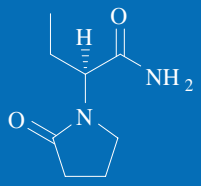
ARK™ Levetiracetam II Assay



The ARK™ Levetiracetam II Assay is a homogeneous enzyme immunoassay for the quantitative determination of levetiracetam in human serum or plasma on automated clinical chemistry analyzers. The measurements obtained are used in monitoring levels of levetiracetam to help ensure appropriate therapy.

KEY POINTS

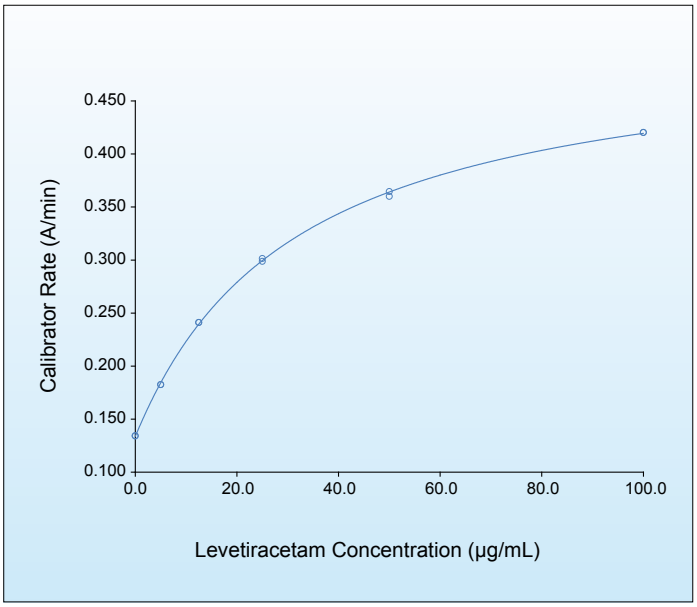
- Improved precision and stability
- Homogenous enzyme immunoassay
- Applicable to many automated clinical chemistry analyzers
- Convenient, liquid-stable, ready-to-use
- Tested drugs and endogenous substances do not interfere

Next Generation Assays

ARK Diagnostics, Inc.

CE Mark, FDA Cleared

CALIBRATION RANGE



ARK™ Levetiracetam II Assay Measurement Range: 2.0 – 100.0 µg/mL.
Linearity: 2.0 – 100.0 µg/mL
LOQ: 2.0 µg/mL

ACCURACY

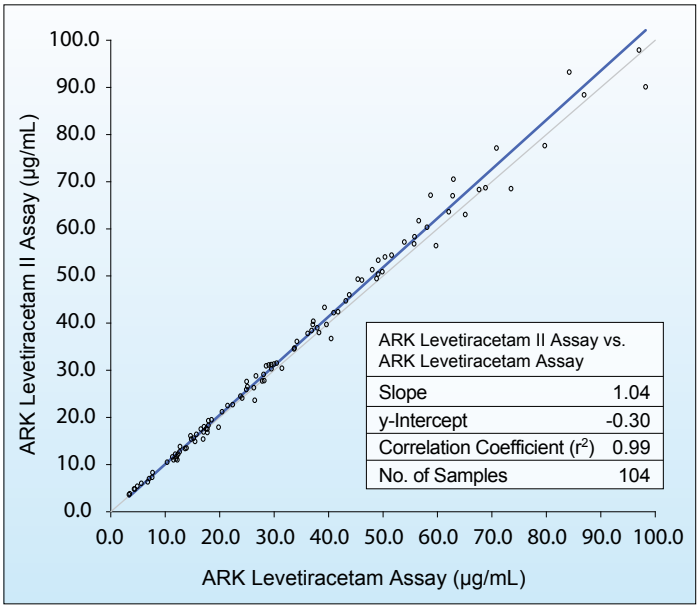
Target (µg/mL)	Mean (µg/mL)	SD	CV (%)	Recovery (%)
2.0	1.9	0.09	4.7	95.0
4.0	3.9	0.10	2.5	97.5
10.0	9.8	0.17	1.8	98.0
20.0	20.1	0.16	0.8	100.5
45.0	46.2	0.58	1.3	102.6
80.0	77.8	2.26	2.9	97.3
100.0	100.3	0.47	0.5	100.3

PRECISION

Sample	N	Mean (µmol/L)	Within Run SD	Within Run CV (%)	Between Day SD	Between Day CV (%)	Total (Within Lab) SD	Total (Within Lab) CV (%)
Control Low	160	7.6	0.16	2.1	0.09	1.2	0.18	2.3
Control Mid	160	30.5	0.45	1.5	0.34	1.1	0.60	2.0
Control High	160	75.7	1.41	1.9	0.99	1.3	2.19	2.9
Serum Low	160	7.7	0.11	1.4	0.06	0.8	0.12	1.6
Serum Mid	160	32.6	0.47	1.4	0.34	1.1	0.61	1.9
Serum High	160	80.5	1.62	2.0	0.80	1.0	1.79	2.2

Precision was performed according to (CLSI) Protocol EP5-A3.

METHOD COMPARISON



INTERFERENCE

Tested endogenous substances and co-administered drugs do not interfere* with ARK™ Levetiracetam II 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

Shelf Life of Reagents, Calibrators, and Controls

18 months from date of manufacturing when stored at 2 – 8 °C

Safety

Nonhazardous preservatives
Contains sodium azide ≤0.09%

Available upon request: CAP Proficiency Testing for Anti-epileptic Drugs.

ORDERING INFORMATION

ARK™ Levetiracetam II Assay (R1 x 28 mL / R2 x 14 mL)	5070-0001-00
ARK™ Levetiracetam II Assay (R1 X 115 mL / R2 X 58 mL)	5070-0001-01
ARK™ Levetiracetam II Calibrator (1 x 4mL / 5 x 2mL)	5070-0002-00
ARK™ Levetiracetam II Control (3 x 4mL)	5070-0003-00

ARK Diagnostics, Inc.
48089 Fremont Boulevard
Fremont, CA 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

MKT 24-001 Rev 02 July 2024

ARK Diagnostics, Inc.