

ARK™ Zopiclone Assay

The ARK Zopiclone Assay is intended for the qualitative and semi-quantitative determination of zopiclone in human urine at a cutoff concentration of 10 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers.



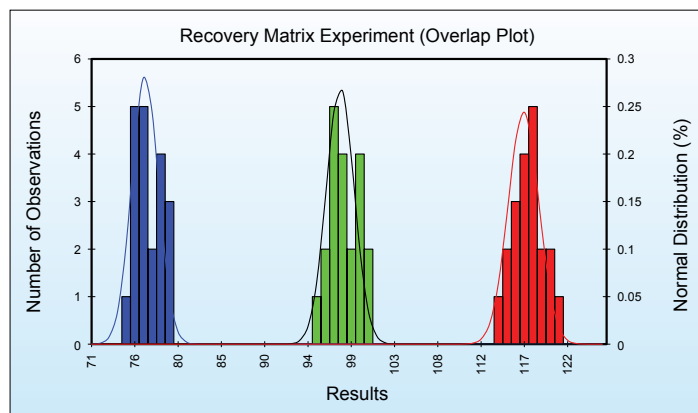
The ARK Zopiclone Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is 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
- Applicable to many automated clinical chemistry analyzers
- 0 – 40 ng/mL semi-quantitative calibration range, 10 ng/mL Cutoff
- High specificity for Zopiclone and its metabolites in human urine
- Nonhazardous preservatives

Next Generation Assays

QUALITATIVE PRECISION



Qualitative Control Precision vs 10 ng/mL Cutoff Calibrator

SEMI-QUANTITATIVE PRECISION

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Semi-quantitative Precision Results
0	-100	160	0.2	160 Negative
2.5	-75	160	2.6	160 Negative
5.0	-50	160	5.0	160 Negative
7.5	-25	160	7.3	160 Negative
10.0	Cutoff	160	9.8	123 Negative/37 Positive
12.5	+25	160	12.4	160 Positive
15.0	+50	160	15.0	160 Positive
17.5	+75	160	17.7	160 Positive
20.0	+100	160	20.1	160 Positive

Pooled Human Urine Samples containing zopiclone were assayed in quadruplicate twice a day for 20 days.

ACCURACY – ANALYTICAL RECOVERY

Concentration Tested (ng/mL)	Mean (ng/mL)	Recovery (%)
2.5	3.0	107.6
4.5	4.6	102.7
9.0	8.8	97.5
18.0	18.1	100.3
24.0	24.6	102.4
32.0	32.6	101.9
40.0	39.6	99.0

METHOD COMPARISON

	LC-MS/MS	
	(+)	(-)
ARK Zopiclone Assay	(+) 49	0
	(-) 1*	60

*One (1) sample was positive for N-desmethylzopiclone by LC-MS/MS (1.4 ng/mL N-desmethylzopiclone LOQ) and tested negative by the ARK Zopiclone Assay relative to the 10 ng/mL Cutoff. Semi-quantitative results showed the presence of 6.3 ng/mL zopiclone.

ANALYTICAL SPECIFICITY

Compounds	Concentration Approximately Equivalent to the Cutoff (ng/mL)	Percent Cross-reactivity (%)
Eszopiclone-N-oxide	4.3	232.6
Eszopiclone	4.7	212.8
N-Desmethylyzopiclone	9.5	105.3
N-Desmethylzopiclone	11.1	90.1
Zopiclone-N-Oxide	11.1	90.1
(R) – Zopiclone	106.1	9.4
ACP (2-amino-5-chloropyridine)	>100,000	<0.01
Zaleplon	>100,000	<0.01
Zolpidem	>100,000	<0.01

SAFETY AND STABILITY

Reagent on-board stability

Up to at least 60 days

Shelf Life of Reagents, Calibrators, and Controls

12 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™ Zopiclone Assay	5043-0001-00	R1 28 mL, R2 14 mL
ARK™ Zopiclone Calibrator	5043-0002-00	5 x 10 mL
	5043-0002-01	2 x 10 mL; Negative
	5043-0002-02	2 x 10 mL; 10 ng/mL Cutoff
ARK™ Zopiclone Control	5043-0003-00	2 x 10 mL; LOW 7.5 ng/mL 2 x 10 mL; HIGH 12.5 ng/mL

For Criminal Justice and Forensic Use Only

ARK™ Zopiclone Assay	5043-0004-00	R1 28 mL, R2 14 mL
ARK™ Zopiclone Calibrator	5043-0005-00	5 x 10 mL
	5043-0005-01	2 x 10 mL; Negative
	5043-0005-02	2 x 10 mL; 10 ng/mL Cutoff
ARK™ Zopiclone Control	5043-0006-00	2 x 10 mL; LOW 7.5 ng/mL 2 x 10 mL; HIGH 12.5 ng/mL

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