FEN Rapid Test (Powder)
Package Insert

REF: DPFEN- S91	EN

Intended for Harm Reduction Use Only

【INTENDED USE】

The Fentanyl (FEN) Rapid Test (Powder) is a rapid visual immunoassay for the qualitative, presumptive detection of Fentanyl in suspicious substances at the cut-off concentration listed below:

Abbreviation	Drug	Calibrator	Concentration (ng/mL)
FEN	Fentanyl	Fentanyl	20

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary analytical test result for Harm Reduction. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography mass spectrometry (GC/MS) or Liquid Chromatography mass spectrometry (LC/MS) is the preferred confirmatory method.

【SUMMARY】

"Overdose" means taking too much of a drug, and it is always accidental. The Fentanyl (FEN) Rapid Test Intend for Harm Reduction to end accidental overdoses.

Fentanyl, belongs to powerful narcotics analgesics, and is a μ special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations "Single Convention of narcotic drug in 1961". Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain[1]. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc[2,3], which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose[4].

【PRINCIPLE】

The Fentanyl (FEN) Rapid Test (Powder) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the sample compete against the drug conjugate for binding sites on the antibody.

During testing, the sample migrates upward by capillary action. Fentanyl, if present in the sample below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Fentanyl-protein conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the fentanyl level exceeds the cut-off level, because it will saturate all the binding sites of anti-Fentanyl antibody.

A drug-positive sample will not generate a colored line in the test line region because of drug competition, while a drug-negative sample or a sample containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains mouse monoclonal anti-Fentanyl antibody coupled particles and Fentanyl-protein conjugate. Goat antibody and rabbit antibody are employed in the control line system.

【PRECAUTIONS】

- People who use fentanyl test strips accept all responsibility for any injury, or death that could occur after taking drugs, whether they have been tested or not tested for fentanyl.
- For forensic use only. Do not use after the expiration date.
- For individually packed test, the test should remain in the sealed pouch until use.
- The used test should be discarded according to local regulations.
- If any serious incident that has occurred in relation to this test shall be reported to us and the competent authority of the Member State in which the user and/or the patient is established.
- Please read all the information in this package insert before performing the test.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed. **DO NOT FREEZE**. Do not use beyond the expiration date.

【MATERIALS】

Materials Provided

- Test device
- Package insert

Materials Required but Not Provided

- Timer
- Water

【DIRECTIONS FOR USE】

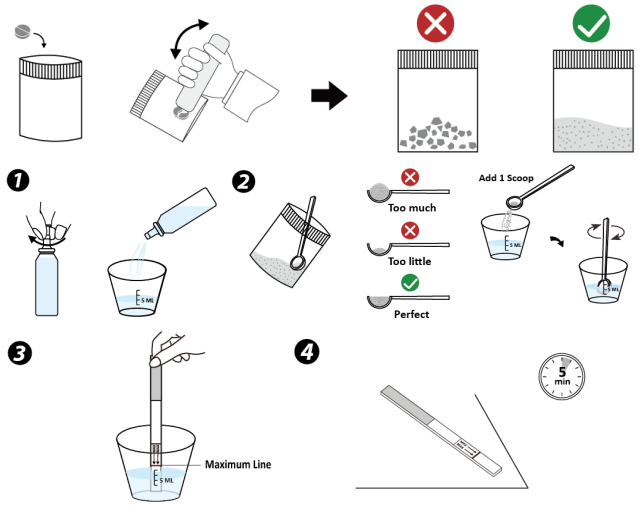
1. Allow the test, water, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.

Preparation of drug specimen

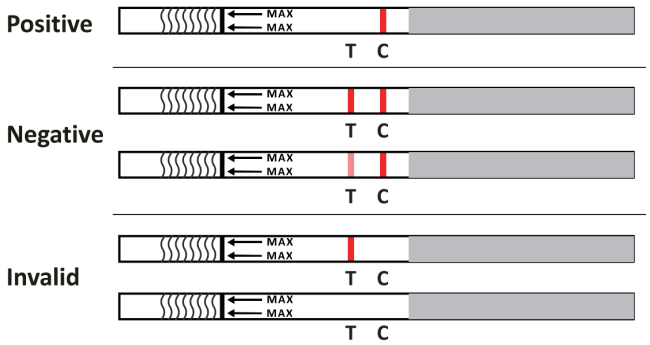
Crush the drug specimen in the sampling bag, shake and mix it.

