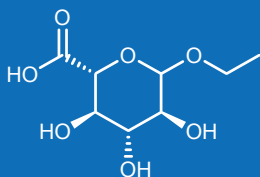


ARK™ Ethyl Glucuronide Assay

The ARK™ Ethyl Glucuronide Assay is intended for the qualitative and semi-quantitative determination of ethyl glucuronide in human urine at two cutoff concentrations of 500 and 1000 ng/mL. The assay provides a simple and rapid analytical screening procedure for detecting ethyl glucuronide in urine and is designated for professional use on automated clinical chemistry analyzers.

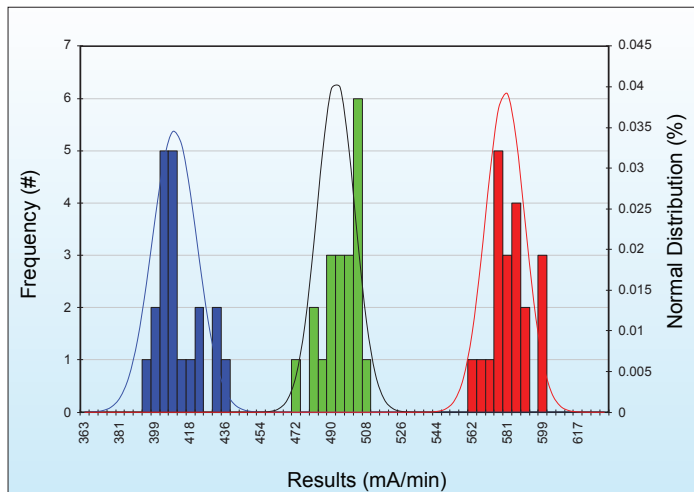


KEY POINTS

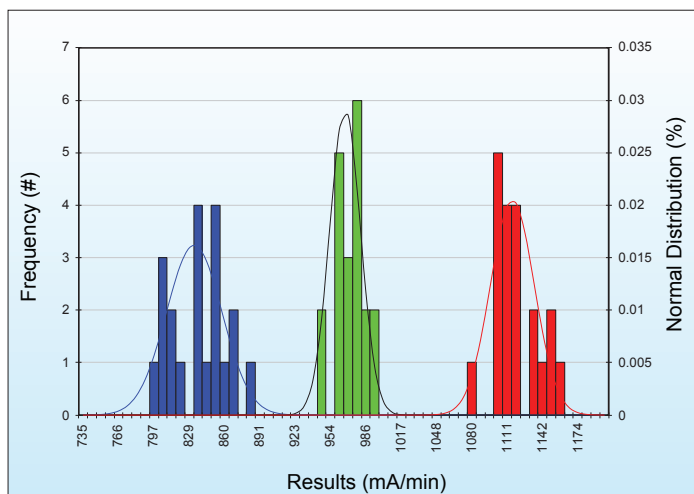
- Convenient, liquid-stable, ready-to-use homogeneous enzyme immunoassay
- Qualitative and/or semi-quantitative applications available for clinical chemistry systems
- 0 – 2000 ng/mL calibration range; 500 ng/mL and 1000 ng/mL cutoff
- Excellent sensitivity and specificity for detection of ethyl glucuronide in human urine
- Nonhazardous preservatives

Next Generation Assays

QUALITATIVE PRECISION



Qualitative Control Precision vs 500 ng/mL Cutoff Calibrator



Qualitative Control Precision vs 1000 ng/mL Cutoff Calibrator

ACCURACY

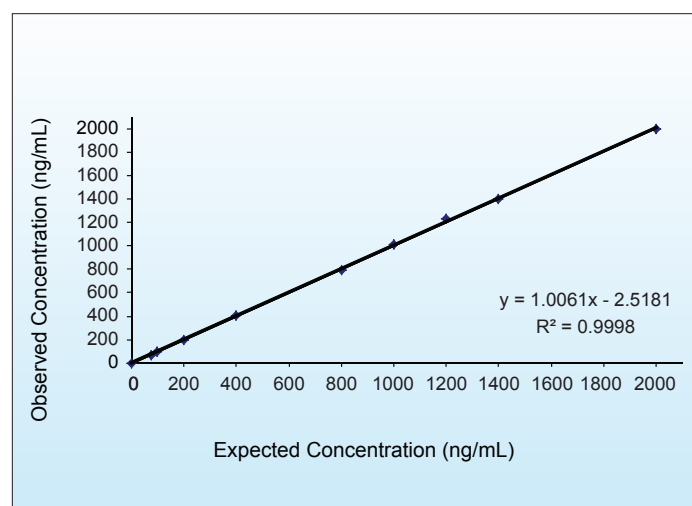
Concentration Tested (ng/mL)	Mean (ng/mL)	Recovery (%)
0.0	0.0	NA
50.0	47.6	95.2
100.0	106.3	106.3
250.0	264.2	105.7
500.0	521.7	104.3
700.0	714.1	102.0
1000.0	989.4	98.9
1300.0	1338.6	103.0
1500.0	1551.2	103.4
1800.0	1749.9	97.2
2000.0	2010.4	100.5

