

Fact Sheet

ARK™ Zonisamide Assay

The ARK™ Zonisamide Assay is a homogeneous enzyme immunoassay for the quantitative determination of zonisamide in human serum on automated clinical chemistry analyzers. The measurements obtained are used in the monitoring of zonisamide levels to help ensure appropriate therapy.

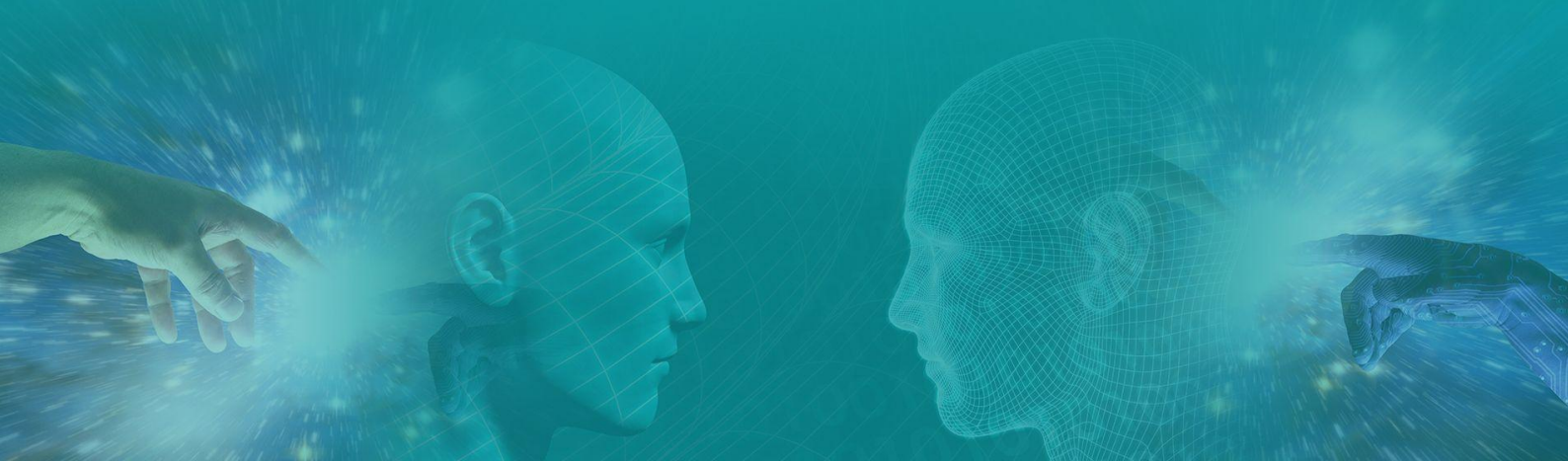
Assay Characteristics

- Excellent precision, even in trough concentrations
- Fast and efficient routine monitoring for lacosamide
- Liquid, ready-to-use reagents, calibrators and controls
- Storage at 2-8°C
- On-board stability for at least 60 days
- Does not contain any harmful preservatives, only $\leq 0.09\%$ sodium azide

Background

Zonisamide (ZONEGRAN®, 1,2-Benzisoxazole-3-methanesulfonamide,) is an anti-convulsant drug approved for use as adjunctive therapy in the treatment of partial seizures in adults with epilepsy.

A therapeutic range for zonisamide has not been well established. A reference range between 10 to 40 $\mu\text{g}/\text{mL}$ has been suggested. In one study, a 50% reduction in seizures was observed at serum concentrations ranging from 7 to 40 mg/L. Some studies indicate an increased incidence of adverse effects at serum concentrations in excess of 30 mg/L. In general the relationship between these serum concentrations and clinical effect has not been well-defined, and considerable overlap in zonisamide concentrations has been observed between serum responders and non-responders as well as between serum levels associated with seizure control and adverse effects.



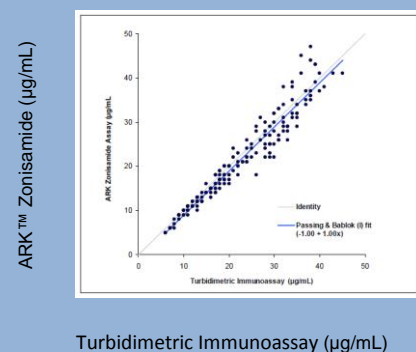
Properties of Zonisamide

Bioavailability	~ 100%
Peak level	~2 hours after oral dose of 400 mg
Plasma Protein Binding	13 to 17%
Elimination	Excretion almost unchanged in urine
Metabolization	70% of administered dose is eliminated unchanged in the urine; the remaining 30% is metabolized hepatically to six metabolites (formed by hydroxylation, hydrolysis, and glucuronidation)
Elimination half time	50 - 70 hours

Assay Precision

Sample	N	M (µg/ml)	Within-Run		Between Day		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)
ARK™ Zonisamide Control								
LOW	160	5.0	0.21	4.1	0.16	3.2	0.25	5.1
MID	160	24.4	0.96	3.8	0.56	2.3	1.12	4.5
HIGH	160	50.6	1.97	3.9	1.33	2.6	2.63	5.3
Human Serum								
LOW	160	7.0	0.29	4.0	0.21	3.0	0.36	4.9
MID	160	22.6	0.81	3.5	0.59	2.6	1.01	4.4
HIGH	160	51.6	2.47	4.9	1.66	3.2	2.96	5.9

Method Comparison



Order Information

Product Description	Size	Order No.
ARK™ Zonisamide Assay	28 mL R1 & 14 mL R2	5022-0001-00
ARK™ Zonisamide Calibrator	1 x 4 mL & 5 x 2 mL	5022-0002-00
ARK™ Zonisamide Control	6 x 4 mL	5022-0003-00