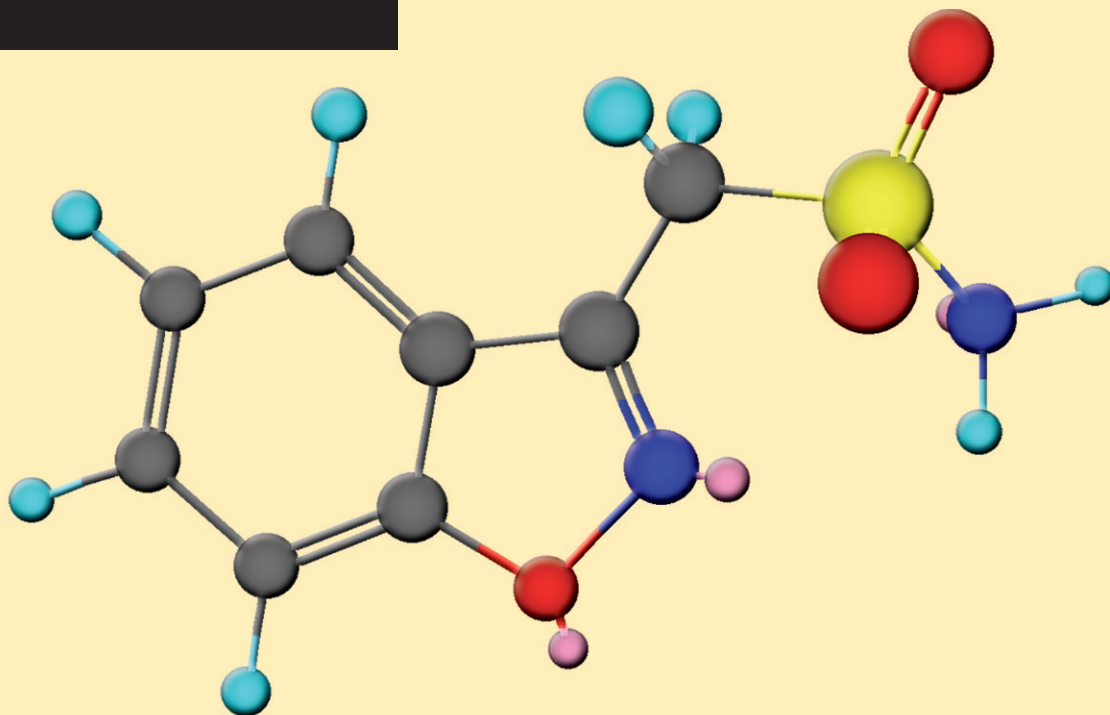
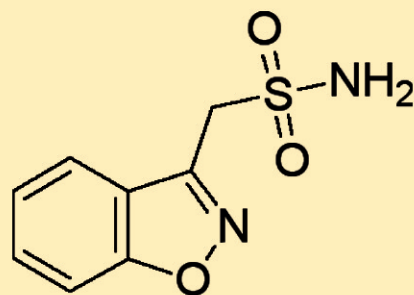
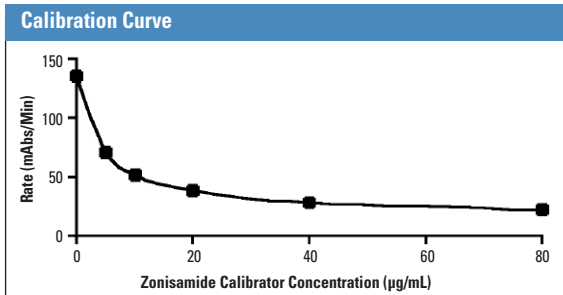


**Thermo Scientific  
QMS® Zonisamide**



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

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



**Assay Range:** 3.0 to 50.0 µg/mL  
**LDD:** 1.0 µg/mL  
**LOQ:** 3.0 µg/mL

**Accuracy**

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

Theoretical Concentration (µg/mL)	Mean Concentration (µg/mL)	Percent Recovery
48.00	45.49	95%
32.00	30.25	95%
16.00	15.30	96%
8.00	7.86	98%
4.00	4.41	110%

**Precision**

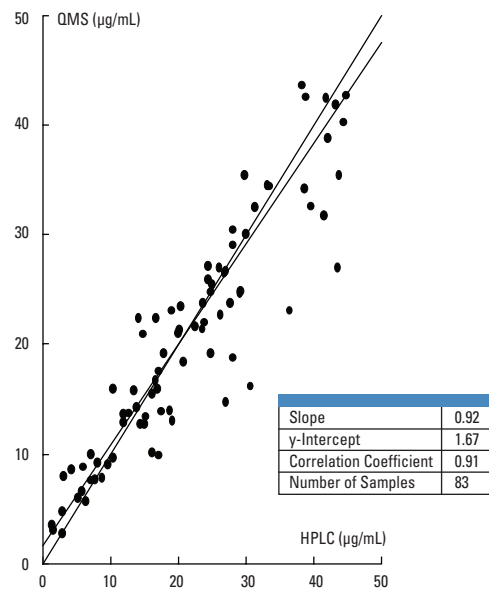
A tri-level human serum based commercial control containing zonisamide and patient sample pools representing low, medium and high therapeutic values were used in the study. Representative results are shown below.

WITHIN RUN			
n = 80	Mean (µg/mL)	SD	CV
PT Pool Low	10.42	0.59	5.70%
PT Pool Mid	27.74	1.38	5.00%
PT Pool High	40.74	2.45	6.00%
Low Control	8.90	0.37	4.20%
Mid Control	27.39	1.50	5.50%
High Control	52.30	2.17	4.10%

TOTAL RUN			
n = 80	Mean (µg/mL)	SD	CV
PT Pool Low	10.42	0.86	8.30%
PT Pool Mid	27.74	2.19	7.90%
PT Pool High	40.74	3.06	7.50%
Low Control	8.90	0.61	6.80%
Mid Control	27.39	1.80	6.60%
High Control	52.30	3.00	5.70%

**Method Comparison**

Results of serum and plasma samples analyzed for zonisamide by the QMS Zonisamide Immunoassay were compared with the results obtained using an HPLC assay. The zonisamide concentrations ranged from 2.30 to 44.70 µg/mL. Representative results are shown below.



**Stability**

**Calibration Curve Stability:**

Up to 2 weeks\*

**Shelf Life of Reagents and Calibrators:**

15 months from date of manufacturing

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

**Ordering Information**

QMS Zonisamide Reagent Kit .....0373571  
 QMS Zonisamide Calibrator Set .....0373381  
 QMS Zonisamide Control Set.....0373373

Application sheets for specific clinical chemistry analyzers available upon request.

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