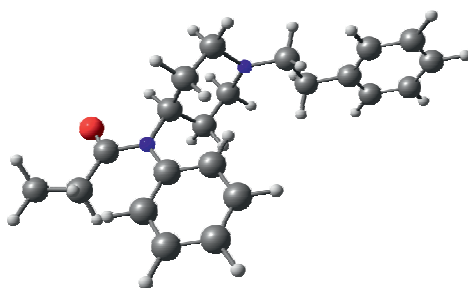


SEFRIA™ Fentanyl Assay

Immunoanalysis and Specialty Diagnostix introduce the next generation of homogeneous enzyme immunoassays. SEFRIA™ Technology utilizes both synthetic and recombinant enzyme fragments of β -galactosidase for superb sensitivity and vastly improved analysis. The SEFRIA™ Fentanyl Assay will be the first of this new exclusive range. Due to its extremely low cut-off, this assay is particularly suited for the monitoring of transdermal patches and oral transmucosal Fentanyl citrate lollipops.

Assay Characteristics

- **Cutting-edge, next generation technology**
- **Cut-off as low as 1 ng/mL with fewer false-negative results**
- **Excellent separation between controls and calibrators**
- **No cross-reactivity with norfentanyl**
- **Liquid-stable, ready-to-use reagents, calibrators, and controls**
- **Application protocols for all major clinical chemistry analyzers**
- **Packaging tailored to your laboratory's unique needs**
- **Use of synthetic material to enhance stability of calibrators and controls, and to decrease risk of contamination**



Background

First synthesized in the late 1950s, Fentanyl was found to be significantly more potent than commonly used opioids, such as morphine or pethidine. It is a potent synthetic opioid analgesic which has been introduced as a widespread palliative, especially in form of transdermal patches and other quick-acting prescription forms in chronic pain management and for cancer patients.

As of the mid-1970s, Fentanyl has also been used as a recreational drug. Apparently, its effects are similar to that of heroin, with

stronger sedative results. Fentanyl is also a very short-acting drug so users become addicted quite rapidly. On the illicit markets, Fentanyl is sold in all available forms. Users may cut up patches and eat them or take the gel inside the patch to smoke it.

The SEFRIA™ Fentanyl Assay is a strong screening tool to monitor compliance on the one hand, and for the detection of Fentanyl abuse on the other.

Cross-Reactivities

Analyte	Concentration (ng/mL)	Cross-Reactivity (%)	Analyte	Concentration (ng/mL)	Cross-Reactivity (%)
Fentanyl	1	100	Meta-Chlorophenylpiperazine (mCPP)	100 000	< 0.05
6-Acetylcodeine	100 000	< 0.05	Meperidine	100 000	< 0.05
6-Acetylmorphine	100 000	< 0.05	Methadone	100 000	< 0.05
Acetylfentanyl	1	109	Methamphetamine	70 000	< 0.05
Amitriptyline	75 000	< 0.05	Morphine	100 000	< 0.05
Benzylpiperazine	50 000	< 0.05	Morphine-3-Glucuronide	100 000	< 0.05
Buprenorphine	100 000	< 0.05	Morphine-6-Glucuronide	100 000	< 0.05
Bupropion	100 000	< 0.05	Nalorphine	100 000	< 0.05
Butyryl Fentanyl	0.8	106.2	Naloxone	100 000	< 0.05
Chlorpromazine	75 000	< 0.05	Naltrexone	100 000	< 0.05
Clomipramine	45 000	< 0.05	Norcodeine	100 000	< 0.05
Codeine	100 000	< 0.05	Nordiazepam	100 000	< 0.05
Cyclobenzaprine	100 000	< 0.05	Norfentanyl	20 000	< 0.05
Desipramine	100 000	< 0.05	Normorphine	100 000	< 0.05
Despropionyl Fentanyl	40	2.6	Nortriptyline	100 000	< 0.05
Diacetylmorphine	100 000	< 0.05	Oxycodone	100 000	< 0.05
Dihydrocodeine	100 000	< 0.05	Oxymorphone	100 000	< 0.05
Diphenhydramine	100 000	< 0.05	Pentazocine	75 000	< 0.05
Doxepin	100 000	< 0.05	Phencyclidine (PCP)	100 000	< 0.05
EDDP	100 000	< 0.05	Pipamperone	1 500	0.059
EMDP	100 000	< 0.05	Propoxyphene	100 000	< 0.05
Fenfluramine	60 000	< 0.05	Protriptyline	100 000	< 0.05
Fluoxetine	60 000	< 0.05	Risperidone	2 500	0.040
Haloperidol	1 250	0.092	Sufentanil	175	0.474
Hydrocodone	100 000	< 0.05	Tramadol	100 000	< 0.05
Hydromorphone	100 000	< 0.05	Trazodone	10 000	0.011
Imipramine	100 000	< 0.05	Trimethoprim	100 000	< 0.05
Labetalol	15 000	< 0.05	Trimipramine	100 000	< 0.05
Levorphanol	100 000	< 0.05	Venlafaxine	100 000	< 0.05

Accuracy

A total of 80 urine specimens were analysed by the Immunoassay SEFRIA™ Fentanyl Urine Assay on an AU400 Analyzer System and by an LC-MS method.

39 specimens showed negative results by both methods, while 40 samples were positive with both methods. One (1) urine specimen that screened positive via immunoassay did not confirm positive with LC-MS.

1 ng/mL Cut-off	LC-MS		
	+	-	
SEFRIA™ Fentanyl	+	40	1
	-	0	39

Ordering Information

Reagents	Size	Order No.
Fentanyl Urine SEFRIA	25 mL	618UR-0025EX
Fentanyl Urine SEFRIA	60 mL	618UR-0060WEX
Fentanyl Urine SEFRIA	100 mL	618UR-0100EX
Calibrators		
Fentanyl Urine Calibrator Level 1, 1 ng/mL	1 x 5 mL	10019-5EX
Fentanyl Urine Calibrator Level 2, 2 ng/mL	1 x 5 mL	10020-5EX
Fentanyl Urine Calibrator Level 3, 4 ng/mL	1 x 5 mL	10021-5EX
Controls		
Fentanyl Urine Control Set, 0.5 ng/mL & 1.5 ng/mL	2 x 5 mL	3009-5EX

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