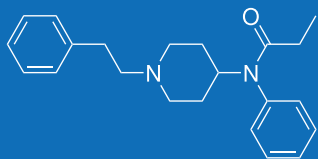


ARK™ Fentanyl II Assay



The ARK Fentanyl II Assay is an immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 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.



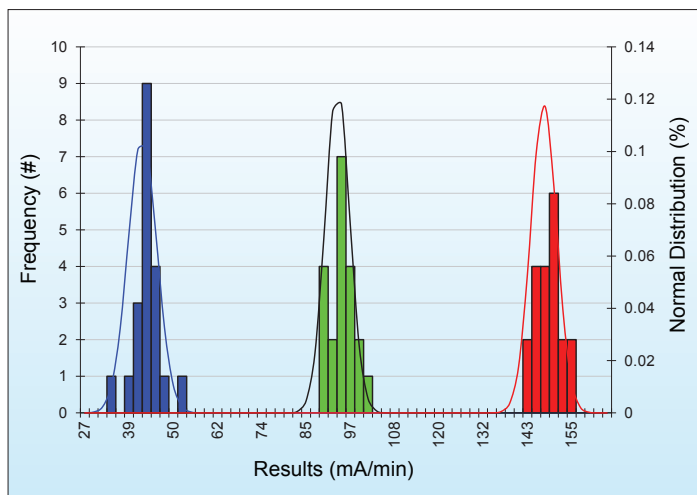
The ARK Fentanyl II Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is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



Control Precision vs 1.0 ng/mL Cutoff Calibrator

QUALITATIVE 20 DAY PRECISION

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Results
0.00	-100	160	160 Negative
0.25	-75	160	160 Negative
0.50	-50	160	160 Negative
0.75	-25	160	160 Negative
1.00	Cutoff	160	84 Negative; 76 Positive
1.25	+25	160	160 Positive
1.50	+50	160	160 Positive
1.75	+75	160	160 Positive
2.00	+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 (< 0.5 ng/mL by LC-MS/MS)	Near Cutoff Negative (0.5 – 0.9 ng/mL by LC-MS/MS)	Near Cutoff Positive (1.0 – 1.5 ng/mL by LC-MS/MS)	High Positive (> 1.5 ng/mL by LC-MS/MS)
Positive	1*	21	11	62
Negative	50	2	0	0

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

CROSS-REACTIVITY

Norfentanyl (Major Metabolite)

Compound	Concentration Approximately Equivalent to the Cutoff (ng/mL)
Norfentanyl	15

Other Metabolites and Structural Analogs of Fentanyl

Compound	Concentration Approximately Equivalent to the Cutoff (ng/mL)	Percent Cross-reactivity (%)
Acetyl fentanyl	1.1	90.91
Isobutyryl fentanyl	1.1	90.91
ω-1-Hydroxyfentanyl	1.2	83.33
Acrylfentanyl	1.3	76.92
Butyryl fentanyl	1.4	71.43
Furanyl fentanyl	1.5	66.67
Para-fluoro fentanyl	1.5	66.67
Ocfentanil	1.6	62.50
4-Fluoro-isobutyryl fentanyl	1.9	52.63
Para-fluorobutyryl fentanyl (p-FBF)	1.9	52.63
Valeryl fentanyl	2.3	43.48
β-hydroxyfentanyl	9.5	10.53
Acetyl norfentanyl	12.1	8.26
(±) β-hydroxythiofentanyl	32.7	3.06
(±)-3-cis-methyl fentanyl	144.1	0.69
Carfentanil	448.2	0.22
Despropionyl fentanyl (4-ANPP)	471.8	0.21
Sufentanil	2,362	0.04
Norcarfentanil	2,418	0.04
Remifentanil	>10,000	<0.01
Alfentanil	>100,000	<0.001

- High cross-reactivity to Norfentanyl, Other Metabolites and Structural Analogs of Fentanyl
- No cross-reactivity with other Opioids at concentrations tested
- Tested Endogenous substances do not interfere

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 ≤ 0.09%

Results shown are typical and may vary among laboratory analyzers.

ORDERING INFORMATION

ARK™ Fentanyl II Assay	5069-0001-00
	5069-0001-01
	5069-0001-02
ARK™ Fentanyl Calibrator A (Negative)	5031-0002-01
ARK™ Fentanyl Calibrator B (Cutoff)	5031-0002-02
ARK™ Fentanyl Control	5031-0003-00

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