

## Fact Sheet

# ARK™ Gabapentin Assay

The ARK Gabapentin Assay is a homogeneous enzyme immunoassay intended for the quantitative determination of gabapentin in human serum or plasma on automated clinical chemistry analyzers. The measurements obtained are used in the monitoring of gabapentin levels to help ensure appropriate therapy.

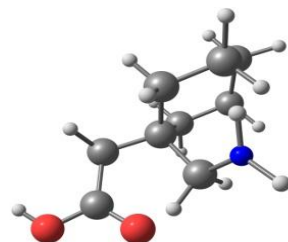
### Assay Characteristics

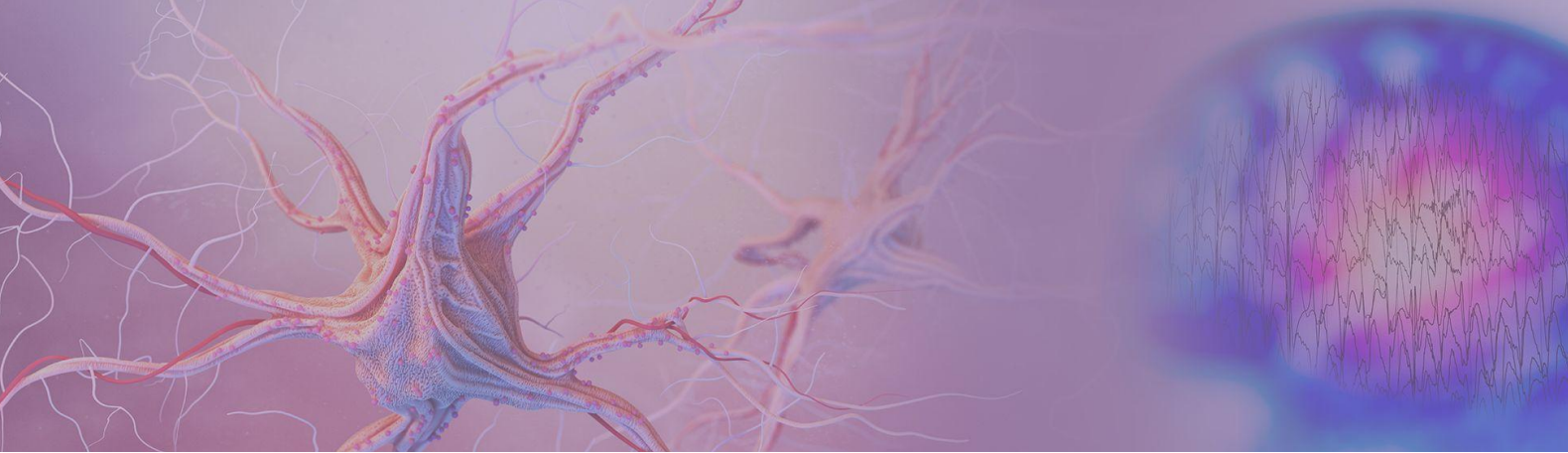
- Excellent precision, even in trough concentrations
- Fast and efficient routine monitoring for gabapentin
- Liquid, ready-to-use reagents, calibrators and controls
- Storage at 2-8°C
- On-board stability for at least 60 days
- Does not contain any harmful preservatives, only  $\leq 0.09\%$  sodium azide

### Background

Gabapentin [Neurontin®, 1-(aminomethyl)-cyclohexaneacetic acid] is indicated for use as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients over 12 years of age and as adjunctive therapy in the treatment of partial seizures in pediatric patients age 3-12 years. Gabapentin is also indicated for the management of postherpetic neuralgia in adults.

A therapeutic range for gabapentin has not been well established. A reference range of 2  $\mu\text{g/mL}$  to 20  $\mu\text{g/mL}$  has been proposed. Studies have suggested that optimal responses to gabapentin in patients with difficult-to-treat partial seizures are achieved at concentrations  $>2 \mu\text{g/mL}$  or in a range of 4 to 11  $\mu\text{g/mL}$ , while others proposed a higher range of 6 to 21  $\mu\text{g/mL}$ . It has been reported that toxicity with gabapentin tends to occur with increasing frequency when serum concentrations exceed 25  $\mu\text{g/mL}$ . Interindividual variability may be influenced by dose-related saturable drug absorption, and hence, variable pharmacokinetic properties.





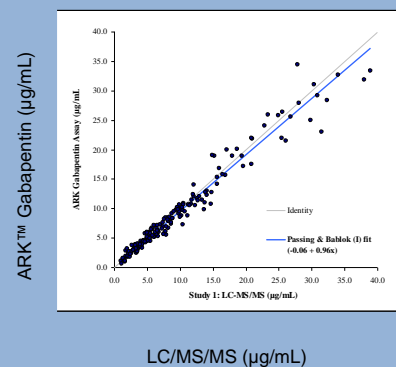
## Properties of Gabapentin

<b>Dose</b>	<b>Adults &amp; adolescents</b> (ab 12) 3 x daily 300 mg, independent of meals; <b>Children</b> (6-12) dosing according to body weight
<b>Bioavailability</b>	27 – 60% (inversely proportional to dose; fatty meals increase bioavailability)
<b>Peak level</b>	For low doses ~1 to 2 hours, for high doses 3 to 4 hours
<b>Plasma protein binding</b>	Less than 3%
<b>Elimination</b>	Renal excretion
<b>Metabolization</b>	No significant metabolization
<b>Elimination half time</b>	5 to 7 hours

## Assay Precision

Sample	N	M (µg/ml)	Repeatability				Reproducibility	
			Within-Run		Between Day		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)
<b>ARK™ Gabapentin Control</b>								
LOW	160	2.5	0.08	3.3	0.10	3.9	0.14	5.6
MID	160	7.9	0.21	2.6	0.26	3.3	0.35	4.4
HIGH	160	24.6	0.48	1.9	0.65	2.7	0.88	3.6
<b>Human Serum</b>								
LOW	160	2.2	0.11	4.7	0.11	4.8	0.17	7.7
MID	160	7.3	0.58	2.4	0.25	3.4	0.33	4.6
HIGH	160	24.9	0.54	2.2	0.97	3.9	1.17	4.7

## Method Comparison



## Order Information

Product Description	Size	Order No.
ARK™ Gabapentin Assay	28 mL R1 & 14 mL R2	5025-0001-00
ARK™ Gabapentin Calibrator	1 x 4 mL & 5 x 2 mL	5025-0002-00
ARK™ Gabapentin Control	6 x 4 mL	5025-0003-00