Strip

1. Add about 5ml water into container.
2. Take a spoonful of the powder with the spoon and transfer into the prepared water, stir with the spoon to mix well.
3. Dip test strip in water for 10-15 seconds and then take out.
4. Remove the strips to a flat surface, read the results after 5 minutes. Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】



(Please refer to the illustration above)

NEGATIVE: * Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Fentanyl concentration is below the detectable cut-off level.

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Fentanyl concentration exceeds the detectable cut-off level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The FEN Rapid Test (Powder) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography mass spectrometry (GC/MS) or Liquid Chromatography mass spectrometry (LC/MS) is the preferred confirmatory method.[5,6]
2. It is possible that technical or procedural errors, as well as other interfering substances in the sample may cause erroneous results.
3. This test strip is NOT intended to determine the purity, composition, or if the substance being examined is safe to use.
4. A positive or negative test result is NOT an indication that the substance being examined is safe to use. Many factors come into play when examining the samples, including but not limited to mixture of multiple substances, solubility and pH of the sample.
5. The test shall not encourage the use, supply, or production of illegal drugs or controlled substances in any way. The test is intended for harm reduction purposes. Follow the advice of your local harm reduction or public health agency.
6. A positive result indicates the presence of drugs only and does not indicate quantity.
7. A negative result does not at any time rule out the presence of drugs, as they may be present below the minimum detection level of the test.
8. Not for testing Cocaine, methamphetamine, ketamine or any other nonopioid substances.
9. This test strip does not distinguish between illicit drugs and certain medications.
10. Do not use after the expiration date. Do not use if test strip pouch has been punctured or damaged. Do not reuse test strip.

【EXPECTED VALUES】

This negative result indicates that the Fentanyl concentration is below the detectable level. Positive result means the concentration of Fentanyl is above the level.

【PERFORMANCE CHARACTERISTICS】

Analytical Sensitivity

Purified water was spiked with Fentanyl at the following concentrations: 0% cutoff, -50% cutoff, +50% cutoff , -25% cutoff, +25% cutoff and 3X cutoff. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

FEN Concentration	n	Strip	
		Negative	Positive
0% cutoff	30	30	0
-50% cutoff	30	30	0
-25% cutoff	30	27	3
Cut-off	30	16	14
+25% cutoff	30	2	28
+50% cutoff	30	0	30
3X cutoff	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected by the FEN Rapid Test (Powder) at 5 minutes.

