Fact Sheet

ARK™ Lamotrigine Assay

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

Assay Characteristics

- Excellent precision, even in trough concentrations
- Fast and efficient routine monitoring for lamotrigine
- 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

Lamotrigine (LAMICTAL®, 3,5-diamino-6-(2,3-dichlorophenyl)-1,2,4-triazine) is an anti-convulsant drug approved for use in the treatment of epilepsy and is often prescribed as monotherapy or as one component of a multiple anti-epileptic drug therapy.

A therapeutic range for lamotrigine has not been well established. Some reports in the literature suggest a target range for steady-state concentrations of 3 to 15 µg/mL. However, there is not a clear relationship between lamotrigine serum concentrations and clinical response. Due to individual patient differences and other co-administered medications, considerable overlap in lamotrigine concentrations has been observed between serum responders and non-responders as well as between serum levels associated with seizure control and adverse effects. In one study, the highest mean serum level (trough) reported was 8.8 µg/mL, and less than 15% of patients reported an adverse event at serum concentrations less than 10 µg/mL. Mild to moderate adverse effects are more commonly associated with patients with lamotrigine concentrations above 15 µg/mL.

Specialty Diagnostix

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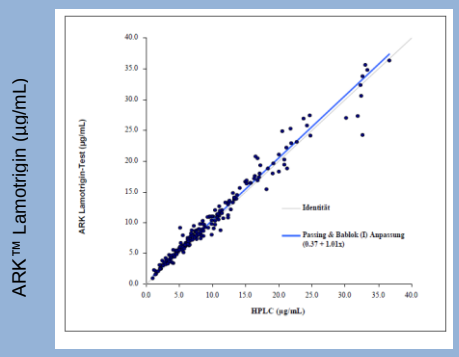
Properties of Lamotrigine

Dose	Patient specific dosing, starting with a low dosing regimen of 25 mg, slow titration until maintenance dose has been reached, usually 100 - 200 mg per day; in co-medication with other anti-epileptics, a dose adjustment may become necessary
Bioavailability	98%
Plasma protein binding	55%
Elimination	Excretion in urine (94%) and feces (2%)
Metabolization	Metabolization in the liver
Elimination half time	25 - 33 hours, depending on dosage, co-medication and clinical picture

Assay Precision

Sample	N	M (µg/ml)	Repeatability				Reproducibility	
			Within-Run		Between Day		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)
ARK™ Gabapentin Control								
LOW	160	2.08	0.07	3.4	0.05	2.5	0.08	4.1
MID	160	11.70	0.42	3.6	0.28	2.4	0.49	4.2
HIGH	160	24.23	0.99	4.1	1.06	4.4	1.47	6.1
Human Serum								
LOW	160	2.41	0.08	3.5	0.09	3.7	0.12	5.2
MID	160	10.75	0.41	3.8	0.42	3.9	0.59	5.5
HIGH	160	38.24	2.78	7.3	0.61	1.6	3.38	8.8

Method Comparison



Order Information

Product Description	Size	Order No.
ARK™ Lamotrigine Assay	28 mL R1 & 14 mL R2	5023-0001-00
ARK™ Lamotrigine Calibrator	1 x 4 mL & 5 x 2 mL	5023-0002-00
ARK™ Lamotrigine Control	6 x 4 mL	5023-0003-00

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