

Fentanyl

Urine HEIA[®] Drug Screening Kit

IMMUNALYSIS[®]

Fentanyl is a synthetic narcotic analgesic of high potency and short duration of action. Though 200 times more potent than morphine, fentanyl has a high safety margin. The drug is available as a citrate salt in an injectable solution containing 50 µg/mL. It is also available as a transdermal patch containing 2.5-16 mg fentanyl and provides a dose of 25-100 µg/hr for 72 hours for management of chronic pain.¹

While fentanyl has all the properties of morphine, it is structurally different and therefore cannot be detected by screening tests for morphine and related opiates. Because of the potency of the drug, concentrations encountered in biological fluids are in the sub nanogram range.²

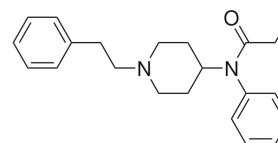
Administration: Intravenous, transdermal patch, flavored lozenges, lollipop, buccal tablets, nasal spray, and inhalant.

Elimination: Fentanyl plasma protein binding capacity decreases with increasing ionization of the drug. Fentanyl is metabolized primarily via human cytochrome P450 3A4 isoenzyme system. In humans, the drug appears to be metabolized primarily by oxidative n-dealkylation to norfentanyl and other inactive metabolites that do not contribute materially to the observed activity of the drug. Within 72 hours of IV fentanyl administration, approximately 75% of the dose is excreted in urine, mostly as metabolites with less than 10% representing unchanged drug.³

Abuse Potential: Fentanyl can be abused and is subject to criminal diversion. Mixing fentanyl with street-sold heroin or cocaine markedly amplifies potency and potential dangers. It produces significantly worse respiratory depression and non-medical use of fentanyl has resulted in numerous deaths.⁴

The Centers for Disease Control and Prevention (CDC) has released a report regarding the increase in the number of illicit drug overdose deaths, potentially due to the use of acetyl fentanyl.⁵ Acetyl fentanyl is a fentanyl analog previously undocumented in illicit drug use and is not available as a prescription drug in the U.S. The CDC recommends to laboratories to exercise increased vigilance in the detection of this substance.

Fentanyl



Formula: C₂₂H₂₈N₂O

Systematic Name:

N-(1-(2-phenylethyl)-4-piperidinyl)-N-phenylpropanamide

Brand Names: Actiq[®], Duragesic[®], Fentora[®], Onsolis[®], and lonsys[®]

- Demonstrated cross-reactivity with carfentanil, acetyl fentanyl, and butyryl fentanyl
- Designed for qualitative or semi-quantitative testing
- Accurate and tested results
- Liquid stable and ready to use

1. R.C. Baselt and R.H. Cravey. Disposition of Toxic Drugs and Chemicals in Man. 8th edition. 450-453.

2. L.S. Goodman and A. Gilman. The Pharmaceutical Basis of Therapeutics. 4th edition. 258.

3. DURAGESIC[®] (Fentanyl Transdermal System) package insert, © Ortho-McNeil-Janssen Pharmaceuticals, Inc. 2009 0017974-1, Revised July 2009.

4. Boddiger, D. (2006, August 12). Fentanyl-laced street drugs "kill hundreds". In EBSCOhost. Retrieved March 7, 2007.

5. CDC Health Alert Network 350: Recommendations for Laboratory Testing for Acetyl Fentanyl and Patient Evaluation and Treatment for Overdose with Synthetic Opioids, June 2013.



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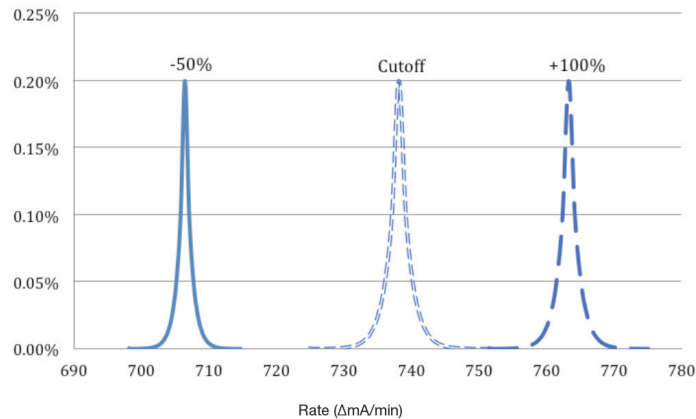
Assay Specifications

