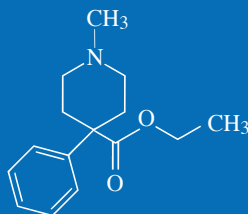


ARK™ Meperidine Assay



The ARK Meperidine Assay is an immunoassay intended for the qualitative and/or semiquantitative determination of meperidine in human urine at a cutoff concentration of 100 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers.



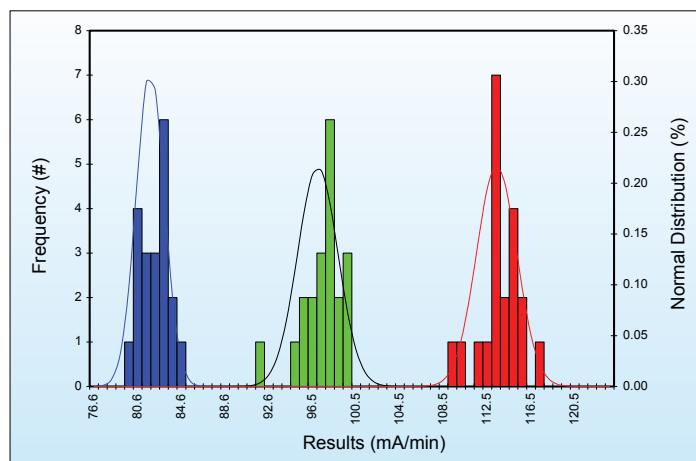
The ARK Meperidine Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is 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 – 1000 ng/mL calibration range; 100 ng/mL cutoff
- Excellent sensitivity and specificity for detection of meperidine in human urine
- Demonstrated cross-reactivity with normeperidine
- Nonhazardous preservatives

Next Generation Assays

QUALITATIVE PRECISION



Control Precision vs 100 ng/mL Cutoff Calibrator

SEMIQUANTITATIVE 20 DAY PRECISION

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Semiquantitative Precision Results
0.0	-100	160	1.0	160 Negative
25.0	-75	160	26.8	160 Negative
50.0	-50	160	50.0	160 Negative
75.0	-25	160	74.5	160 Negative
100.0	Cutoff	160	101.0	47 Negative / 113 Positive
125.0	+25	160	124.0	160 Positive
150.0	+50	160	148.0	160 Positive
175.0	+75	160	172.5	160 Positive
200.0	+100	160	195.8	160 Positive

Pooled Human Urine Samples containing meperidine 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	51.9	103.8
100.0	99.4	99.4
200.0	203.4	101.7
300.0	304.9	101.6
400.0	399.2	99.8
500.0	497.6	99.5
600.0	581.4	96.9
700.0	667.1	95.3
800.0	767.6	96.0
900.0	847.5	94.2
1000.0	965.4	96.5

METHOD COMPARISON

ARK Meperidine Assay (100 ng/mL Cutoff)	Confirmatory Method		
		(+)	(-)
	(+)	50	0
(-)	0	50	

CROSS-REACTIVITY AND INTERFERENCE

- 33.33% cross-reactivity with normeperidine.
- No cross-reactivity to other pain medications at the levels tested.
- Tested endogenous substances do not interfere except Boric Acid.

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™ Meperidine Assay 5039-0001-00 R1 28mL, R2 14mL
5039-0001-01 R1 115mL, R2 58mL

ARK™ Meperidine Calibrator 5039-0002-00 5 x 10mL
5039-0002-01 2 x 10mL; Negative
5039-0002-02 2 x 10mL; 100 ng/mL Cutoff

ARK™ Meperidine Control 5039-0003-00 2 x 10mL; LOW 75 ng/mL
2 x 10mL; HIGH 125 ng/mL

For Criminal Justice and Forensic Use Only

ARK™ Meperidine Assay 5039-0004-00 R1 28mL, R2 14mL
5039-0004-01 R1 115mL, R2 58mL

ARK™ Meperidine Calibrator 5039-0005-00 5 x 10mL
5039-0005-01 2 x 10mL; Negative
5039-0005-02 2 x 10mL; 100 ng/mL Cutoff

ARK™ Meperidine Control 5039-0006-00 2 x 10mL; LOW 75 ng/mL
2 x 10mL; HIGH 125 ng/mL

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