Fact Sheet

ARK™ Topiramate Assay

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

Assay Characteristics

- Excellent precision, even in trough concentrations
- Fast and efficient routine monitoring for topiramate
- 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 ≤ 0.09% sodium azide

Background

Topiramate (2,3:4,5-Di-O-Isopropylidene-ß-D-fructopyranose sulfamate) is an anti-convulsant drug approved for use in the treatment of epilepsy and is often prescribed as monotherapy or as one component of a multiple anti-epileptic drug therapy.

A therapeutic range for topiramate has not been well established. The proposed therapeutic range (trough sample) for seizure control is 2 to 25 µg/mL. There is an inconsistent correlation between levels of circulating topiramate to toxicity, adverse affect or clinical efficacy, which justifies the careful therapeutic drug monitoring of topiramate concentration in patients.

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Properties of Topiramate

Bioavailability	~ 80%
Peak level	~ 2 hours after oral dose of 400 mg
Plasma Protein Binding	13 - 17%
Elimination	Excretion almost unchanged in the urine (70 - 80%)
Metabolization	Hepatic (20 - 30%)
Elimination half time	19 to 25 hours

Assay Precision

Sample	N	M (µg/ml)	Within-Run		Between Day		Total	
			SD	CV(%)	SD	CV (%)	SD	CV (%)
ARK™ Topiramate Control								
LOW	160	2.4	0.08	3.4	0.05	2.0	0.10	4.3
MID	160	10.2	0.24	2.4	0.14	1.4	0.28	2.7
HIGH	160	40.2	1.19	2.9	0.64	1.6	1.29	3.2

Order information

Product Description	Size	Order No.
ARK™ Topiramate Assay	28 mL R1 & 14 mL R2	5015-0001-00
ARK™ Topiramate Calibrator	1 x 4 mL & 5 x 2 mL	5015-0002-00
ARK™ Topiramate Control	6 x 4 mL	5015-0003-00

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