Methodology: Homogeneous enzyme immunoassay

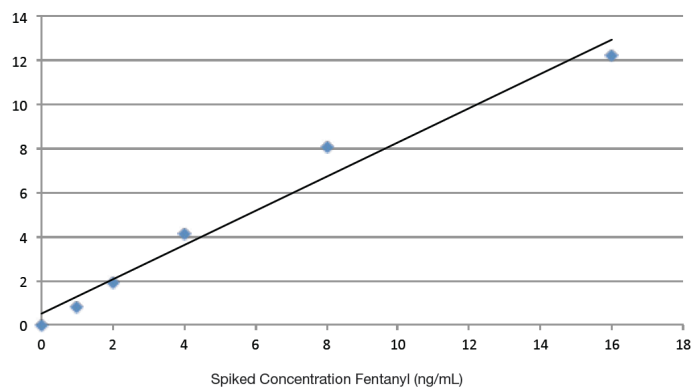
Cutoff: 2 ng/mL

Calibration Range: 0-16 ng/mL

Overlap: Fentanyl (2 ng/mL cutoff)



Analytical Recovery: Fentanyl



Semi-Quantitative Precision at 2 ng/mL

Interday Precision (N = 10)

Concentration	Mean (mA/min)	S.D.	C.V.%
2 ng/mL calibrator	0.343	1.24	0.36
4 ng/mL calibrator	0.367	2.00	0.56
8 ng/mL calibrator	0.379	0.91	0.24
16 ng/mL calibrator	0.392	1.32	0.35

Semi-Quantitative Cross-Reactivity

Analyte	Analyte Concentration (ng/mL)	Fentanyl Equivalents (ng/mL)	Cross-Reactivity (%)
Fentanyl	2	2	100
1-(3-Chlorophenyl)piperazine	500,000	2	N/D
Acetylfentanyl	4	2.1	53
Despropionylfentanyl	25	2	8
Labetalol	35,000	2	0.006
Methamphetamine	150,000	2	0.001
Trazodone	100,000	2	0.002
Carfentanil	4	2	50
Sufentanil	75	2	3
Butyryl Fentanyl	1.9	2	111
Cis-Methylfentanyl	95	2	2.3
Trans-Methylfentanyl	3.7	2	57
4-Methoxybutyryl Fentanyl	3	2	77
MT-45	18,000	2	0.01
Valeryl Fentanyl	2.5	2	80
Isobutyryl Fentanyl	2.7	2	74
Para-fluorobutyryl	2.2	2	100
U-47700	27,000	2	0.01
Furanyl Fentanyl	2.8	2	75

The following analytes were tested at 100,000 ng/mL and no cross-reactivity was detected: buprenorphine, codeine, cyclobenzaprine, dihydrocodeine, hydrocodone, hydromorphone, meperidine, morphine, morphine-3-gluc., naloxone, naltrexone, norcodeine, norfentanyl, normorphine, oxycodone, oxymorphone, propoxyphene, tramadol, and venlafaxine.

Accuracy:

		GC-MS Confirmation (2 ng/mL)	
		Positive	Negative
HEIA (2 ng/mL)	Positive	75	3
	Negative	0	39

Order - Fentanyl (HEIA)

Catalog Number	Description
318-0025	25 mL kit
318-0060W	60 mL wedge kit
318-0100	100 mL kit
318-0500	500 mL kit
C318-10-1	2 ng/mL calibrator
C318-10-1-5	5 ng/mL control
C318-10-2	1 and 4 ng/mL controls
C318-10-5	0, 2, 4, 8, and 16 ng/mL calibrators
Neg-10-1	10 mL negative reference calibrator

The charts and data provided above were generated in studies conducted by Immunalysis Corporation. This information is intended to be representative of the performance of the assay. Refer to the product insert for a full description of the performance characteristics for semi-quantitative and qualitative testing. For forensic use only.