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
Fentanyl	20(100%)	Norfentanyl	>100,000(< 0.02%)
Carfentanil Oxalate	>10,000(< 0.2%)	α -methyl Acetyl Fentanyl	25(80%)
Norcarfentanil	>10,000(< 0.2%)	Ocfentanil	2000(1%)
Alfentanil HCl	>100,000(< 0.02%)	para-Methylacetyl fentanyl	>10,000(< 0.2%)
Acetyl norfentanyl oxalate	>100,000(< 0.02%)	Acetyl fentanyl	150(13.3%)
4-ANPP	>100,000(< 0.02%)	Acryl fentanyl HCl	100(20%)
Furanyl fentanyl HCl	250(8%)	para-Fluorobutyryl fentanyl(PFBF)	50(40%)
para-Fluorofentanyl	250(80%)	Remifentanil acid	>10,000(< 0.2%)
N-methyl Norfentanyl(HCl)	>100,000(< 0.02%)	Butyryl fentanyl	50(40%)
Sufentanil Citrate	>10,000(< 0.2%)	Valeryl fentanyl HCl	5000(0.4%)
AP-237(hydrochloride)	>100,000(< 0.02%)	AP-238(hydrochloride)	>100,000(< 0.02%)
NPP(N-Pyrrolidino Protonitazene)	>100,000(< 0.02%)	Cyclopropyl fentanyl HCl	25(80%)
Despropionyl para-Fluorofentanyl	>100,000(< 0.02%)	Methoxyacetyl fentanyl HCl	100(20%)
para-Methoxybutyryl fentanyl HCl	>100,000(< 0.02%)	ortho-Methylfentanyl(hydrochloride)	10,000(0.2%)
Benzyl fentanyl	1000(2%)	FIBF(4-Fluoroisobutyryl Fentanyl)(HCl)	> 10,000(< 0.2%)
o-Fluorofentanyl HCl	50(40%)	Despropionyl ortho-Fluorofentanyl	>100,000(< 0.02%)
2'-fluoro ortho-Fluorofentanyl(hydrochloride)	100(20%)	Phenyl fentanyl(HCl)	>10,000(< 0.2%)
α -methy Fentanyl (hydrochloride)	25(80%)	4-methly Fentanyl (hydrochloride)	250(0.8%)
para-Chlorofentanyl (hydrochloride)	87.5(22.9%)	Isobutyryl fentanyl HCl	3000(0.67%)
Levomisole	>10,000,000(< 0.0002%)	Diphenhydramine	>10,000,000(< 0.0002%)
Methamphetamine	>5,000,000(< 0.0004%)	Ketamine	>10,000,000(< 0.0002%)

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
Cocaine	>5,000,000(< 0.0004%)	Methadone	>10,000,000(< 0.0002%)
MDMA	>10,000,000(< 0.0002%)	Procaine	>10,000,000(< 0.0002%)
Lidocaine hydrochloride	>10,000,000(< 0.0002%)	Morphine hydrochloride	>10,000,000(< 0.0002%)
Tramadol	>10,000,000(< 0.0002%)	Xylazine	>10,000,000(< 0.0002%)
Certirizine Hydrocloride	>1,000,000(< 0.002%)	Pheniramine	>10,000,000(< 0.0002%)
Quinine	>5,000,000(< 0.0004%)	Etizolam	>100,000(< 0.02%)
Codeine	>10,000,000(< 0.0002%)	Hydrocodone	>10,000,000(< 0.0002%)
Caffeine	>10,000,000(> 0.0002%)	Diacetylmorphine(Heroin)	>5,000,000(< 0.004%)
Flubromazolam	>100,000(< 0.02%)	MT-45 diHCl	5,000(0.4%)
MDPV	>100,000(< 0.02%)	R(+)-Methcathinone	>100,000(< 0.02%)
Metonitazene HCl	>100,000(< 0.02%)	Clonazolam	>100,000(< 0.02%)
Meperidine	>10,000,000(> 0.0002%)	Brorphine (HCl)	>100,000(< 0.02%
U-47700	>100,000(< 0.02%)	Deschloroetizolam	>100,000(< 0.02%)
Etodesnitazene HCl	>100,000(< 0.02%)	Flubromazepam	>100,000(< 0.02%)
R,R(-)-Pseudoephedrine	>100,000(< 0.02%)	Bromazepam	>100,000(< 0.02%)
N-Piperidinyl Etonitazene (citrate)	>100,000(< 0.02%)	N-desethyl Etonitazene	>100,000(< 0.02%)
Dimethyl sulphone	>10,000,000(< 0.0002%)	Acetaminophen	>10,000,000(< 0.0002%)
AB-FVBINACA	>100,000(< 0.02%)	AB-PINACA	>100,000(< 0.02%)
Amphetamine	>100,000(< 0.02%)	Oxycodone	>100,000(< 0.02%)
Clonazepam	>10,000,000(< 0.0002%)	Oxazepam	>100,000(< 0.1%)
Alprazolam	>250,000(< 0.08%)	Buprenorphine	>100,000(< 0.02%)
N-Benzyl-4-Piperidone	>100,000(< 0.02%)	4-Piperidone(hydrochloride hydrate)	>100,000(< 0.02%)
4-Anilinopiperidine(hydrochloride)	>100,000(< 0.02%)	4-Anilino-1-benzylpiperidine	>100,000(< 0.02%)
2-fluoro Viminol	>100,000(< 0.02%)	Metodesnitazene HCl	>100,000(< 0.02%)
4-Anilino-1-Boc-piperidine	>100,000(< 0.02%)	U-48800	>100,000(< 0.02%)
Metizolam	>100,000(< 0.02%)	Fluorphine	>100,000(< 0.02%)
Menitazene (citrate)	>100,000(< 0.02%)	Iodorphine	>100,000(< 0.02%)
N-Pyrrolidino Etonitazene	>100,000(< 0.02%)	Protonitazene (hydrochloride)	>100,000(< 0.02%)
Chlorphine	>100,000(< 0.02%)	AH-7921	>100,000(< 0.02%)
Metamizole	>100,000(< 0.02%)	Piperidylthiambutene (hydrochloride)	>100,000(< 0.02%)

