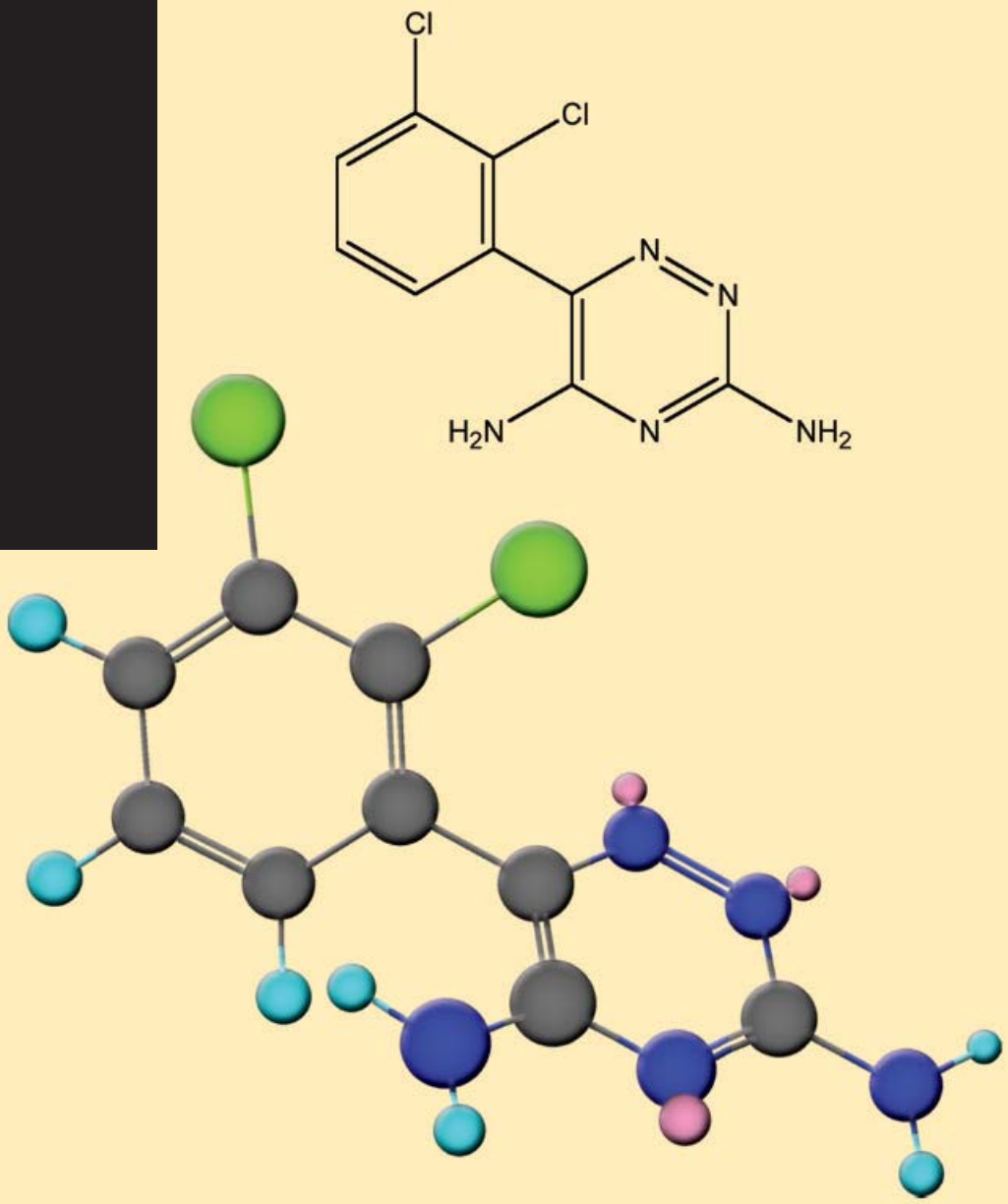
Thermo Scientific QMS® Lamotrigine

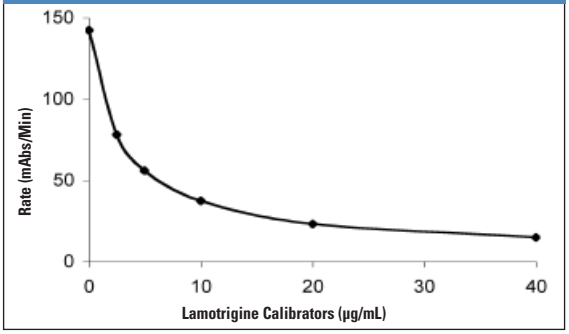


The Thermo Scientific QMS Lamotrigine Immunoassay is intended for the quantitative determination of lamotrigine in human serum or plasma on automated clinical chemistry analyzers. Lamotrigine concentrations can be used as an aid in management of patients treated with lamotrigine.

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

Thermo Scientific QMS® Lamotrigine

Calibration Curve



Assay Range: 0 to 40 µg/mL
LDD: 0.13 µg/mL
LOQ: 2.0 µg/mL

Accuracy

Recovery was determined by spiking lamotrigine into human serum 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
40.02	38.61	96%
30.02	32.74	109%
20.03	19.07	95%
15.00	16.05	107%
9.00	9.37	104%
5.02	5.33	106%
3.75	3.94	105%
2.50	2.49	100%

Precision

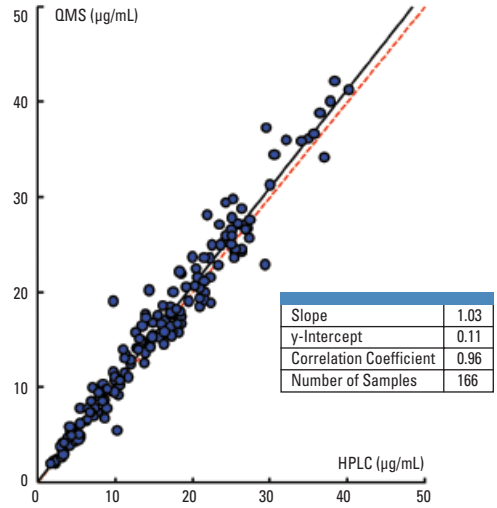
A 20-day study was conducted using commercially available, tri-level, serum-based controls and patient sample pools. Results are shown below.

WITHIN RUN			
n = 80	Mean (µg/mL)	SD	CV
PT Pool Low	2.81	0.05	1.61%
PT Pool Mid	10.79	0.10	0.94%
PT Pool High	23.93	0.40	1.67%
Low Control	2.17	0.04	1.64%
Mid Control	15.51	0.18	1.15%
High Control	25.57	0.39	1.52%

TOTAL RUN			
n = 80	Mean (µg/mL)	SD	CV
PT Pool Low	2.81	0.08	2.77%
PT Pool Mid	10.79	0.21	1.95%
PT Pool High	23.93	0.58	2.43%
Low Control	2.17	0.06	2.89%
Mid Control	15.51	0.29	1.88%
High Control	25.57	0.52	2.02%

Method Comparison

Results of serum and plasma samples analyzed for lamotrigine by the QMS Lamotrigine Immunoassay were compared with the results obtained using an HPLC assay. The lamotrigine concentrations ranged from 2.02 to 43.13 µg/mL. Results are shown below.



Stability

Reagent Open-Vial Stability:
Greater than 50 days*

Calibration Curve Stability:
Greater than 35 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

All common and co-administered drugs tested exhibited a cross reactivity of less than 10%.

Linear throughout reportable assay range.

Ordering Information

QMS Lamotrigine Reagent Kit 0373795
QMS Lamotrigine Calibrator Set 0373787
QMS Lamotrigine Control Set.....0374090

Application sheets for specific clinical chemistry analyzers available upon request.

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

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