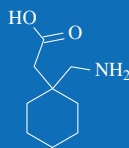


ARK™ Gabapentin Assay



The ARK™ Gabapentin Assay is intended for the quantitative determination of gabapentin in human serum or plasma on automated clinical chemistry analyzers. Gabapentin concentrations can be used as an aid in management of patients treated with gabapentin.

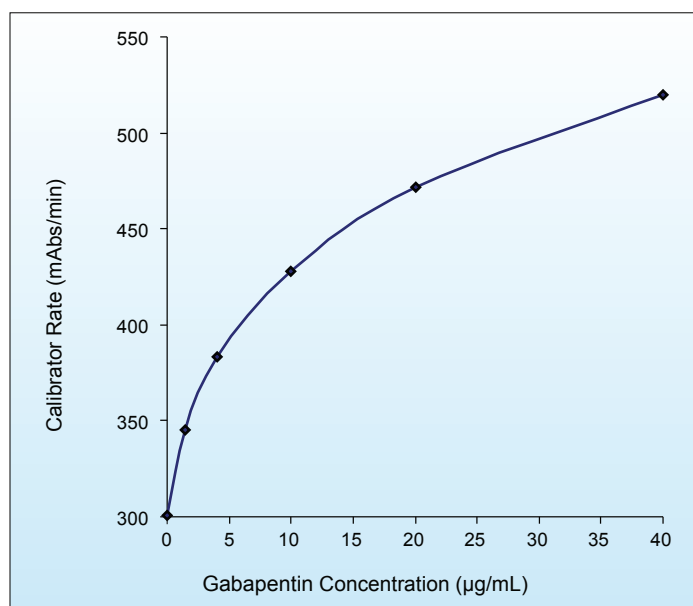


KEY POINTS

- 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

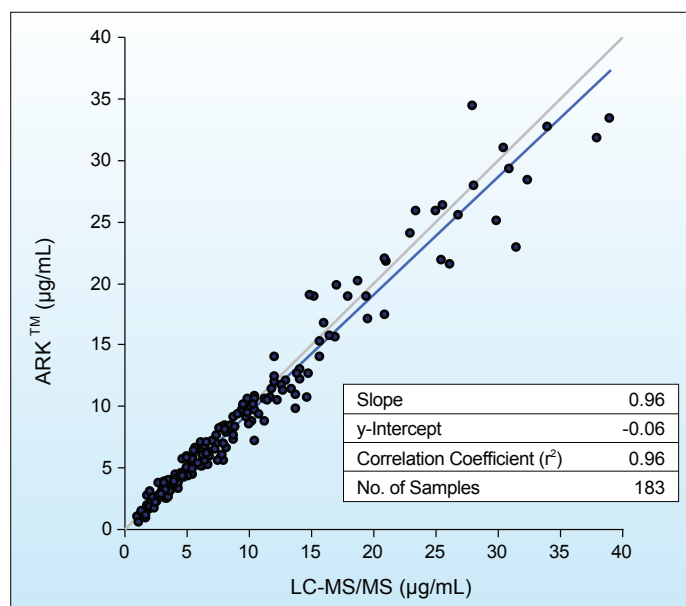
Next Generation Assays

CALIBRATION RANGE



ARK™ Gabapentin Assay Calibration Range: 0.0 to 40.0 µg/mL
LOQ: 0.75 µg/mL

METHOD COMPARISON



ARK™ Gabapentin Assay Range: 0.75 to 40.0 µg/mL

ACCURACY

Theoretical Concentration (µg/mL)	Mean Recovered Concentration (µg/mL)	Percent Recovery N = 6
40.0	41.2	103.0
35.0	35.6	101.7
28.0	27.9	99.5
22.0	22.0	100.0
16.0	16.0	100.2
9.0	9.0	99.7
3.5	3.6	101.3
2.0	2.1	103.3
1.0	1.0	98.5

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

PRECISION

WITHIN-RUN			
n = 160	Mean (µg/mL)	SD	CV (%)
Control low	2.5	0.08	3.3
Control mid	7.9	0.21	2.6
Control high	24.6	0.48	1.9
TOTAL			
n = 160	Mean (µg/mL)	SD	CV (%)
Control low	2.5	0.14	5.6
Control mid	7.9	0.35	4.4
Control high	24.6	0.88	3.6

Tri-level controls containing gabapentin 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™ Gabapentin Assay.

*≤10% error

SAFETY AND STABILITY

Reagent on-board stability

Up to at least 60 days

Calibration Curve Stability

Up to 84 days

Shelf Life of Reagents, Calibrators, and Controls

18 months from date of manufacturing

Safety

Nonhazardous preservatives

Contains sodium azide ≤ 0.09%

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

ORDERING INFORMATION

ARK™ Gabapentin Assay	5025-0001-00
ARK™ Gabapentin Calibrator	5025-0002-00
ARK™ Gabapentin Control	5025-0003-00

ARK Diagnostics, Inc.

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