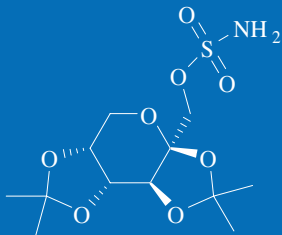


# ARK™ Topiramate Assay

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.

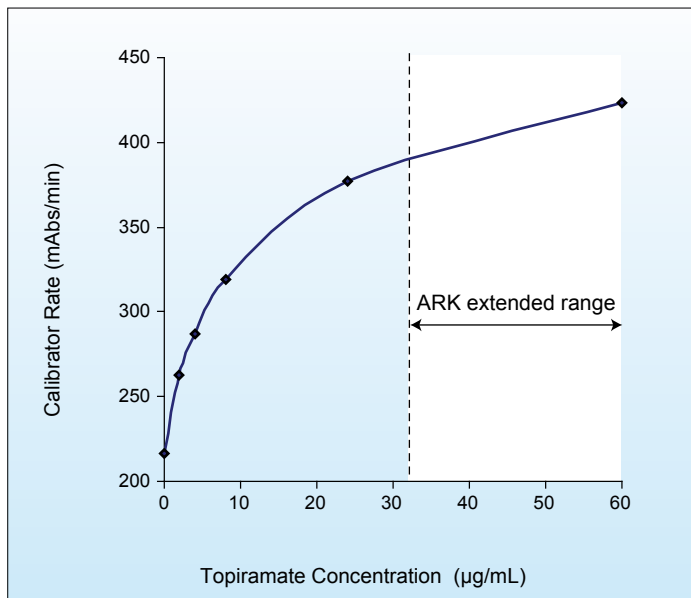


## KEY POINTS

- 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

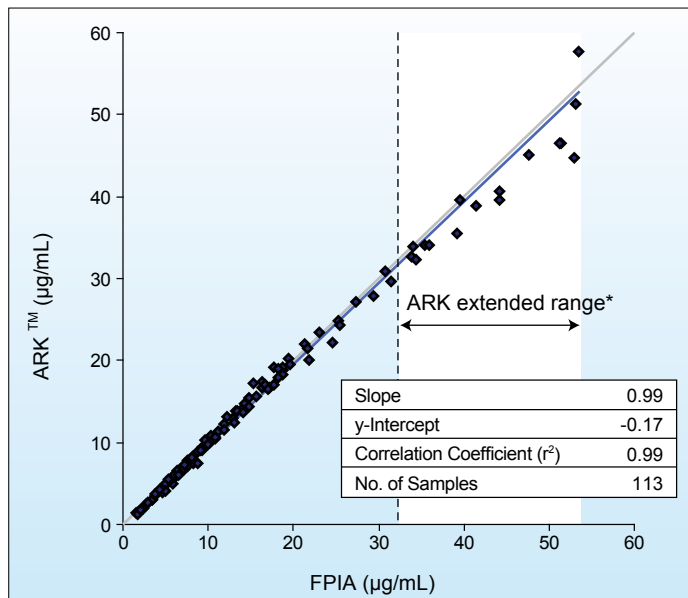
*Next Generation Assays*

## CALIBRATION RANGE



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

## METHOD COMPARISON



\*Specimens  $\geq 32$  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.

\* $\leq 10\%$  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 when stored at 2 – 8 °C

### Safety

Nonhazardous preservatives (contains 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.

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