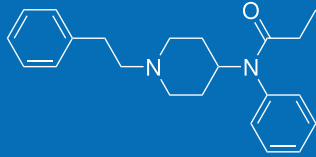


ARK™ Fentanyl Assay



The ARK™ Fentanyl Assay is intended for the qualitative and/or semiquantitative determination of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL. The assay provides a simple and rapid analytical screening procedure for detecting fentanyl in urine and is designated for professional use on automated clinical chemistry analyzers.

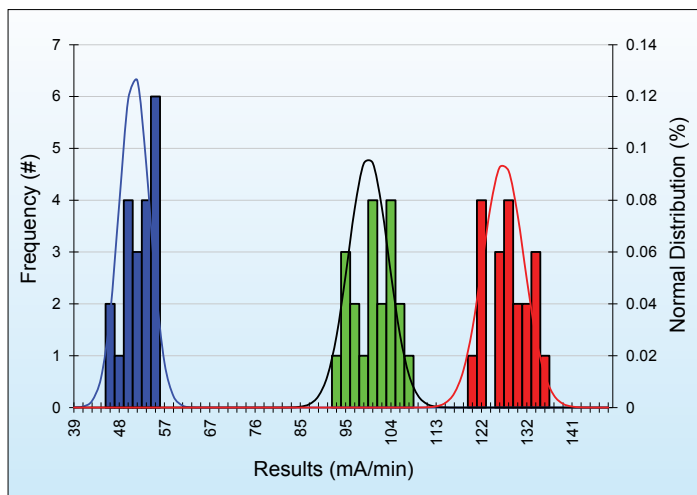


KEY POINTS

- Convenient, liquid-stable, ready-to-use homogeneous enzyme immunoassay
- Qualitative and/or semi-quantitative applications available for clinical chemistry systems
- 0 – 10 ng/mL calibration range; 1 ng/mL cutoff
- Excellent sensitivity and specificity for detection of fentanyl in human urine
- Nonhazardous preservatives

Next Generation Assays

QUALITATIVE CONTROL PRECISION



Qualitative Control Precision vs 1.0 ng/mL Cutoff Calibrator

SEMI-QUANTITATIVE PRECISION

Urine Spiked Samples N=160		WITHIN-RUN			TOTAL	
Fentanyl (ng/mL)	% Cutoff	Mean (ng/mL)	SD	CV (%)	SD	CV (%)
0.50	-50	0.44	0.04	8.8	0.05	11.3
0.75	-25	0.72	0.04	5.8	0.05	7.0
1.00	Cutoff	0.95	0.04	4.1	0.05	5.5
1.25	+25	1.12	0.05	4.7	0.07	5.8
1.50	+50	1.34	0.07	5.0	0.08	6.0
2.00	+100	1.80	0.06	3.2	0.08	4.4

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

ACCURACY – SPIKED URINE SAMPLES

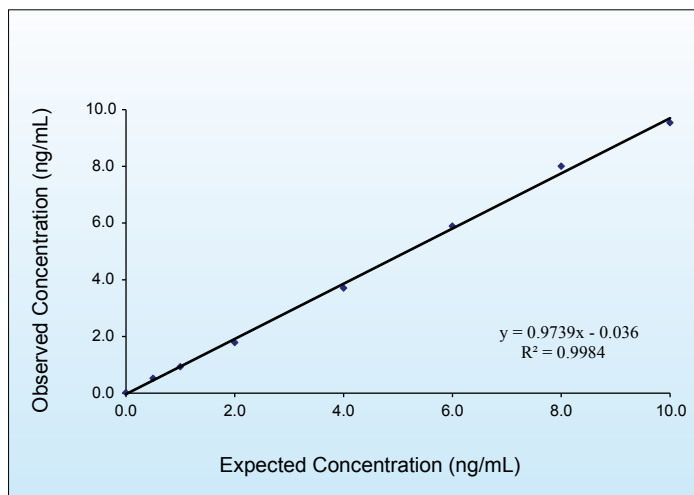
Theoretical Concentration (ng/mL)	Mean Recovered Concentration (ng/mL)	Percent (%) Recovery	N
0.40	0.40	100.4	6
0.75	0.69	91.6	6
1.75	1.68	96.0	6
3.00	2.94	97.8	6
4.00	4.11	102.6	6
6.00	6.28	104.7	6
10.00	9.59	95.9	6

METHOD COMPARISON

	LC-MS/MS	
	(+)	(-)
ARK Fentanyl Assay	97	0
	(-)	3

ARK Fentanyl Assay compared to LC-MS/MS with 0.2 ng/mL Cutoff.

LINEARITY



ARK™ Fentanyl Assay Calibrator Range: 0 to 10 ng/mL

CROSS-REACTIVITY AND INTERFERENCE

- No cross-reactivity with Opioids at concentrations tested
- High cross-reactivity to Norfentanyl at 300 ng/mL
- Tested Endogenous substances do not interfere

SAFETY AND STABILITY

Reagent on-board stability

At least 60 days

Shelf Life of Reagents, Calibrators, and Controls

18 months from date of manufacturing when stored at 2 – 8 °C

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™ Fentanyl Assay	5031-0001-00
	5031-0001-01
ARK™ Fentanyl Calibrator	5031-0002-00
	5031-0002-01
	5031-0002-02
ARK™ Fentanyl Control	5031-0003-00

For Criminal Justice and Forensic Use Only

ARK™ Fentanyl Assay	5031-0004-00
	5031-0004-01
ARK™ Fentanyl Calibrator	5031-0005-00
	5031-0005-01
	5031-0005-02
ARK™ Fentanyl Control	5031-0006-00

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