Harm Reduction Fentanyl Test Strips

Analytical Performance Evaluation

Summary and Explanation

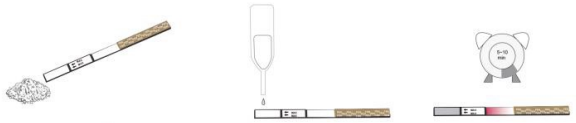
Fentanyl is an extremely fast acting synthetic opioid related to the phenylpiperidiens. It has the brand names of Sublimaze, Actiq, Durogestic, Fentora and others. Fentanyl is approximately100 times more potent than morphine, with 100 micrograms of fentanyl approximately equivalent to 10 mg of morphine or 75 mg of meperidine in analgesic activity (1.2). Fentanyl is a potent narcotic analgesic with rapid onset and short duration of action. Historically, it has been used to treat chronic breakthrough pain and is commonly used pre-procedures. Illicit use of pharmaceutical fentanyl first appeared in the mid- 1970s. Because the effects offentanyl last for only a very short time, it is even more addictive than heroin. The regular users may become addicted very quickly. Fentanyl is much more potent than heroin, and tends to produce significantly worse respiratory depression, making it somewhat more dangerous than heroin to users. The overdose of fentanyl has caused death. 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 intravenous (IV) administration, approximately 75% of the dose is excreted in urine, mostly as metabolites with <10% representing unchanged drug (3,4).

Fentanylis a controlled substance. As an analgesic, fentanyl can be used for cancer pain treatment. It can also be used to treat severe chronic pain that requires opioid analgesics. Fentanyl can also be abused in a manner similar to other opioid antagonists (legal or illicit).Illegal drug consumption contributes to many accidents, injuries and medical conditions.

Jiangsu Well Biotech Ltd. a immunoassay manufacturer, has developed a fentanyl test strip designed to facilitate the rapid, low-cost, and accurate detection of fentanyl drug residues on suspected surface, in powder or in liquid. It is designed to integrate the collection of sample and lateral flow immunoassay screen testing in one single device. As fentanyl is often mixed with other illicit substances and cutting agents, researchers have conducted the following studies to assess the fentanyl test strip's analytical sensitivity, its potential cross-reactivity in the presence of high concentrations of common cutting agents and illicit compounds.

Equipment Test Procedure

1. Open the device kit and remove the test strip from the sealed pouch.
2. Powder Form: Dab the powder with the end of the strip or crush drug to a powder then swipe with the end of the strip. Add 3 drops of buffer onto sample pad until the fluid shows up in the window area.
Liquid Form: Add one drop of liquid sample onto the sample pad of the strip. Then add one or two drops of buffer onto sample pad until the fluid shows up in the window area.



3. Lay the device on a flat surface and read results in approximately 5 minutes. Do not read results after 10 minutes.

Fentanyl Precision

For precision test of fentanyl drugs, dilute fentanyl standards at different concentrations (0, 50%, 150%, 300% and 600% cutoff) into negative buffer solutions. For each concentration, a total of 10 tests were conducted to verify the testing performance.Each study device was tested in accordance with the instructions.

Test Strip	0ng/mL	0.5ng/mL	1.5ng/mL	3ng/mL	6ng/mL
1	Neg	Neg	Pos	Pos	Pos
2	Neg	Neg	Pos	Pos	Pos
3	Neg	Neg	Pos	Pos	Pos
4	Neg	Neg	Pos	Pos	Pos
5	Neg	Neg	Pos	Pos	Pos
6	Neg	Neg	Pos	Pos	Pos
7	Neg	Neg	Pos	Pos	Pos
8	Neg	Neg	Pos	Pos	Pos
9	Neg	Neg	Pos	Pos	Pos
10	Neg	Neg	Pos	Pos	Pos

The Harm Reduction device detects Fentanyl at the cutoff of 1 ng/ml.

Analytical Specificity Research (Cross-Reactivity)

In the study 56 fentanyl analogs were tested using the Fentanyl Test Strip. The specificity was evaluated by adding fentanyl analogs to negative buffer. The results are expressed as the lowest concentration of the compound, in ng/mL, that produced a positive result. Percent cross reactivity of a compound is calculated by dividing the cutoff concentration by the lowest concentration required to obtain a positive result and the multiplying by 100%. Each study device was tested in accordance with the instructions.

Fentanyl Analog Compounds showing various degrees of cross-reactivity.

