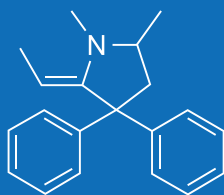


# ARK™ EDDP Assay



The ARK EDDP Assay is an immunoassay intended for the qualitative and/or semiquantitative determination of EDDP in human urine at cutoff concentrations of 100 ng/mL and 300 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers. This *in vitro* diagnostic device is for prescription use only.

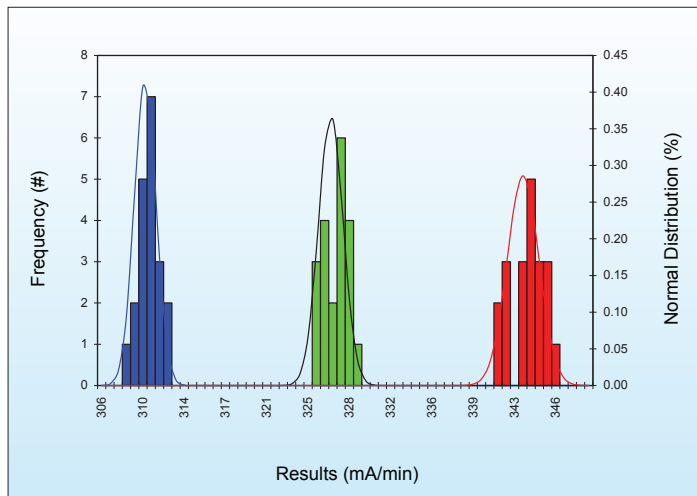


## KEY POINTS

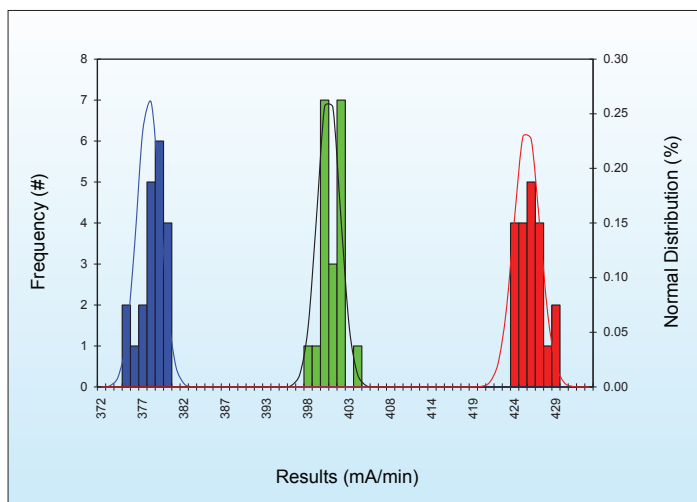
- Convenient, liquid-stable, ready-to-use homogeneous enzyme immunoassay
- Qualitative and/or semi-quantitative applications available for automated clinical chemistry systems
- 0 – 1000 ng/mL calibration range; 100 ng/mL and 300 ng/mL cutoffs
- Excellent sensitivity and specificity for detection of EDDP in human urine
- Low cross-reactivity to Methadone

*Next Generation Assays*

## QUALITATIVE PRECISION



Qualitative Control Precision vs 100 ng/mL Cutoff Calibrator



Qualitative Control Precision vs 300 ng/mL Cutoff Calibrator

## ACCURACY – ANALYTICAL RECOVERY

Theoretical Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
50.0	47.6	95.1
75.0	72.1	96.1
100.0	97.1	97.1
200.0	189.1	94.6
300.0	286.6	95.5
400.0	414.5	103.6
500.0	506.6	101.3
600.0	647.4	107.9
700.0	722.7	103.2
800.0	800.6	100.1
900.0	880.8	97.9
1000.0	955.8	95.6

## SEMI-QUANTITATIVE PRECISION

### 100 ng/mL Cutoff

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Semiquantitative Precision Results
0.0	-100	160	0.3	160 Negative
25.0	-75	160	22.6	160 Negative
50.0	-50	160	47.7	160 Negative
75.0	-25	160	72.2	160 Negative
100.0	Cutoff	160	98.1	114 Negative; 46 Positive
125.0	+25	160	125.3	160 Positive
150.0	+50	160	145.1	160 Positive
175.0	+75	160	169.4	160 Positive
200.0	+100	160	190.7	160 Positive

### 300 ng/mL Cutoff

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Semiquantitative Precision Results
0.0	-100	160	0.3	160 Negative
75.0	-75	160	72.2	160 Negative
150.0	-50	160	145.1	160 Negative
225.0	-25	160	205.9	160 Negative
300.0	Cutoff	160	298.8	85 Negative; 75 Positive
375.0	+25	160	381.4	160 Positive
450.0	+50	160	461.0	160 Positive
525.0	+75	160	539.8	160 Positive
600.0	+100	160	620.0	160 Positive

Pooled Urine Samples containing EDDP were assayed in quadruplicate twice a day for 20 days. CLSI Guideline EP5-A3.

## METHOD COMPARISON

### 100 ng/mL Cutoff

ARK Immunoassay Result	Low Negative Less than 50% below the Cutoff (< 50 ng/mL by GC/MS)	Near Cutoff Negative Between 50% below the Cutoff and the Cutoff (50 – 99 ng/mL by GC/MS)	Near Cutoff Positive Between the Cutoff and 50% above the Cutoff (100 – 150 ng/mL by GC/MS)	High Positive Greater than 50% above the Cutoff (> 150 ng/mL by GC/MS)
Negative	40	5	0	0
Positive	0	0	4	60

### 300 ng/mL Cutoff

ARK Immunoassay Result	Low Negative Less than 50% below the Cutoff (< 150 ng/mL by GC/MS)	Near Cutoff Negative Between 50% below the Cutoff and the Cutoff (150 – 299 ng/mL by GC/MS)	Near Cutoff Positive Between the Cutoff and 50% above the Cutoff (300 – 450 ng/mL by GC/MS)	High Positive Greater than 50% above the Cutoff (> 450 ng/mL by GC/MS)
Negative	49	4	0	0
Positive	0	1*	3	52

\* Discordant Result

Sample ID Number	ARK Immunoassay Result	EDDP (ng/mL by GC/MS)
51	Positive	294

## CROSS-REACTIVITY AND INTERFERENCE

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- Low cross-reactivity to Methadone – Negative results with 2,000,000 ng/mL and 4,500,000 ng/mL Methadone at 100 ng/mL and 300 ng/mL cutoffs, respectively.
- No cross-reactivity to other pain medications tested.
- Tested endogenous substances do not interfere.

## SAFETY AND STABILITY

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### 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  $\leq 0.09\%$

Results shown are typical and may vary among laboratory analyzers.

## ORDERING INFORMATION

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ARK™ EDDP Assay	5051-0001-00	R1 28mL, R2 14mL
	5051-0001-01	R1 115mL, R2 58mL
	5051-0001-02	R1 500mL, R2 250mL
ARK™ EDDP Calibrator	5051-0002-00	5 x 10mL
	5051-0002-01	2 x 10mL; Negative
	5051-0002-02	2 x 10mL; 100 ng/mL Cutoff
	5051-0002-03	2 x 10mL; 300 ng/mL Cutoff
ARK™ EDDP Control	5051-0003-00	2 x 10mL; LOW 75 ng/mL 2 x 10mL; HIGH 125 ng/mL
	5051-0003-01	2 x 10mL; LOW 225 ng/mL 2 x 10mL; HIGH 375 ng/mL

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