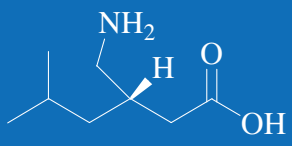
ARK™ Pregabalin II Assay



The ARK™ Pregabalin II Assay is an immunoassay intended for the qualitative and/or semi-quantitative determination of pregabalin in human urine at a cutoff concentration of 500 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers.

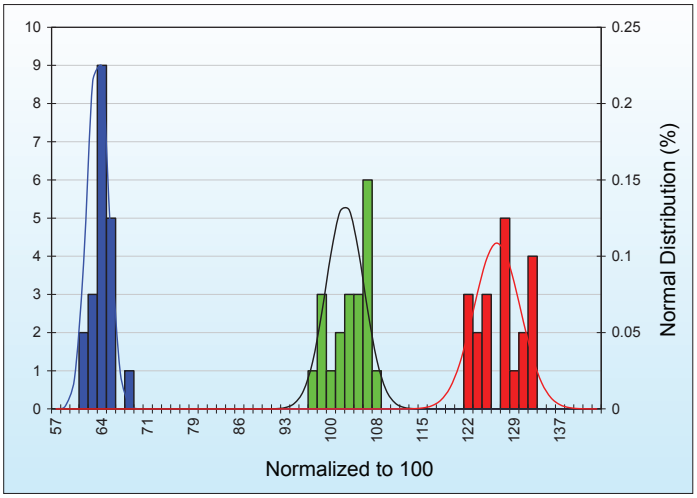
The ARK Pregabalin II Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug test result, particularly when the preliminary test result is positive.

KEY POINTS

- Convenient, liquid-stable, ready-to-use homogeneous enzyme immunoassay
- 0 – 2000 ng/mL calibration range: 500 ng/mL cutoff
- Excellent sensitivity and specificity for detection of pregabalin in human urine
- Qualitative/semi-quantitative application available for clinical chemistry systems

Next Generation Assays

QUALITATIVE PRECISION



Control Precision vs 500 ng/mL Cutoff Calibrator – Normalized to 100

SEMI-QUANTITATIVE 20 DAY PRECISION

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Results
0.0	-100	160	2.6	160 Negative
125.0	-75	160	133.6	160 Negative
250.0	-50	160	263.3	160 Negative
375.0	-25	160	392.3	160 Negative
500.0	Cutoff	160	525.3	19 Negative / 141 Positive
625.0	+25	160	645.8	160 Positive
750.0	+50	160	786.6	160 Positive
875.0	+75	160	882.6	160 Positive
1000.0	+100	160	1048.3	160 Positive

Pooled human urine samples containing pregabalin were assayed in quadruplicate twice a day for 20 days. CLSI Guideline EP5-A3.

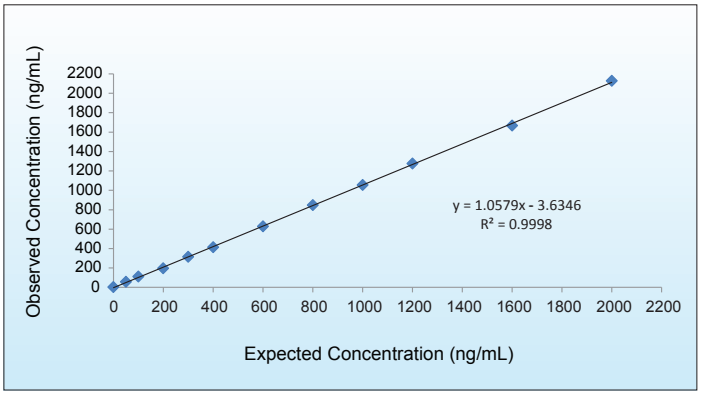
ACCURACY – ANALYTICAL RECOVERY

Theoretical Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0.0	0.8	NA
50.0	56.6	113.2
100.0	110.1	110.1
200.0	195.0	97.5
300.0	313.1	104.4
400.0	412.3	103.1
600.0	628.5	104.8
800.0	845.9	105.7
1000.0	1054.3	105.4
1200.0	1274.3	106.2
1600.0	1665.2	104.1
2000.0	2127.7	106.4

METHOD COMPARISON

		LC-MS/MS	
		(+)	(-)
ARK Pregabalin II 500 ng/mL Cutoff	(+)	67	0
	(-)	0	66

LINEARITY



ARK™ Pregabalin II Assay Calibration Range: 0 to 2000 ng/mL

CROSS-REACTIVITY AND INTERFERENCE

- No cross-reactivity with L-amino acids at 200 µg/mL
- No cross-reactivity with Gabapentin at 5000 µg/mL
- Tested endogenous substances do not interfere

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.

ORDERING INFORMATION

For Export Only Not for Sale in USA

ARK™ Pregabalin II Assay	5059-0001-00
ARK™ Pregabalin II Calibrator	5059-0002-00
ARK™ Pregabalin II Control	5059-0003-00

For Criminal Justice and Forensic Use Only

ARK™ Pregabalin II Assay	5059-0004-00
ARK™ Pregabalin II Calibrator	5059-0005-00
ARK™ Pregabalin II Control	5059-0006-00

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