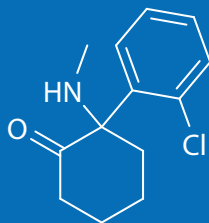


# ARK™ Ketamine Assay



The ARK Ketamine Assay is an immunoassay intended for the qualitative and/or semiquantitative determination of ketamine in human urine at a cutoff concentration of 50 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers.



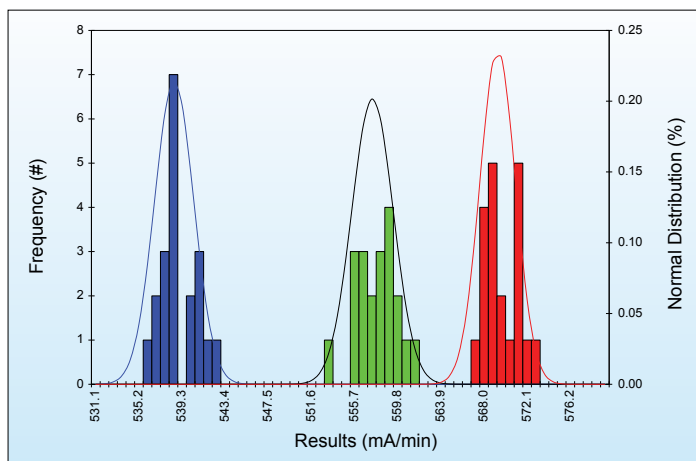
The ARK Ketamine Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is the 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
- 0 – 500 ng/mL calibration range: 50 ng/mL cutoff
- Excellent sensitivity and specificity for detection of ketamine in human urine
- Demonstrated cross-reactivity with norketamine and dehydronorketamine
- Nonhazardous preservatives

*Next Generation Assays*

## QUALITATIVE PRECISION



Control Precision vs 50.0 ng/mL Cutoff Calibrator

## QUALITATIVE 20 DAY PRECISION

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Results
0.0	-100	160	160 Negative
12.5	-75	160	160 Negative
25.0	-50	160	160 Negative
37.5	-25	160	160 Negative
50.0	Cutoff	160	83 Negative / 77 Positive
62.5	+25	160	160 Positive
75.0	+50	160	160 Positive
87.5	+75	160	160 Positive
100.0	+100	160	160 Positive

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

## ACCURACY – ANALYTICAL RECOVERY

Theoretical Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
50.0	52.2	104.4
100.0	102.7	102.7
200.0	193.4	96.7
300.0	274.2	91.4
400.0	408.9	102.2
500.0	511.6	102.3

## METHOD COMPARISON

ARK Ketamine Assay 50 ng/mL Cutoff	LC-MS/MS		
		(+)	(-)
	(+)	50	1
(-)	0	49	

## CROSS-REACTIVITY AND INTERFERENCE

Compound	Concentration Tested (ng/mL)	ARK Immunoassay Result
Norketamine	100	Positive
Dehydronorketamine	100	Positive
Methoxetamine	100,000	Negative

- Excellent cross-reactivity with norketamine and dehydronorketamine.
- No cross-reactivity to hallucinogens tested.
- 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  $\leq$  0.09%

Results shown are typical and may vary among laboratory analyzers.

## ORDERING INFORMATION

### For Export Only – Not for Sale in USA

ARK™ Ketamine Assay	5056-0001-00	R1 28mL, R2 14mL
	5056-0001-01	R1 115mL, R2 58mL

ARK™ Ketamine Calibrator	5056-0002-00	5 x 10mL
	5056-0002-01	2 x 10mL; Negative
	5056-0002-02	2 x 10mL; 50 ng/mL Cutoff

ARK™ Ketamine Control	5056-0003-00	2 x 10mL; LOW 25 ng/mL
		2 x 10mL; HIGH 75 ng/mL

### For Criminal Justice and Forensic Use Only

ARK™ Ketamine Assay	5056-0004-00	R1 28mL, R2 14mL
	5056-0004-01	R1 115mL, R2 58mL

ARK™ Ketamine Calibrator	5056-0005-00	5 x 10mL
	5056-0005-01	2 x 10mL; Negative
	5056-0005-02	2 x 10mL; 50 ng/mL Cutoff

ARK™ Ketamine Control	5056-0006-00	2 x 10mL; LOW 25 ng/mL
		2 x 10mL; HIGH 75 ng/mL

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