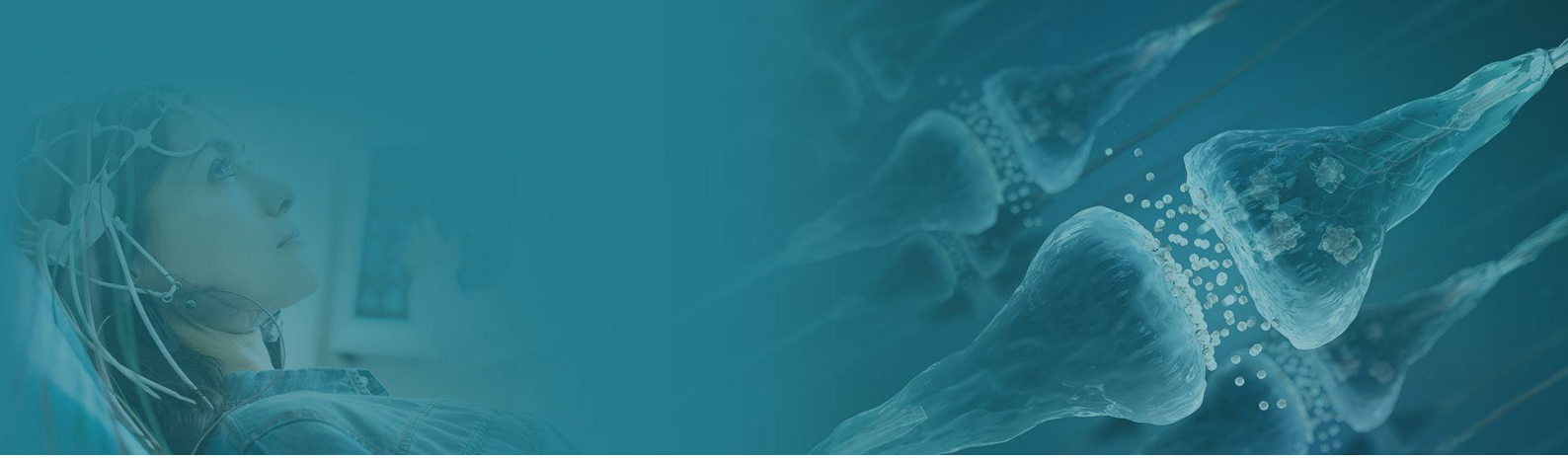

Fact Sheet

ARK™ Levetiracetam Assay

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

Assay Characteristics

- Excellent precision, even in trough concentrations
- Fast and efficient routine monitoring for levetiracetam
- 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 ≤ 0.09% sodium azide

Background

Levetiracetam (KEPPRA® (S)-a-Ethyl-2-oxo-1-pyrrolidine acetamide) is an anti-convulsant drug approved for use as an adjunctive therapy in the treatment of epilepsy. It is also indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalization in adults and adolescents from 16 years of age with newly diagnosed epilepsy.

The reference ranges for seizure control have been proposed, which include concentrations from 6 to 46 µg/mL (35 to 270 µmol/L; trough samples). Circulating levels of levetiracetam (serum blood concentrations) may be affected by compliance, renal function, pregnancy, drug-drug interactions and timing of the sample draw. Furthermore, the clinical effect of these serum blood concentrations may be further altered by changes in progression in the severity of the disease and the addition or withdrawal of concomitant drugs which may interact pharmacodynamically with circulating levels of levetiracetam.

