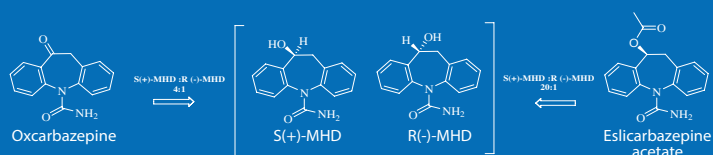


ARK™ Oxcarbazepine Metabolite Assay

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



10-hydroxycarbazepine (MHD, monohydroxy derivative): both enantiomers, R and S



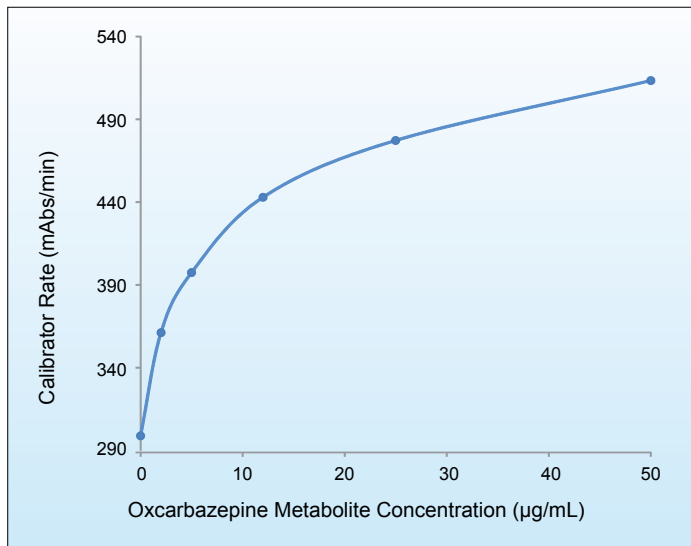
KEY POINTS

- Convenient, liquid-stable, ready-to-use homogeneous enzyme immunoassay
- Applications available for clinical chemistry systems
- Clinical needs addressed through excellent performance
- Detects both the S and R enantiomers of MHD
- Excellent calibration range (0.0 – 50.0 µg/mL)
- Nonhazardous preservatives

Caution: Rx Only- Federal Law restricts this device to sale by or on the order of a licensed practitioner

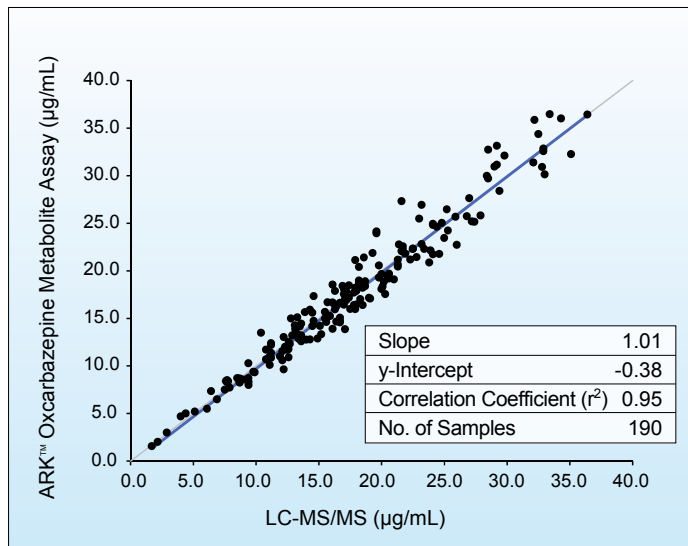
Next Generation Assays

CALIBRATION RANGE



ARK™ Oxcarbazepine Metabolite Assay Calibration Range: 0.0 to 50.0 µg/ml
LOQ: 1.0 µg/ml

METHOD COMPARISON



PRECISION

Sample n = 160	Mean (µg/mL)	WITHIN-RUN		BETWEEN DAY		TOTAL	
		SD	CV (%)	SD	CV (%)	SD	CV (%)
ARK Control							
LOW	3.0	0.12	4.0	0.12	4.1	0.17	5.7
MID	10.1	0.37	3.6	0.33	3.2	0.48	4.8
HIGH	30.2	0.99	3.3	1.19	3.9	1.54	5.1
Human Serum							
LOW	3.1	0.12	3.9	0.12	4.0	0.17	5.5
MID	10.1	0.38	3.8	0.36	3.6	0.55	5.5
HIGH	30.4	1.10	3.6	1.11	3.7	1.55	5.1

Tri-level controls containing Oxcarbazepine Metabolite were assayed in quadruplicate twice a day for 20 days. CLSI Guideline EP5-A3.

PROFICIENCY SAMPLES

LGC Proficiency Sample	Assigned Value (µg/ml)	Consensus Mean (µg/ml)	ARK Result (µg/ml)
Round 124	0.00	NA	0.00
Round 125	22.81	22.95	21.05
Round 126	42.41	42.93	41.06
Round 127	11.75	11.96	10.78
Round 128	3.99	4.06	3.61
Round 129	21.20	21.46	19.42
Round 130	7.33	7.25	6.68
Round 131	30.75	30.73	27.36
Round 132	17.25	17.24	15.28
Round 133	14.20	14.18	11.40
Round 134	34.08	33.83	33.05
Round 135	9.08	9.03	8.28
Round 136	14.17	14.27	12.44
Round 137	4.69	4.69	4.39
Round 138	25.83	26.02	23.28

The ARK results represent singlicate determinations. LGC Standards Proficiency Testing, UK.

ACCURACY

Theoretical Concentration (µg/mL)	Mean Recovered Concentration (µg/mL)	Percent Recovery N=6
45.0	44.63	99.2
35.0	33.52	95.8
20.0	19.81	99.0
15.0	14.91	99.4
8.0	8.16	102.0
4.0	3.94	98.5
1.0	0.98	98.5

Analytical recovery was determined by spiking Oxcarbazepine Metabolite into human serum to produce concentrations across the assay range.

INTERFERENCE

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

ARK™ Oxcarbazepine Metabolite Assay	5032-0001-00
ARK™ Oxcarbazepine Metabolite Calibrator	5032-0002-00
ARK™ Oxcarbazepine Metabolite Control	5032-0003-00

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