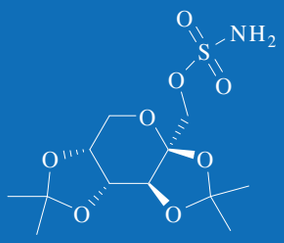


ARK™ Topiramate Assay

The ARK™ Topiramate Assay 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.

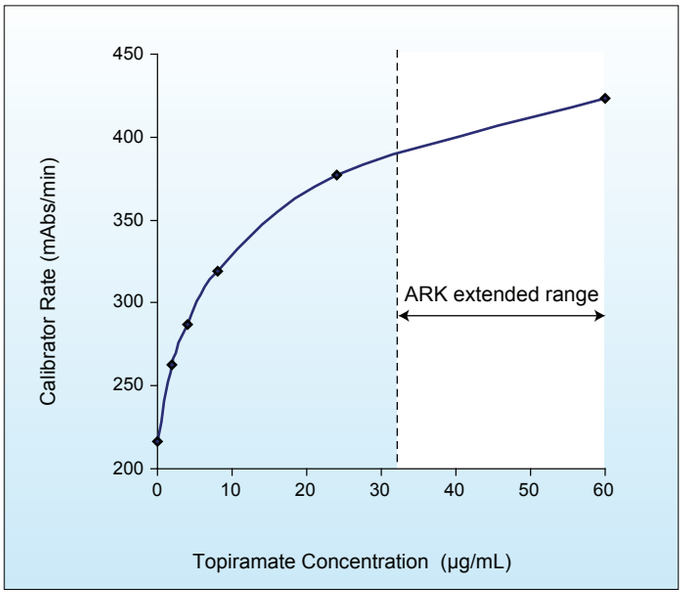
KEY POINTS

- Homogeneous enzyme immunoassay
- Applicable onboard automated clinical chemistry analyzers
- Convenient, liquid-stable, ready-to-use
- Extended calibration range
- Tested drugs and endogenous substances do not interfere
- Nonhazardous preservatives contain no sodium azide

Next Generation Assays

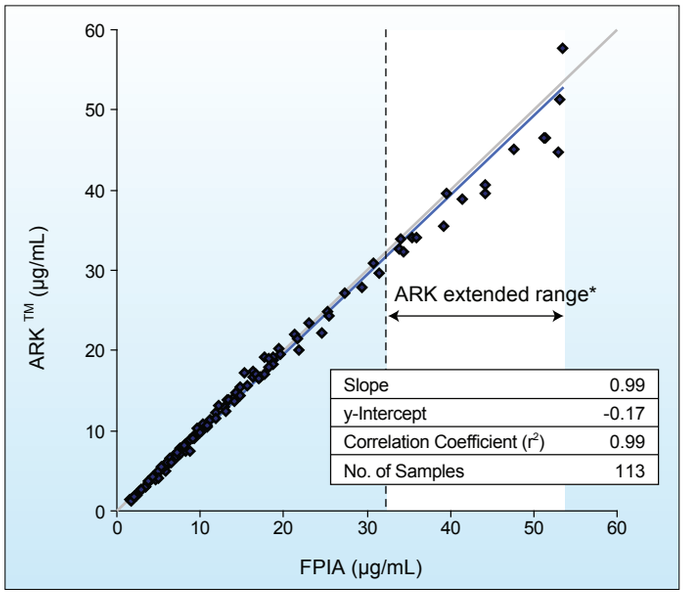
ARK Diagnostics, Inc.

CALIBRATION RANGE



ARK™ Topiramate Assay Calibration Range: 0.0 to 60.0 µg/mL
LOQ: 1.5 µg/mL

METHOD COMPARISON



*Specimens ≥32 µg/mL by FPIA were diluted and retested.

ARK™ Topiramate Assay Range: 1.5 to 54.0 µg/mL

ACCURACY

Theoretical Concentration (µg/mL)	Mean Recovered Concentration (µg/mL)	Percent Recovery N = 6
55.0	58.9	107.1
45.0	47.3	105.0
30.0	30.8	102.6
15.0	15.5	103.4
10.0	10.4	103.8
6.0	6.4	106.7
5.0	5.3	106.0
4.0	4.2	104.2
2.5	2.7	106.7
1.5	1.4	95.6

Analytical recovery was determined by spiking topiramate into human serum to produce concentrations across the assay range.

PRECISION

WITHIN-RUN			
n = 160	**Mean (µg/mL)**	**SD**	**CV (%)**
Control low	2.4	0.08	3.4
Control mid	10.2	0.24	2.4
Control high	40.2	1.19	2.9
TOTAL			
n = 160	**Mean (µg/mL)**	**SD**	**CV (%)**
Control low	2.4	0.1	4.3
Control mid	10.2	0.28	2.7
Control high	40.2	1.29	3.2

Tri-level controls containing topiramate were assayed in quadruplicate twice a day for 20 days. CLSI Guideline EP5-A2.

INTERFERENCE

Tested endogenous substances and co-administered drugs, including phenytoin, ibuprophen, and tiagabine, do not interfere* with ARK™ Topiramate Assay.

*≤10% error

SAFETY AND STABILITY

Reagent on-board stability
Up to at least 60 days

Calibration Curve Stability
Up to 49 days

Shelf Life of Reagents, Calibrators, and Controls
18 months from date of manufacturing

Safety
Nonhazardous preservatives (no sodium azide)

Results shown are typical and may vary among laboratory analyzers. Available upon request: UKNEQAS proficiency data.

ORDERING INFORMATION

ARK™ Topiramate Assay	5015-0001-00
ARK™ Topiramate Calibrator	5015-0002-00
ARK™ Topiramate Control	5015-0003-00

ARK Diagnostics, Inc.
48089 Fremont Boulevard
Fremont, California 94538
Tel: 510-270-6270 Fax: 510-270-6298

For Customer Support:
Call toll free: 877-869-2320
customersupport@ark-tdm.com
www.ark-tdm.com

ARK Diagnostics, Inc.

MKT12-010 Rev 04 September 2015