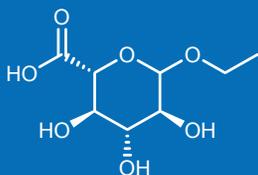


ARK™ Ethyl Glucuronide II Assay

The ARK Ethyl Glucuronide II Assay is intended for the qualitative detection and/or semi-quantitative estimation of ethyl glucuronide in human urine at cutoff concentrations of 500 ng/mL and 1000 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers.



The ARK Ethyl Glucuronide II Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug test result, particularly when the preliminary test result is positive.

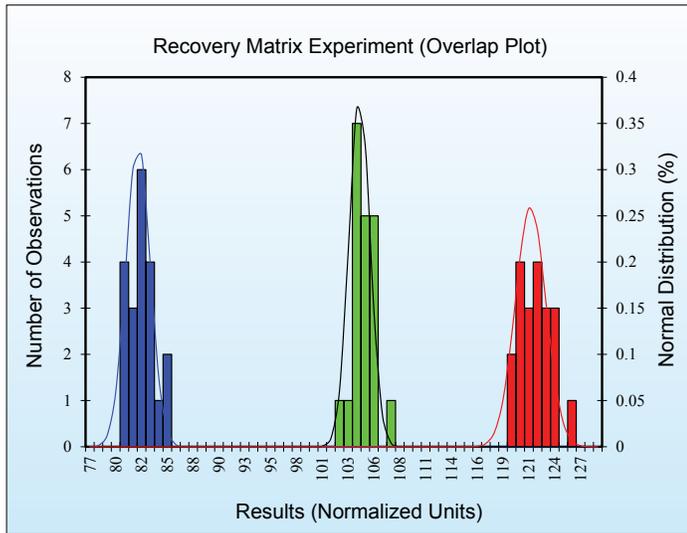
KEY POINTS

- 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

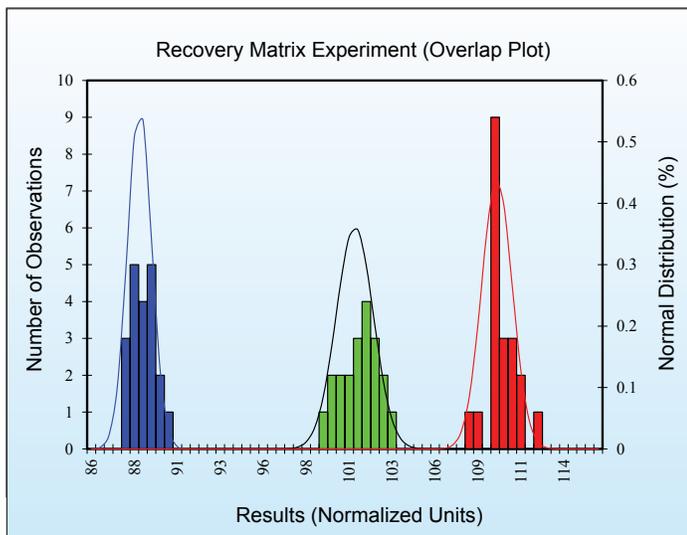
Next Generation Assays

QUALITATIVE PRECISION

In qualitative mode, the 500 ng/mL or 1000 ng/mL cutoff is assigned as 100 normalized units, such that qualitative results ≥ 100 are positive and qualitative results < 100 are negative.



Qualitative Control Precision vs 500 ng/mL Cutoff Calibrator



Qualitative Control Precision vs 1000 ng/mL Cutoff Calibrator

SEMI-QUANTITATIVE PRECISION

500 ng/mL Cutoff

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Semi-quantitative Precision Results
0	-100	160	18	160 Negative
125	-75	160	136	160 Negative
250	-50	160	266	160 Negative
375	-25	160	388	160 Negative
500	Cutoff	160	518	138 Negative / 22 Positive
625	+25	160	648	160 Positive
750	+50	160	768	160 Positive
875	+75	160	894	160 Positive
1000	+100	160	1018	160 Positive

1000 ng/mL Cutoff

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Semi-quantitative Precision Results
0	-100	160	18	160 Negative
250	-75	160	266	160 Negative
500	-50	160	518	160 Negative
750	-25	160	768	160 Negative
1000	Cutoff	160	1018	111 Negative / 49 Positive
1250	+25	160	1280	160 Positive
1500	+50	160	1546	160 Positive
1750	+75	160	1765	160 Positive
2000	+100	160	2038	160 Positive

Pooled Urine Samples containing Ethyl Glucuronide were assayed in quadruplicate twice a day for 20 days.

ACCURACY – ANALYTICAL RECOVERY

Concentration Tested (ng/mL)	Mean (ng/mL)	Recovery (%)
0	0	N/A
50	52	104
100	97	97
250	259	104
500	500	100
750	739	99
1000	976	98
1250	1179	94
1500	1430	95
1750	1670	95
2000	1905	95

METHOD COMPARISON

500 ng/mL Cutoff

	LC-MS/MS		
		(+)	(-)
ARK Ethyl Glucuronide II Assay	(+)	100	0
	(-)	0	99

1000 ng/mL Cutoff

	LC-MS/MS		
		(+)	(-)
ARK Ethyl Glucuronide II Assay	(+)	96	0
	(-)	4*	99

*Specimens Contained LC-MS/MS values between 500 and 1000 ng/mL Ethyl Glucuronide.

SAFETY AND STABILITY

Reagent on-board stability

Up to at least 60 days

Shelf Life of Reagents, Calibrators, and Controls

Reagents: 18 months from date of manufacturing

Calibrators and Controls: 30 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 II Assay	5077-0001-00	R1 28mL, R2 14mL
	5077-0001-01	R1 115mL, R2 58mL
	5077-0001-02	R1 500mL, R2 250mL
	5077-0001-03	R1 58 mL, R2 29 mL
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 II Assay	5077-0004-00	R1 28mL, R2 14mL
	5077-0004-01	R1 115mL, R2 58mL
	5077-0004-02	R1 500mL, R2 250mL
	5077-0004-03	R1 58 mL, R2 29 mL
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

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