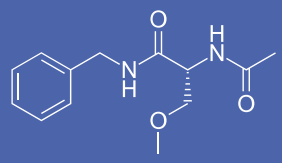


ARK™ Lacosamide Assay

The ARK™ Lacosamide Assay is intended for the quantitative determination of lacosamide in human serum on automated clinical chemistry analyzers. The measurements obtained are used in monitoring levels of lacosamide to help ensure appropriate therapy.

KEY POINTS

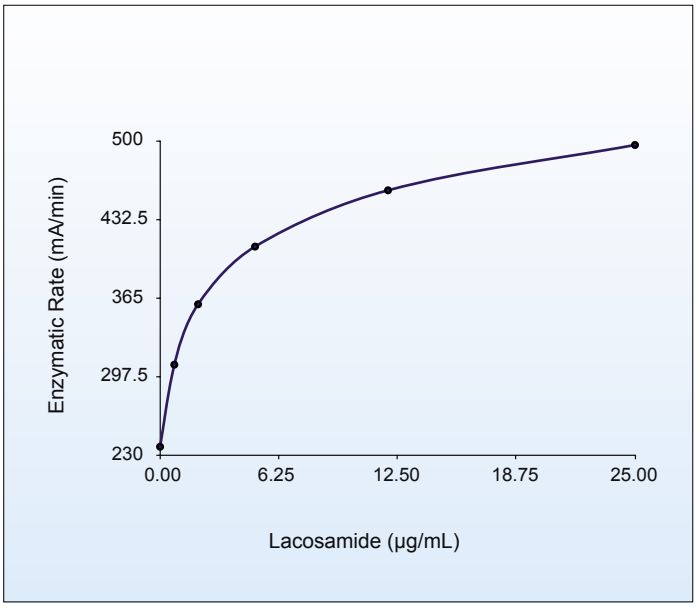
- Homogeneous enzyme immunoassay
- Applicable onboard automated clinical chemistry analyzers
- Convenient, liquid-stable, ready-to-use
- Excellent calibration range
- Tested drugs and endogenous substances do not interfere
- The crossreactivity of O-desmethyl lacosamide metabolite was not clinically significant (≤ 3.0%)

Next Generation Assays

ARK Diagnostics, Inc.

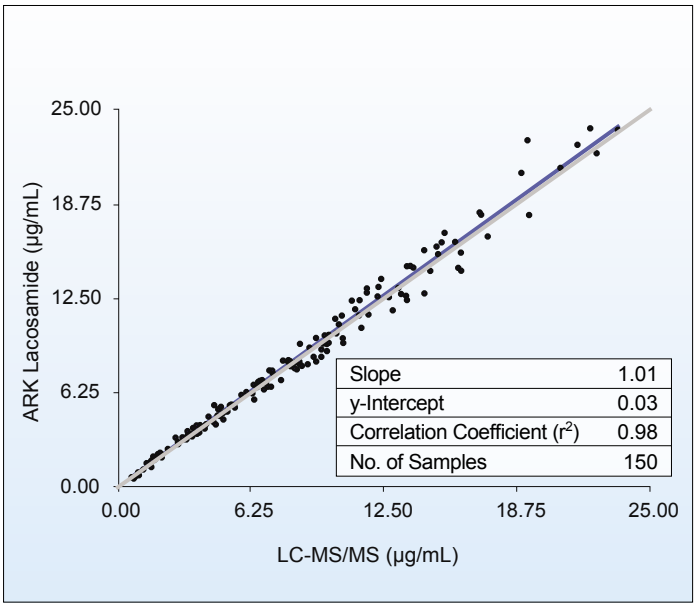
CE Mark, FDA Cleared

CALIBRATION RANGE



ARK™ Lacosamide Assay Calibration Range: 0.00 to 25.00 µg/mL.
LOQ: 0.40 µg/mL

METHOD COMPARISON



ARK™ Lacosamide Assay: Measurement Range: 0.50 to 24.00 µg/mL.

ACCURACY

Theoretical Concentration (µg/mL)	Mean Recovered Concentration (µg/mL)	Percent Recovery (%)
0.40	0.36	90.4
0.50	0.47	93.3
1.00	1.04	104.2
3.00	3.07	102.3
6.00	6.15	102.6
9.00	8.92	99.1
15.00	14.42	96.1
20.00	21.15	105.8

Accuracy (analytical recovery) was determined by adding concentrated lacosamide drug into human serum negative for lacosamide, representing drug concentrations across the assay range.

PRECISION

		WITHIN-RUN		BETWEEN DAY		TOTAL	
Sample n = 160	Mean (µg/mL)	SD	CV (%)	SD	CV (%)	SD	CV (%)
ARK Lacosamide Control							
LOW	1.55	0.049	3.1	0.049	3.1	0.070	4.5
MID	7.13	0.202	2.8	0.204	2.9	0.287	4.0
HIGH	14.94	0.450	3.0	0.445	3.0	0.664	4.4
Human Serum							
LOW	1.49	0.045	3.0	0.037	2.5	0.058	3.9
MID	7.10	0.175	2.5	0.217	3.1	0.283	4.0
HIGH	15.18	0.456	3.0	0.432	2.8	0.657	4.3

Tri-level controls and sera containing lacosamide were assayed in quadruplicate twice a day for 20 days. CLSI EP05-A3.

INTERFERENCE

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

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

Safety

Nonhazardous preservatives
Contains sodium azide ≤ 0.09%

Results shown are typical and may vary among laboratory analyzers. Available Upon request: LGC Proficiency Testing for Anti-epileptic Drugs.

ORDERING INFORMATION

ARK™ Lacosamide Assay	5033-0001-00
ARK™ Lacosamide Calibrator	5033-0002-00
ARK™ Lacosamide Control	5033-0003-00

ARK Diagnostics, Inc.
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MKT17-023 Ver. 0 August 2021