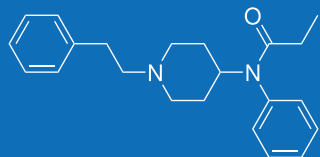


ARK™ Fentanyl 0.5 ng/mL Assay



The ARK Fentanyl 0.5 ng/mL Assay is an immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 0.5 ng/mL fentanyl. The assay is intended solely for use in employment and insurance testing.



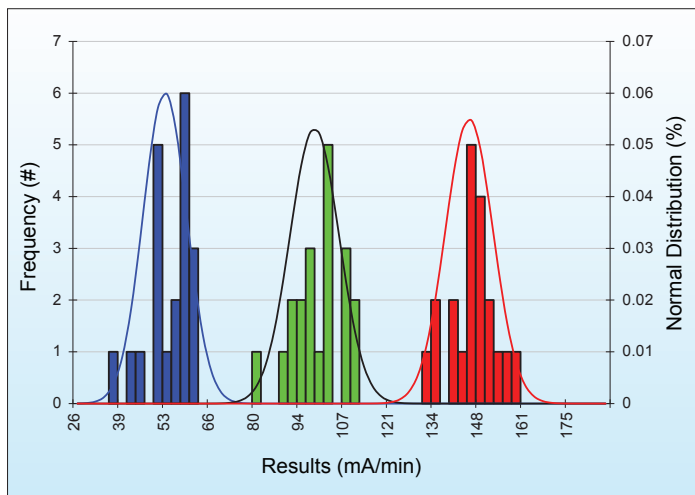
The ARK Fentanyl 0.5 ng/mL Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is 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.

KEY POINTS

- Convenient, liquid-stable, ready-to-use homogeneous enzyme immunoassay
- 0.5 ng/mL cutoff
- Excellent sensitivity and specificity for detection of fentanyl in human urine
- Demonstrated cross-reactivity with norfentanyl
- Nonhazardous preservatives

Next Generation Assays

QUALITATIVE PRECISION



Control Precision vs 0.5 ng/mL Cutoff Calibrator
LOW Control 0.25 ng/mL and HIGH Control 0.75 ng/mL

QUALITATIVE 20 DAY PRECISION

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Results
0.000	-100	160	160 Negative
0.250	-50	160	160 Negative
0.375	-25	160	157 Negative; 3 Positive
0.500	Cutoff	160	33 Negative; 127 Positive
0.625	+25	160	160 Positive
0.750	+50	160	160 Positive
1.000	+100	160	160 Positive

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

METHOD COMPARISON

ARK Immunoassay Result	Low Negative (< 0.25 ng/mL by LC-MS/MS)	Near Cutoff Negative (0.25 – 0.49 ng/mL by LC-MS/MS)	Near Cutoff Positive (0.50 – 0.75 ng/mL by LC-MS/MS)	High Positive (> 0.75 ng/mL by LC-MS/MS)
Positive	0	1*	15	84
Negative	50	0	0	0

*Norfentanyl was detected in this discordant sample (Sample ID #052) and contributed to the positive result obtained with the ARK Fentanyl 0.5 ng/mL Assay for this sample.

CROSS-REACTIVITY

Norfentanyl (Major Metabolite)

Compound	Conc. Tested (ng/mL)	Percent Crossreactivity (%)
Norfentanyl (Major Metabolite)	25	2.00

Other Metabolites and Structural Analogs of Fentanyl

Compound	Lowest Conc. Equivalent to Cutoff (ng/mL)	Percent Cross-reactivity (%)
Acetyl fentanyl	0.60	83.33
Ocfentanil	0.60	83.33
Isobutyryl fentanyl	0.75	66.67
Acrylfentanyl	0.80	62.50
Butyrylfentanyl	0.80	62.50
ω-1-Hydroxy fentanyl	0.80	62.50
Furanyl fentanyl	0.88	56.82
Valeryl fentanyl	1.00	50.00
(±) β-hydroxythiofentanyl	1.40	35.71
4-Fluoro-isobutyryl fentanyl	2.00	25.00
(±)-3-cis-Methylfentanyl	2.50	20.00
para-Fluorobutyryl fentanyl	2.50	20.00
para-Fluorofentanyl	2.50	20.00
Despropionyl fentanyl	65	0.77
Carfentanil	150	0.33
Sufentanil	313	0.16
Acetyl norfentanyl	1000	0.05
Norcarfentanil	5000	<0.01
Remifentanil	10000	<0.005
Alfentanil	100000	<0.0005

- High cross-reactivity to Norfentanyl, Other Metabolites and Structural Analogs of Fentanyl
- No cross-reactivity with Opioids at concentrations tested
- 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

Safety

- Nonhazardous preservatives
- Contains sodium azide ≤ 0.09%

Results shown are typical and may vary among laboratory analyzers.

ORDERING INFORMATION

ARK™ Fentanyl 0.5 ng/mL Assay	5052-0001-00
ARK™ Fentanyl Calibrator	5052-0002-01 5052-0002-02
ARK™ Fentanyl Control	5052-0003-00

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