Fentanyl

Urine SEFRIA™ Drug Screening Kit

IMMUNALYSIS®

First-ever FDA 510(k) cleared fentanyl enzyme immunoassay brings high-performance qualitative screening to a wide range of healthcare settings

The illegal use of fentanyl plays a large part in the U.S. opioid abuse epidemic. According to the Centers for Disease Control and Prevention (CDC), death rates from synthetic opioids such as fentanyl increased by 72.2 percent from 2014 to 2015, due in part to its low cost and high potency, which can be up to 50 times greater than heroin and 100 times greater than morphine. Drug overdoses associated with fentanyl are often linked to unintentional ingestion when fentanyl is laced in street-sold heroin or cocaine, which significantly amplifies its potency.[1]

Fentanyl is a synthetic narcotic analgesic of high potency and short duration of action. 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 2.5–10 mg fentanyl and provides a dose of 25–100 µg/hr for 72 hours for management of chronic pain.[2]

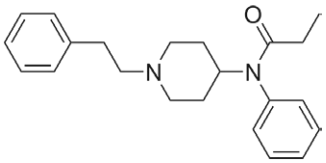
While fentanyl has all the properties of morphine, it is structurally different and therefore cannot be detected by screening tests for morphine and related opiates.

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

The Immunalysis® Fentanyl Urine SEFRIA™ Drug Screening Kit detects the presence of fentanyl and its major metabolites in human urine samples with a cutoff of 1 ng/mL for qualitative testing. In clinical performance studies, testing with the Fentanyl Urine SEFRIA™ Drug Screening Kit compared favorably to liquid chromatography-mass spectrometry (LC-MS) analysis in both sensitivity (identification of positive results) and specificity (identification of negative results).

SEFRIA™ technology
with exquisite sensitivity

SEFRIA™ reagents are the next generation β-galactosidase enzyme with lower cutoffs and enhanced precision, without reconstitution



Formula: $C_{22}H_{28}N_2O$

Systematic Name:
N-(1-(2-phenylethyl)-4 piperidinyl)-N-phenyl-propanamide

Brand Names: Actiq®, Sublimaze®, Duragesic®, Fentora®, Onsolis®, and Ionsys®

- Designed for qualitative testing at 1 ng/mL cutoff
- Demonstrated cross-reactivity with acetyl fentanyl and butyryl fentanyl
- Accurate and trusted results
- Liquid stable and ready to use

SEFRIA IVD ISO 13485:2003 CERTIFIED

Fentanyl Urine SEFRIA™ Drug Screening Kit

Assay Specifications

Methodology: Synthetic enzyme fragment immunoassay
Cutoff: 1.0 ng/mL

Qualitative		LC-MS Confirmation (1 ng/mL)	
		Positive	Negative
Fentanyl (1 ng/mL)	Positive	40	1*
	Negative	0	39

*Positive SEFRIA sample confirmed at 0.9 ng/mL

Qualitative Precision at 1 ng/mL

Interday Precision (N = 80)		
Concentration	**Result**	**Total Result**
0.0 ng/mL	NEG	80 Negative
0.5 ng/mL (control LOW)	NEG	80 Negative
1.0 ng/mL calibrator	NEG/POS	32 Negative/ 48 Positive
1.5 ng/mL (control HIGH)	POS	80 Positive
2.0 ng/mL	POS	80 Positive

Qualitative Cross-Reactivity

Analyte	Analyte Concentration (ng/mL)	Cross-Reactivity (%)
Fentanyl	1.0	100.0
Butyryl Fentanyl	0.8	125.0
Acetyl Fentanyl	1.0	100.0
Despropionyl Fentanyl	40	2.50
Sufentanil	175	<0.5714
Haloperidol	1250	0.0800
Pipamperone	1500	0.0667
Risperidone	2500	0.0400
Norfentanyl	20,000	0.0050
Trazodone	10,000	0.0100
Labetalol	15,000	0.0067
Clomipramine	45,000	0.0022
Benzylpiperazine	50,000	0.0020
Fluoxetine	60,000	0.0017
Fenfluramine	60,000	0.0017
Methamphetamine	70,000	0.0014
Amitriptyline	75,000	0.0013
Chlorpromazine	75,000	0.0013
Pentazocine	75,000	0.0013
PCP	100,000	0.0010

Other analytes tested at 100,000 ng/mL with cross-reactivity of 0.001% or less are listed in the product insert.

Order - Fentanyl (SEFRIA)

Kit Catalog Number	Description
618UR-0025	25 mL kit
618UR-0060W	60 mL wedge kit
618UR-0100	100 mL kit
618UR-0500	500 mL kit
10019-5	1.0 ng/mL calibrator
10020-5	2.0 ng/mL calibrator
10021-5	4.0 ng/mL calibrator
3009-5	0.5 and 1.5 ng/mL controls
NEG-600-5	Negative urine calibrator

1. Centers for Disease Control and Prevention (CDC). Synthetic opioids data. https://www.cdc.gov/drugoverdose/data/fentanyl.html; accessed June 19, 2017.
2. R.C. Baselt and R.H. Cravey. *Disposition of Toxic Drugs and Chemicals in Man.* 8th edition. 450-453.

Please refer to the product insert for more information. All charts and data are created and provided by Immunalysis Corporation. For in vitro diagnostic use.
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