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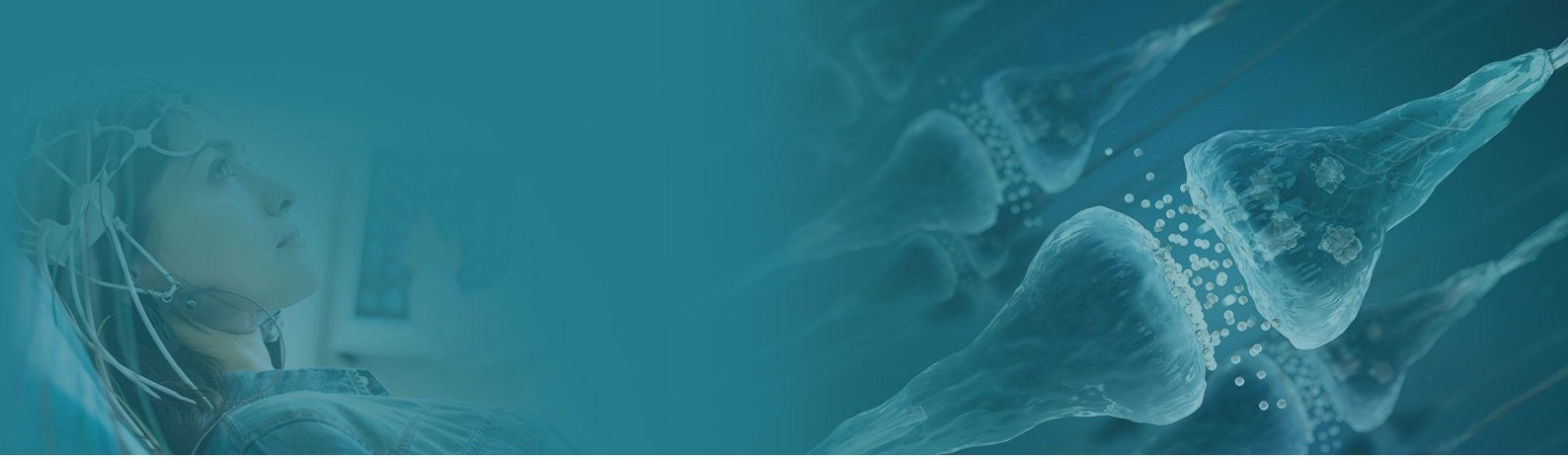


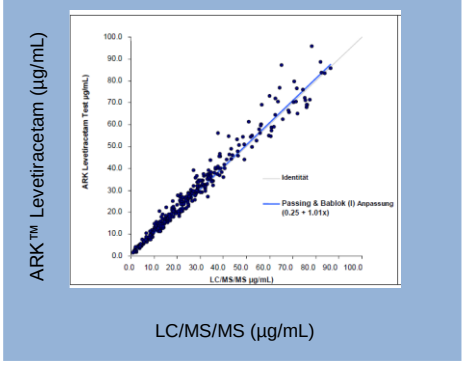
Properties of Levetiracetam

Dose	Adults: 500 – 1500 mg oral; children & adolescents reduced dose; dose adjustment for patients with renal dysfunction
Bioavailability	~ 100%
Peak Plasma Level	approx. 1 hour after dosing
Plasma protein binding	< 10%
Elimination	66% are excreted unchanged in the urine
Metabolization	Enzymatic hydrolysis of the acetamide group
Elimination half time	6 to 8 hours

Assay Precision

Sample	N	M (µg/ml)	Within-Run		Between Day		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)
ARK™ Levetiracetam								
LOW	160	7.5	0.25	3.4	0.23	3.2	0.34	4.5
MID	160	29.4	0.85	2.9	0.83	2.8	1.08	3.7
HIGH	160	73.4	2.14	2.9	2.03	2.8	3.08	4.2
Human Serum								
LOW	160	6.9	0.26	3.8	0.22	3.1	0.33	4.8
MID	160	30.2	0.87	2.9	1.10	3.7	1.23	4.1
HIGH	160	75.5	2.19	2.9	2.35	3.1	3.31	4.4

Method Comparison



Order Information

Product Description	Size	Order No.
ARK™ Levetiracetam Assay	28 mL R1 & 14 mL R2	5024-0001-00
ARK™ Levetiracetam Calibrator	1 x 4 mL & 5 x 2 mL	5024-0002-00
ARK™ Levetiracetam Control	6 x 4 mL	5024-0003-00

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