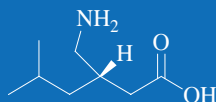


ARK™ Pregabalin Urine Assay



Pregabalin is a gamma-aminobutyric acid (GABA) analogue with structural similarity and actions similar to gabapentin. Like gabapentin, pregabalin has antiepileptic, analgesic, and anxiolytic activity.

The ARK™ Pregabalin Urine Assay is intended for the qualitative and/or semi-quantitative determination of pregabalin in human urine at a cutoff concentration of 500 ng/mL. The assay provides a simple and rapid analytical screening procedure for detecting pregabalin in urine and is designated for professional use on automated clinical chemistry analyzers.

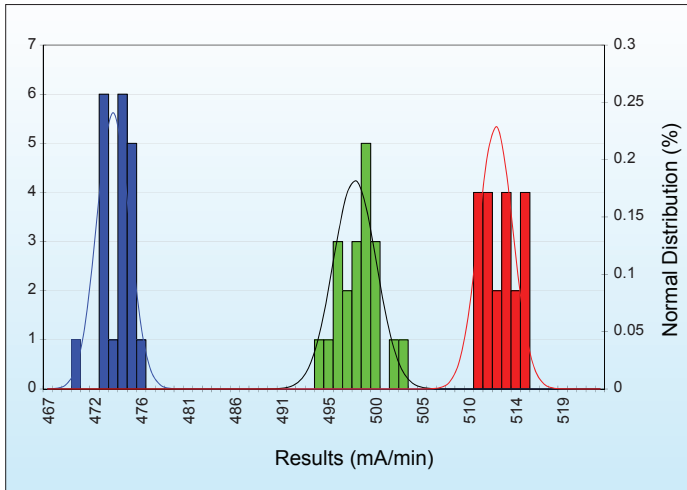


KEY POINTS

- Convenient, liquid-stable, ready-to-use homogeneous enzyme immunoassay
- Qualitative and/or semi-quantitative applications available for clinical chemistry systems
- 0 – 2000 ng/mL calibration range; 500 ng/mL cutoff
- Excellent sensitivity and specificity for detection of pregabalin in human urine
- Nonhazardous preservatives ($\leq 0.09\%$ NaN_3)

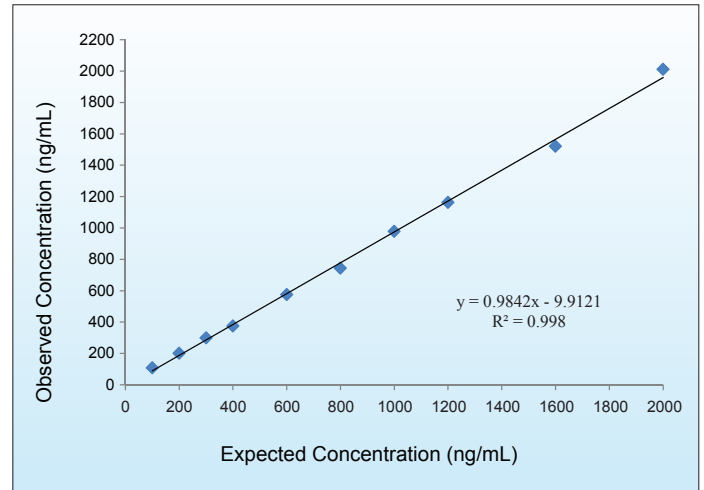
Next Generation Assays

QUALITATIVE CONTROL PRECISION



Qualitative Control Precision vs. 500 ng/ml Cutoff Calibrator

LINEARITY



ARK™ Pregabalin assay Calibrator Range: 0 to 2000 ng/mL

SEMI-QUANTITATIVE PRECISION

Urine Spiked Samples N=160		WITHIN-RUN			TOTAL	
Pregabalin (ng/mL)	% Cutoff	Mean (ng/mL)	SD	CV (%)	SD	CV (%)
250	-50	248	20.2	8.2	26.1	10.5
375	-25	371	31.7	8.5	39.0	10.5
500	Cutoff	479	27.5	5.8	35.7	7.5
625	+25	600	33.3	5.5	46.8	7.8
750	+50	705	33.7	4.8	52.2	7.4
1000	+100	917	50.9	5.5	69.7	7.6

Pooled Urine Samples containing pregabalin were assayed in quadruplicate twice a day for 20 days. CLSI Guideline EP5-A3.

ACCURACY – SPIKED URINE SAMPLES

Theoretical Concentration (ng/mL)	Mean Recovered Concentration (ng/mL)	Percent (%) Recovery	N
50	41.5	83.0	6
100	77.6	77.6	6
250	236.4	94.6	6
625	585.7	93.7	6
750	714.1	95.2	6
1500	1438.7	95.9	6
2000	1864.7	93.2	6

METHOD COMPARISON

	LC-MS/MS	
	(+)	(-)
ARK Pregabalin	69	0
	0	67

ARK Pregabalin Urine Assay compared to LC-MS/MS with 500 ng/mL Cutoff.

CROSS-REACTIVITY AND INTERFERENCE

- No cross-reactivity with L-amino acids at 200 µg/mL
- No cross-reactivity with Gabapentin at 4000 µg/mL
- Endogenous substances do not interfere

SAFETY AND STABILITY

Reagent on-board stability

At least 60 days

Shelf Life of Reagents, Calibrators, and Controls

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

ORDERING INFORMATION

For Export Only Not for Sale in USA

ARK™ Pregabalin Urine Assay	5035-0001-00
ARK™ Pregabalin Urine Calibrator	5035-0002-00
ARK™ Pregabalin Urine Control	5035-0003-00

For Criminal Justice and Forensic Use Only

ARK™ Pregabalin Urine Assay	5035-0004-00
ARK™ Pregabalin Urine Calibrator	5035-0005-00
ARK™ Pregabalin Urine Control	5035-0006-00

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