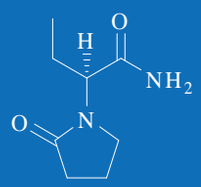


ARK™ Levetiracetam Assay

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

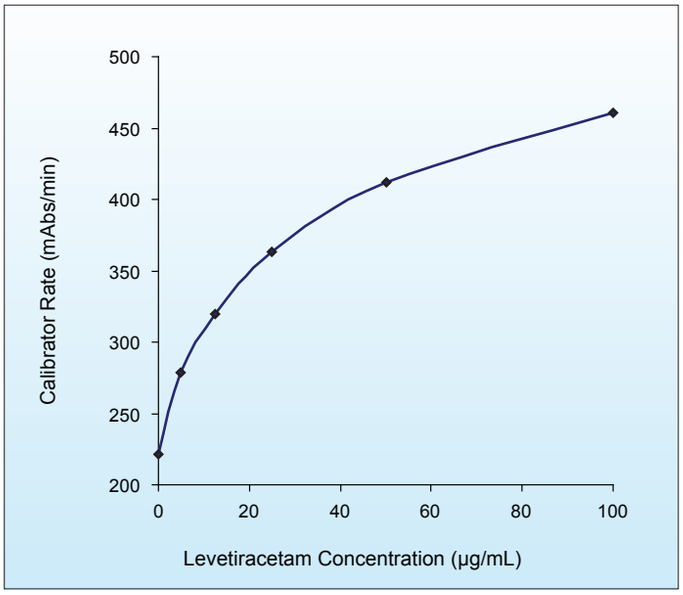
KEY POINTS

- 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

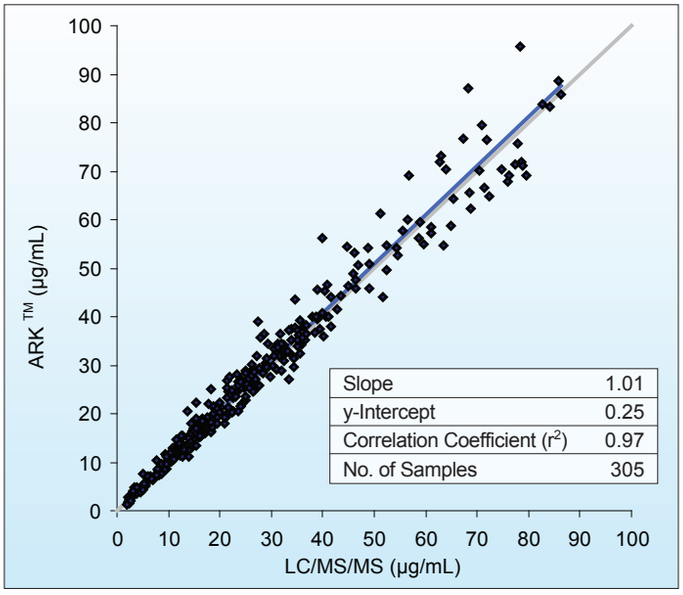
ARK Diagnostics, Inc.

CALIBRATION RANGE



ARK™ Levitracetam Assay Calibration Range: 0.0 to 100.0 µg/mL
LOQ: 2.0 µg/mL

METHOD COMPARISON



ARK™ Levitracetam Assay Range: 2.0 to 100.0 µg/mL
Linearity: 2.0 to 100.0 µg/mL

ACCURACY

Theoretical Concentration (µg/mL)	Mean Recovered Concentration (µg/mL)	Percent Recovery N = 6
100.0	105.3	105.3
80.0	79.3	99.1
45.0	44.1	98.0
20.0	19.2	95.9
10.0	10.0	100.0
4.0	3.8	94.6
2.0	1.9	95.8

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

PRECISION

WITHIN-RUN			
n = 160	**Mean (µg/mL)**	**SD**	**CV (%)**
Control low	7.5	0.25	3.4
Control mid	29.4	0.85	2.9
Control high	73.4	2.14	2.9
TOTAL			
n = 160	**Mean (µg/mL)**	**SD**	**CV (%)**
Control low	7.5	0.34	4.5
Control mid	29.4	1.08	3.7
Control high	73.4	3.08	4.2

Tri-level controls containing levetiracetam 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™ Levetiracetam Assay. The major metabolite ucb L057 does not cross-react.

*≤10% error

SAFETY AND STABILITY

Reagent on-board stability
Up to at least 60 days

Calibration Curve Stability
Up to 40 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™ Levetiracetam Assay	5024-0001-00
ARK™ Levetiracetam Calibrator	5024-0002-00
ARK™ Levetiracetam Control	5024-0003-00

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