Fact Sheet

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 cut-off concentration of 500 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers.

Assay characteristics

- Rapid, convenient screening method
- Highly specific method for the determination of pregabalin in human urine
- No cross-reactivity with gabapentin at 5,000 µg/mL
- No cross-reactivity with L-amino acids at 200 µg/mL
- Tested endogenous compounds did not show any interference with the assay
- Liquid, ready-to-use reagents, calibrators and controls
- Storage at 2-8°C
- On-board stability at least 60 days
- Application protocols for all major clinical chemistry analyzers

Background

Pregabalin is an anticonvulsant originally developed as a successor for gabapentin to which it is structurally closely related. It is considered the drug of choice for central and peripheral neuropathic disorders and for the treatment of fibromyalgia and certain forms of epilepsy.

92-99% of pregabalin is excreted unchanged in urine. Its elimination half-time is approximately 6 to 7 hours. Although pregabalin is officially considered to have a low potential for abuse, a growing number of publications are reporting abuse, especially in patients with a previous history of addiction. In addition, patients treated with pregabalin appear to develop a tolerance that may easily slip into addiction, especially with regular use. The same publications report on serious withdrawal symptoms.

The known side effects include a feeling of euphoria, relaxation, significantly increased self-confidence, loss of inhibitions, as well as concentration issues, dizziness and visual distortions. In combination with alcohol, benzodiazepines or opioids, these effects may be multiplied.

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Properties

Dose	Between 150 and 600 mg two to three times per day
Bioavailability	>90 %, independent of doseage
Peak level	After approx. 1 hour
Elimination	Unchanged excretion via the kidneys
Metabolization	No significant metabolization
Elimination half time	6.3 hours

Assay precision – semi-quantitative

Urine (ng/mL)	Cut-off (%)	# of Samples	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	Cut-off	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
1,000.0	+ 100	160	1,048.3	160 positive

Method comparison

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

Ordering information

Product description	Size	Order No.
ARK™ Pregabalin II Assay	28 mL R1 & 14 mL R2	5059-0001-00
ARK™ Pregabalin II Calibrator	1 x 4 mL & 5 x 2 mL	5059-0002-00
ARK™ Pregabalin II Control	6 x 4 mL	5059-0003-00

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