Precision

A study was conducted at three labs by untrained operators using three different lots of products to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, no Fentanyl, 50% Fentanyl above and below the cut-off and 25% Fentanyl above and below the cut-off was provided to each site. The following results were tabulated:

Biotest FEN Test	FEN Concentration	n per Site	Site A		Site B		Site C	
			-	+	-	+	-	+
Strip	0% cutoff	10	10	0	10	0	10	0
	-50% cutoff	10	10	0	10	0	10	0
	-25% cutoff	10	9	1	9	1	9	1
	+25% cutoff	10	1	9	0	10	1	9
	+50% cutoff	10	0	10	0	10	0	10

Cross-Reactivity

The following compounds show no cross-reactivity when tested with the FEN Rapid Test (Powder) at a concentration of 100 μg/mL.

Non-Cross-Reacting Compounds

Acetone	Dicyclomine	Ketoprofen	Quinacrine
Acetophenetidin	Diflunisal	Labetalol	Quinidine
Aspirin	Digoxin	Lindane	Ranitidine
Albumin	4-Dimethylaminoantipyrine	Loperamide	Riboflavin
Amoxapine	5,5-Diphenylhydantoin	Methoxyphenamine	Sodium chloride
Amoxicillin	Disopyramide	Metoprolol	Sulfamethazine
Ampicillin	Doxylamine	Nalidixic acid	Sulindac
Ascorbic acid	Dopamine	(+)-Naproxen	Temazepam
Aspartame	(1R, 2S) - (-)-Ephedrine	Nimesulide	Tetracycline
Benzoic acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Ethanol (Ethyl alcohol)	Noscapine	Thebaine
(+/-) Brompheniramine	Etodolac	Niacinamide	Theophylline
Benzocaine	Famprofazone	Norephedrine	Thiamine
Buspirone	Fenoprofen	Orphenadrine	Thioridazine
Chloramphenicol	Fluoxetine Hydrochloride	Oxalic acid	Tolbutamide
Chloroquine	Furosemide	Oxolinic acid	Trazodone
(+/-)-Chlorpheniramine	Gentisic acid	Oxymetazoline	Triamterene
S- (+)-Chlorpheniramine	D (+) Glucose	Papaverine	Trifluoperazine
Chlorpromazine	Guaiacol Glyceryl Ether	Pemoline	Trimethoprim
Chlorprothixene	Hemoglobin	Penicillin-G	Trimipramine
Cimetidine	Hydralazine	Perphenazine	Tryptamine
Clomipramine	Hydrochlorothiazide	Phenelzine	Tyramine
Clonidine	Hydroxyzine	Pheniramine	Uric acid
Creatine	Imipramine	Phenothiazine	Verapamil
Cyclobenzaprine	Isoproterenol hydrochloride	β-Phenylethylamine	Zomepirac
Dextromethorphan	Isoxsuprine	Promethazine	Kanamycin
Diclofenac			

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