Compound Name	*Concentration ng/mL*	*Cross Reactivity %*
o-Fluorofentanyl	*2.5ng/mL*	*40%*
p-Fluorobutyryl fentanyl	*10ng/mL*	*10%*
Tetrahydrofuran fentanyl	*500ng/mL*	*0.2%*
2-Thiofuranyl fentanyl	*50ng/mL*	*2%*
4-Piperidone	*2500ng/mL*	*0.04%*
2',4'-dimethoxy Fentanyl	*2.5ng/mL*	*40%*
3',4'-dimethoxy Fentanyl	*1ng/mL*	*100%*
meta-fluoro Acrylfentanyl	*2.5ng/mL*	*40%*
para-chloro Furanyl fentanyl 3-furancarboxamide	*5ng/mL*	*20%*
Thiophene fentanyl 3-thiophenecarboxamide	*25ng/mL*	*4%*
3'-Fluorofentanyl	*2.5ng/mL*	*40%*
ortho-fluoro Valeryl fentanyl	*500ng/mL*	*0.2%*
4-methyl Fentanyl	*5ng/mL*	*20%*
Cyclopropaneacetyl fentanyl	*2.5ng/mL*	*40%*
para-Chloroacetyl fentanyl	*5ng/mL*	*20%*
para-hydroxy Butyryl fentanyl	*2.5ng/mL*	*40%*
2'-Fluoro ortho-Fluorofentanyl	*10ng/mL*	*10%*
meta-methoxy Furanyl fentanyl	*25ng/mL*	*4%*
3'-fluoro ortho-Fluorofentanyl	*5ng/mL*	*20%*
2',3'-dimethoxy Fentanyl	*1ng/mL*	*100%*
2',6'-dimethoxy Fentanyl	*2.5ng/mL*	*40%*
3',5'-dimethoxy Fentanyl	*1ng/mL*	*100%*
Acetyl norfentanyl	*10ng/mL*	*10%*
Acetyl-α-methyl fentanyl	*5ng/mL*	*20%*
Acryl fentanyl	*10ng/mL*	*10%*
α-methyl fentanyl	*1ng/mL*	*100%*
Benzyl fentanyl	*2.5ng/mL*	*40%*
β-hydroxythio fentanyl	*5ng/mL*	*20%*
Cyclopropyl fentanyl	*1ng/mL*	*100%*
4-Fluoroisobutyryl Fentanyl	*50ng/mL*	*2%*
Methoxyacetyl fentanyl	*12.5ng/mL*	*8%*
4-methoxybutyryl fentanyl (para)	*400ng/mL*	*0.25%*
4'-methyl acetyl fentanyl	*25ng/mL*	*4%*

3'-methyl Fentanyl	*10ng/mL*	*10%*
N-methyl norfentanyl	*1.5ng/mL*	*66.7%*

Fentanyl Analog Compounds showing no cross-reactivity.

Isotonitazene	*4-Anilino-1-Boc-piperidine*
O-Desmethyl-cis-tramadol	*Norcarfentanil*
Benzoyl fentanyl (Phenyl fentanyl)	*2-fluoro Viminol*
Despropionyl para-Fluoro fentanyl	*4-Anilino-1-benzylpiperidine*
N-Phenethyl-4-piperidone(NPP)	*Etonitazene*
4-ANPP	*AP-238*
Despropionyl ortho-Fluorofentanyl	*2,3-Benzodioxole fentanyl*
AP-237	*N-Benzyl-4-piperidone*
2-methyl AP-237	*Brorphine*
Tianeptine	*4-Anilinopiperidine*
Piperidylthiambutene	

Within the study there were 35 compounds that demonstrated cross-reac,vity to various degrees and are able to be detected by the Fentanyl Test Strip. The other remaining 21 analog compounds did not cross react with the Fentanyl Test Strips at concentra,ons of up to 100 µg/mL.

The following opioids compounds were tested at a concentration of 100ug/mL.

6-Acetyl morphine	*Naltrexone*
Amphetamine	*Norbuprenorphine*
Buprenorphine	*Norcodeine*
Buprenorphineglucuronide	*Norketamine*
Codeine	*Normeperidine*
Dextromethorphan	*Normorphine*
Dihydrocodeine	*Noroxycodone*
EDDP	*Oxycodone*
EMDP	*Oxymorphone*
Fluoxetine	*Pentazocine (Talwin)*
Heroin	*Pipamperone*
Hydrocodone	*Risperidone*
Hydromorphone	*Tapentadol*
Ketamine	*Thioridazine*
Levorphanol	*Tilidine*
Meperidine	*Tramadol*
Methadone	*Tramadol-O-Desmethyl*
Morphine	*Tramadol-N-Desmethyl*
Morphine-3-glucuronide	*Trazodone*

Naloxone	

Negative results were obtained for all these compounds. There is no cross-reactivity for these compounds using the AllSource Harm Reduction.

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