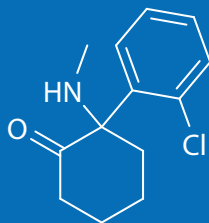


ARK™ Ketamine II Assay



The ARK Ketamine II Assay is an immunoassay intended for the qualitative detection and/or semiquantitative estimation of ketamine in human urine at cutoff concentrations of 50 and 100 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

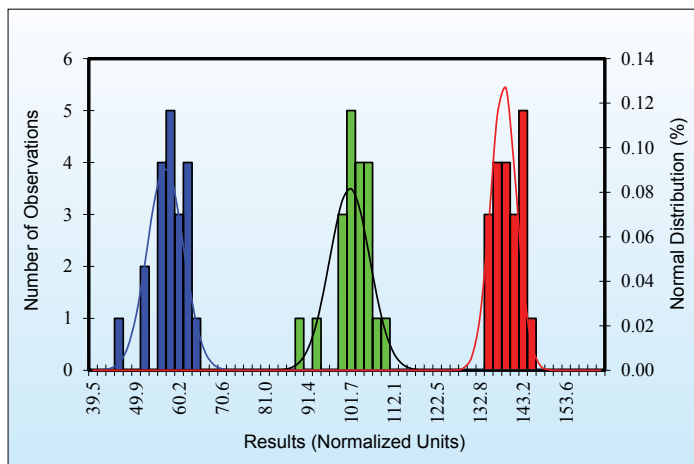
- Convenient, liquid-stable, ready-to-use homogeneous enzyme immunoassay
- 0 – 500 ng/mL calibration range: 50 ng/mL and 100 ng/mL cutoffs
- Excellent sensitivity and specificity for detection of ketamine in human urine
- Qualitative/semi-quantitative application available for clinical chemistry systems
- Demonstrated cross-reactivity with norketamine and dehydronorketamine
- Nonhazardous preservatives

Next Generation Assays

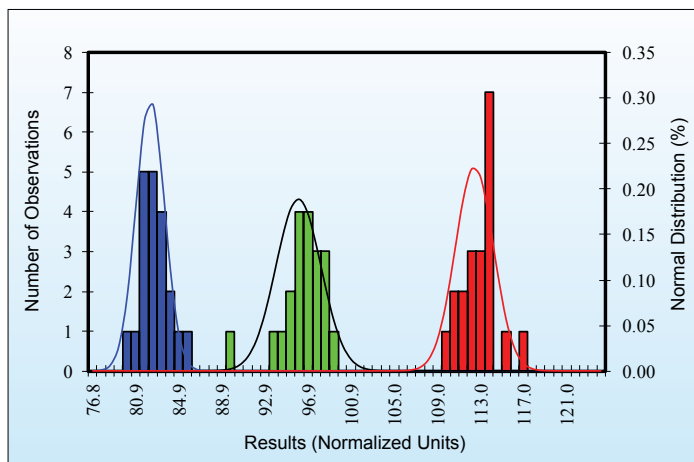
The semi-quantitative mode is for the purpose of (1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method, such as Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS), or (2) permitting laboratories to establish quality control procedures.

The ARK Ketamine II Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed 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.

QUALITATIVE PRECISION



Qualitative Control Precision vs 50.0 ng/mL Cutoff Calibrator



Qualitative Control Precision vs 100.0 ng/mL Cutoff Calibrator

SEMI-QUANTITATIVE PRECISION

50 ng/mL Cutoff

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Semi-quantitative Precision Results
0.0	-100	160	1.04	160 Negative
12.5	-75	160	13.05	160 Negative
25.0	-50	160	26.09	160 Negative
37.5	-25	160	38.87	160 Negative
50.0	Cutoff	160	52.02	39 Negative / 121 Positive
62.5	+25	160	64.53	160 Positive
75.0	+50	160	76.96	160 Positive
87.5	+75	160	89.14	160 Positive
100.0	+100	160	103.06	160 Positive

100 ng/mL Cutoff

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Semi-quantitative Precision Results
0.0	-100	160	1.04	160 Negative
25.0	-75	160	26.09	160 Negative
50.0	-50	160	52.02	160 Negative
75.0	-25	160	76.96	160 Negative
100.0	Cutoff	160	103.06	52 Negative / 108 Positive
125.0	+25	160	128.59	160 Positive
150.0	+50	160	152.84	160 Positive
175.0	+75	160	178.96	160 Positive
200.0	+100	160	202.30	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 (%)
20.0	21.22	106.1
50.0	52.07	104.1
100.0	103.65	103.7
200.0	209.13	104.6
300.0	312.43	104.1
400.0	421.67	105.4
500.0	526.90	105.4