SEMI-QUANTITATIVE PRECISION

Urine Spiked Samples Ethyl Glucuronide (ng/mL)	N=160 Mean (ng/mL)	WITHIN-RUN		TOTAL	
		SD	CV (%)	SD	CV (%)
0.0	0.0	0.00	NA	0.00	NA
250.0	233.6	9.07	3.9	12.12	5.2
375.0	383.5	11.85	3.1	16.97	4.4
500.0	498.6	14.88	3.0	22.43	4.5
625.0	634.5	18.44	2.9	28.55	4.5
750.0	732.0	23.27	3.2	30.63	4.2
1000.0	959.8	27.47	2.9	39.67	4.1
1250.0	1212.7	39.69	3.3	51.27	4.2
1500.0	1462.3	50.22	3.4	68.90	4.7
2000.0	1983.8	86.79	4.4	140.44	7.1

Pooled urine samples containing ethyl glucuronide were assayed in quadruplicate twice a day for 20 days. CLSI Guideline EP5-A3.

LINEARITY



ARK Ethyl Glucuronide Assay Calibrator Range: 0 to 2000 ng/mL

METHOD COMPARISON

500 ng/mL Cutoff			
LC-MS/MS			
	(+)	(-)	
ARK Ethyl Glucuronide Assay	(+) 100	(-) 1*	
	(-) 0	100	

*Specimen #176 shows <50.0 ng/mL by LC-MS/MS and 565.0 ng/mL by ARK semiquantitative mode. ARK qualitative mode using 500 ng/mL cutoff shows a positive result.

1000 ng/mL Cutoff			
LC-MS/MS			
	(+)	(-)	
ARK Ethyl Glucuronide Assay	(+) 95	(-) 0	
	(-) 0	106	

CROSS-REACTIVITY AND INTERFERENCE

- No cross-reactivity to tested glucuronide compounds
- Tested endogenous substances do not interfere

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

For Export Only Not for Sale in USA

ARK™ Ethyl Glucuronide Assay	5036-0001-00	R1 28mL, R2 14mL
	5036-0001-01	R1 115mL, R2 58mL
	5036-0001-02	R1 500mL, R2 250mL
ARK™ Ethyl Glucuronide Calibrator	5036-0002-00	5 x 10mL
	5036-0002-01	2 x 10mL; Negative
	5036-0002-02	2 x 10mL; 500 ng/mL Cutoff
	5036-0002-03	2 x 10mL; 1000 ng/mL Cutoff
ARK™ Ethyl Glucuronide Control	5036-0003-00	2 x 10mL; LOW 375 ng/mL 2 x 10mL; HIGH 625 ng/mL
	5036-0003-01	2 x 10mL; LOW 750 ng/mL 2 x 10mL; HIGH 1250 ng/mL

For Criminal Justice and Forensic Use Only

ARK™ Ethyl Glucuronide Assay	5036-0004-00	R1 28mL, R2 14mL
	5036-0004-01	R1 115mL, R2 58mL
	5036-0004-02	R1 500mL, R2 250mL
ARK™ Ethyl Glucuronide Calibrator	5036-0005-00	5 x 10mL
	5036-0005-01	2 x 10mL; Negative
	5036-0005-02	2 x 10mL; 500 ng/mL Cutoff
	5036-0005-03	2 x 10mL; 1000 ng/mL Cutoff
ARK™ Ethyl Glucuronide Control	5036-0006-00	2 x 10mL; LOW 375 ng/mL 2 x 10mL; HIGH 625 ng/mL
	5036-0006-01	2 x 10mL; LOW 750 ng/mL 2 x 10mL; HIGH 1250 ng/mL

ARK Diagnostics, Inc.
48089 Fremont Boulevard
Fremont, CA 94538
Tel: 510-270-6270 Fax: 510-270-6298

For Customer Support:
Call toll free: 877-869-2320
customersupport@ark-tdm.com
www.ark-tdm.com

