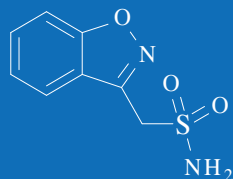


ARK™ Zonisamide Assay



The ARK™ Zonisamide Assay 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.

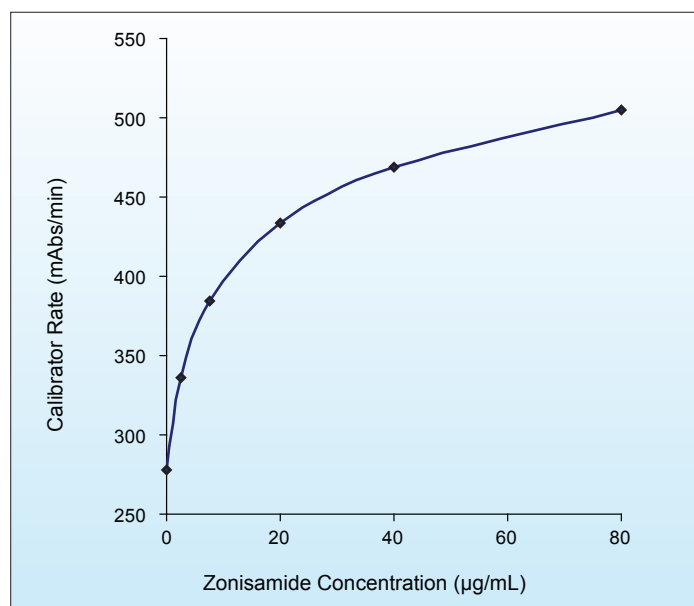


KEY POINTS

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

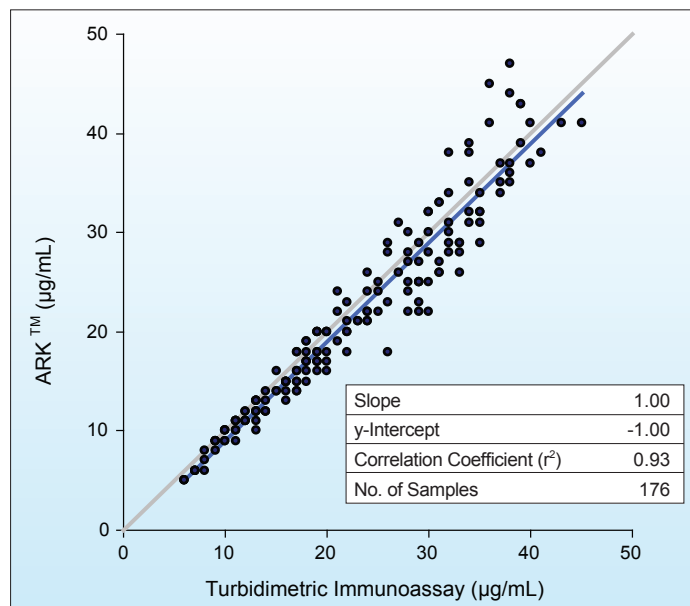
Next Generation Assays

CALIBRATION RANGE



ARK™ Zonisamide Assay Calibration Range: 0.0 to 80.0 µg/mL
LOQ: 2.0 µg/mL

METHOD COMPARISON



ARK™ Zonisamide Assay Range: 2.0 to 50.0 µg/mL
Linearity: 2.4 to 48.0 µg/mL

ACCURACY

Theoretical Concentration (µg/mL)	Mean Recovered Concentration (µg/mL)	Percent Recovery N = 6
50.0	49.1	98.1
35.0	35.0	100.0
25.0	25.3	101.0
15.0	15.7	104.5
5.0	5.5	110.0
3.0	3.0	100.0
2.0	1.7	85.3

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

PRECISION

WITHIN-RUN			
n = 160	Mean (µg/mL)	SD	CV (%)
Control low	5.0	0.21	4.1
Control mid	24.4	0.96	3.8
Control high	50.6	1.97	3.9
TOTAL			
n = 160	Mean (µg/mL)	SD	CV (%)
Control low	5.0	0.25	5.1
Control mid	24.4	1.12	4.5
Control high	50.6	2.63	5.3

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

INTERFERENCE

Tested endogenous substances and co-administered drugs do not interfere* with ARK™ Zonisamide Assay.

*≤10% error

SAFETY AND STABILITY

Reagent on-board stability

Up to at least 60 days

Calibration Curve Stability

Up to 46 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™ Zonisamide Assay	5022-0001-00
ARK™ Zonisamide Calibrator	5022-0002-00
ARK™ Zonisamide Control	5022-0003-00

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