ANALYTICAL SPECIFICITY

Desirable Structurally Related Compounds

Compounds	Concentration approximately equivalent to 50 ng/mL Cutoff (ng/mL)	Concentration approximately equivalent to 100 ng/mL Cutoff (ng/mL)	% Crossreactivity	
			50 ng/mL Cutoff	100 ng/mL Cutoff
Nor-Ketamine	109.8	211.7	45.5	47.2
Dehydronorketamine	410.8	664.6	12.2	15.0
(S)-Ketamine	2,000.0	4,000.0	2.5	2.5

Undesirable Structurally Related Compounds

Compounds	Concentration approximately equivalent to 50 ng/mL Cutoff (ng/mL)	Concentration approximately equivalent to 100 ng/mL Cutoff (ng/mL)	% Crossreactivity	
			50 ng/mL Cutoff	100 ng/mL Cutoff
Methoxetamine	50,000	100,000	0.1	0.1
Normethoxetamine	>100,000	>100,000	0.0	0.0
Desmethylmethoxetamine (hydroxetamine)	17,000	32,500	0.3	0.3
Deoxymethoxetamine	50,000	100,000	0.1	0.1
Tilidine	>100,000	>100,000	0.0	0.0
Nortilidine	>100,000	>100,000	0.0	0.0
Venlafaxine	>100,000	>100,000	0.0	0.0

METHOD COMPARISON

50 ng/mL Cutoff

ARK Ketamine II Assay Results	<50% of cutoff concentration by LC-MS/MS (<25 ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS) (25-49 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS) (50-75 ng/mL)	High Positive (Greater than 50% above the cutoff concentration by LC-MS/MS) (>75 ng/mL)
Positive	0	0	4	46
Negative	223	0	0	0

100 ng/mL Cutoff

ARK Ketamine II Assay Results	<50% of cutoff concentration by LC-MS/MS (<50 ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS) (50-99 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS) (100-150 ng/mL)	High Positive (Greater than 50% above the cutoff concentration by LC-MS/MS) (>150 ng/mL)
Positive	0	0	5	40
Negative	223	5	0	0

SAFETY AND STABILITY

Reagent on-board stability

Up to at least 60 days

Shelf Life of Reagents

18 months from date of manufacturing

Shelf Life of Calibrators, and Controls

24 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™ Ketamine II Assay	5083-0001-00	R1 28mL, R2 14mL
	5083-0001-01	R1 115mL, R2 58mL
	5083-0001-02	R1 500mL, R2 250mL
	5083-0001-03	R1 58mL, R2 29mL
ARK™ Ketamine II Calibrator	5083-0002-00	5 x 10mL
	5083-0002-01	2 x 10mL; Negative
	5083-0002-02	2 x 10mL; 50 ng/mL Cutoff
	5083-0002-03	2 x 10mL; 100 ng/mL Cutoff
ARK™ Ketamine II Control	5083-0003-00	2 x 10mL; LOW 25 ng/mL 2 x 10mL; HIGH 75 ng/mL
	5083-0003-01	2 x 10mL; LOW 75 ng/mL 2 x 10mL; HIGH 125 ng/mL

For Criminal Justice and Forensic Use Only

ARK™ Ketamine II Assay	5083-0004-00	R1 28mL, R2 14mL
	5083-0004-01	R1 115mL, R2 58mL
	5083-0004-02	R1 500mL, R2 250mL
	5083-0004-03	R1 58mL, R2 29mL
ARK™ Ketamine II Calibrator	5083-0005-00	5 x 10mL
	5083-0005-01	2 x 10mL; Negative
	5083-0005-02	2 x 10mL; 50 ng/mL Cutoff
	5083-0005-03	2 x 10mL; 100 ng/mL Cutoff
ARK™ Ketamine II Control	5083-0006-00	2 x 10mL; LOW 25 ng/mL 2 x 10mL; HIGH 75 ng/mL
	5083-0006-01	2 x 10mL; LOW 75 ng/mL 2 x 10mL; HIGH 125 ng/mL

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