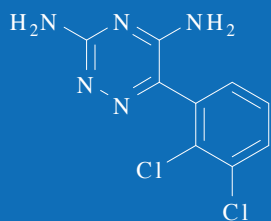


# ARK™ Lamotrigine Assay



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

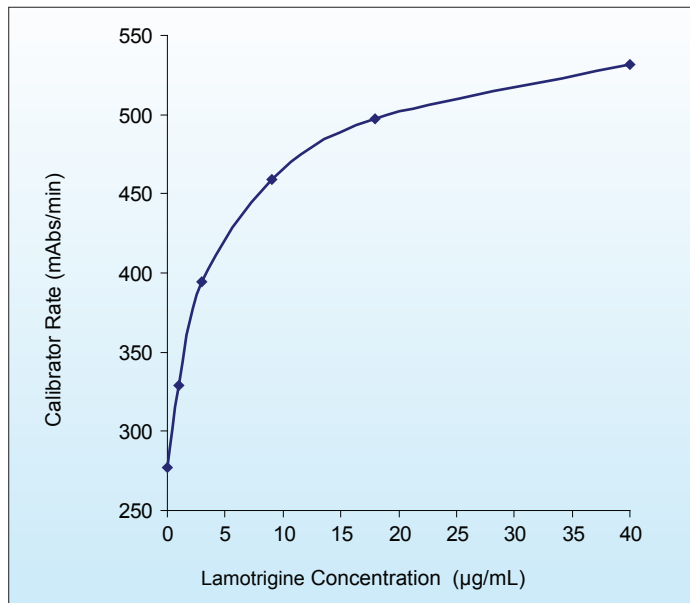


## KEY POINTS

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

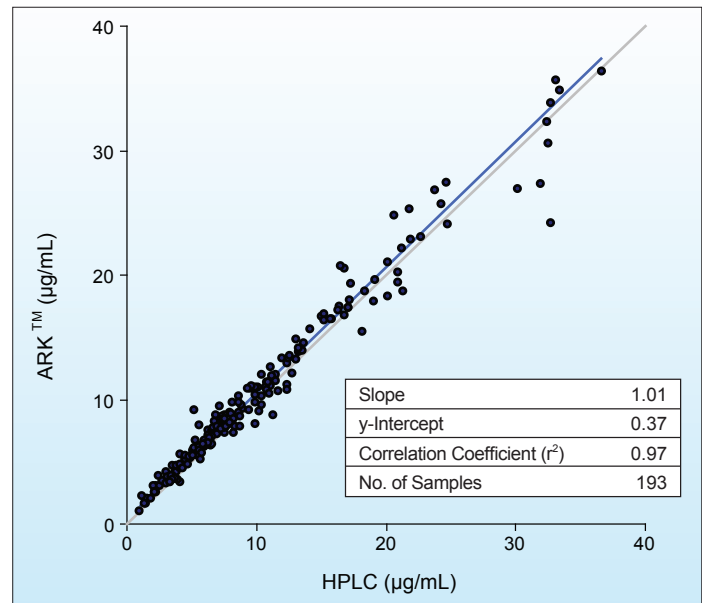
*Next Generation Assays*

## CALIBRATION RANGE



ARK™ Lamotrigine Assay Calibration Range: 0.00 to 40.00 µg/mL  
LOQ: 0.85 µg/mL

## METHOD COMPARISON



ARK™ Lamotrigine Assay Range: 0.85 to 40.00 µg/mL

## ACCURACY

Theoretical Concentration (µg/mL)	Mean Recovered Concentration (µg/mL)	Percent Recovery N = 6
40.00	38.33	95.8
30.00	29.16	97.2
15.00	14.80	98.7
11.00	10.97	99.7
5.00	5.25	105.1
2.50	2.48	99.3
1.00	0.99	99.2
0.85	0.84	98.2

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

## PRECISION

WITHIN-RUN			
n = 160	Mean (µg/mL)	SD	CV (%)
Control low	2.08	0.07	3.4
Control mid	11.70	0.42	3.6
Control high	24.23	0.99	4.1
TOTAL			
n = 160	Mean (µg/mL)	SD	CV (%)
Control low	2.08	0.08	4.1
Control mid	11.70	0.49	4.2
Control high	24.23	1.47	6.1

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

## INTERFERENCE

Other antiepileptic drugs and endogenous substances do not interfere\* with the ARK™ Lamotrigine Assay.

\*≤10% error

## SAFETY AND STABILITY

### Reagent on-board stability

Up to at least 30 days

### Calibration Curve Stability

Up to 30 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™ Lamotrigine Assay	5023-0001-00
ARK™ Lamotrigine Calibrator	5023-0002-00
ARK™ Lamotrigine Control	5023-0003-00

### ARK Diagnostics, Inc.

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