

ARKTM Apixaban Assay

The ARK Apixaban Assay is a homogeneous enzyme immunoassay intended for the quantitative determination of apixaban in 3.2% citrated human plasma on automated clinical chemistry analyzers.

Apixaban concentrations can be used as an aid in management of patients on apixaban therapy in the following situations where measurement of apixaban levels could be useful to have as additional information:

- Patients at risk for major bleeding
- Patients experiencing a bleeding episode

The assay is not a stand-alone test and the results should be used in conjunction with other clinical and laboratory findings.
For use in adult population.

KEY POINTS

- Homogeneous Enzyme immunoassay
- Applicable onboard automated clinical chemistry analyzers
- Convenient, liquid-stable, ready-to-use
- Excellent calibration range
- Tested drugs and endogenous substances do not interfere
- The crossreactivity of O-demethyl apixaban metabolite was not clinically significant ($\leq 5.0\%$ crossreactivity)

Next Generation Assays

PRECISION

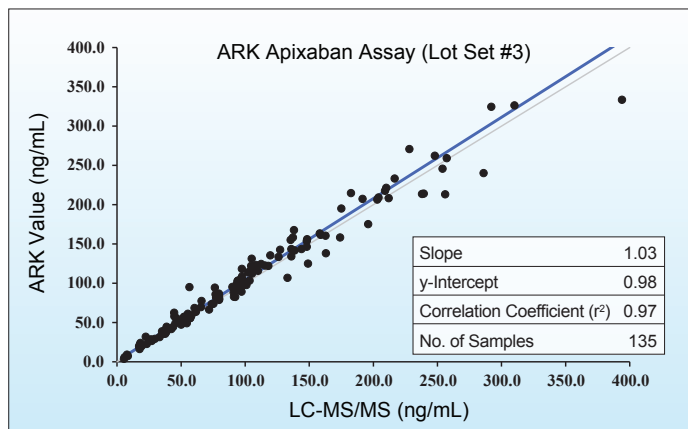
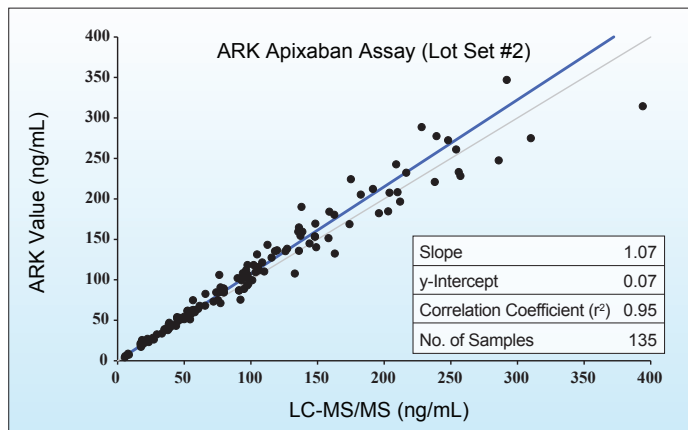
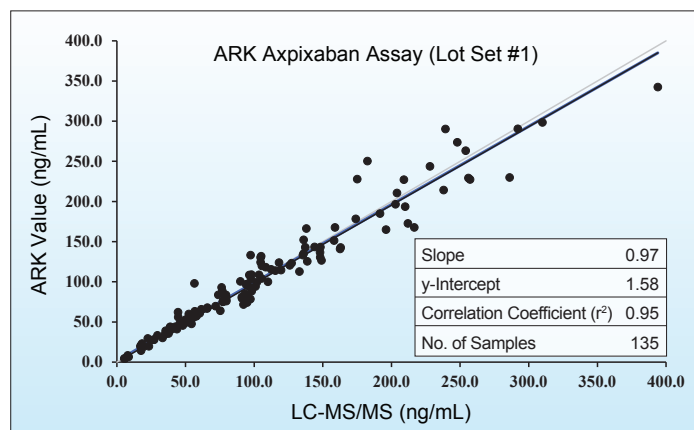
				REPEATABILITY WITHIN RUN		BETWEEN DAY		REPRODUCIBILITY TOTAL	
Sample	N	Lot	Mean (µg/mL)	SD	CV (%)	SD	CV (%)	SD	CV (%)
ARK Apixaban Control									
LOW	160	1	10.1	0.525	5.2	0.398	4.0	0.646	6.4
	160	2	10.0	0.250	2.5	0.212	2.1	0.320	3.2
	160	3	10.3	0.595	5.8	0.319	3.1	0.667	6.5
MID	160	1	29.2	0.944	3.2	0.662	2.3	1.241	4.3
	160	2	27.8	0.510	1.8	0.528	1.9	0.760	2.7
	160	3	28.6	0.971	3.4	0.488	1.7	1.382	4.8
HIGH	160	1	201.1	9.482	4.7	8.831	4.4	13.519	6.7
	160	2	206.7	6.060	2.9	6.266	3.0	8.840	4.3
	160	3	192.4	10.754	5.6	10.678	5.5	15.930	8.3
Human Citrated Plasma									
LOW	160	1	10.2	0.563	5.5	0.276	2.7	0.737	7.2
	160	2	9.3	0.200	2.1	0.158	1.7	0.270	2.9
	160	3	10.2	0.567	5.6	0.207	2.0	0.619	6.1
MID	160	1	29.7	1.221	4.1	0.441	1.5	1.407	4.7
	160	2	28.1	0.400	1.4	0.442	1.6	0.630	2.2
	160	3	29.2	0.845	2.9	0.704	2.4	1.242	4.3
HIGH	160	1	199.6	11.503	5.8	9.122	4.6	14.573	7.3
	160	2	199.6	5.030	2.5	5.112	2.6	7.580	3.8
	160	3	203.1	11.873	5.8	10.470	5.2	15.807	7.8

Tri-level controls and citrated plasma containing apixaban were assayed in quadruplicate twice a day for 20 days. CLSI EP05-A3

ACCURACY – ANALYTICAL RECOVERY

Theoretical Concentration (ng/mL)	Mean Recovered Concentration (ng/mL)	Percent Recovery (%)
3.0	3.4	111.7
16.0	17.2	107.4
40.0	41.3	103.3
80.0	83.4	104.3
160.0	172.9	108.1
300.0	294.8	98.3

METHOD COMPARISON



SAFETY AND STABILITY

Reagent on-board stability

Up to at least 60 days

Shelf Life of Reagents, Calibrators, and Controls

18 months from date of manufacturing

Safety

Nonhazardous preservatives

Contains sodium azide ≤ 0.09%

Results shown are typical and may vary among laboratory analyzers.

ORDERING INFORMATION

ARK™ Apixaban Assay	5047-0001-00	R1 28mL, R2 14mL
ARK™ Apixaban Calibrator	5047-0002-00	1 x 4mL; CAL A 5 x 2mL; CAL B-F
ARK™ Apixaban Control	5047-0003-00	1 x 4mL; LOW 10 ng/mL 1 x 4mL; MID 30 ng/mL 1 x 4mL; High 200 ng/mL

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