Identify Health® Multi-Drug Rapid Test Dipcard (Powder) (FEN20/XYL1000) Package Insert

REF DPMDR-DP92 | English

Intend for Harm Reduction Use Only

【INTENDED USE】

The Multi-Drug Rapid Test Dipcard (Powder) is a rapid chromatographic immunoassay for the detection of multiple drugs in suspicious substances at the following cut-off concentrations listed below:

Test	Calibrator	Cut-off (ng/mL)
Fentanyl(FEN)	Fentanyl	20
Xylazine (XYL)	Xylazine	1000

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 only 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 Multi-Drug Rapid Test Intend for Harm Reduction to end accidental overdoses.

The Multi-Drug Rapid Test is a rapid powder screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in powder.

Fentanyl(FEN)

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].

Xylazine (XYL)

Xylazine was created in 1962 and found to be a potent central alpha2 adrenergic blocking agent. The drug causes sedation and anesthesia, respiratory depression, slow heart rate, muscle relaxation and potentiates pain relief. However, in humans, it also causes significant slowing of the heart rate and low blood pressure. Because of this, it was never FDA approved for human use. However, it is a potent veterinary agent, used as an animal "takedown" agent and anesthetic and is known by the trade name Rompun™. In the early 2000s, xylazine became a drug of abuse in Puerto Rico and was added to heroin or included in "speedballs" as an addition to or as a substitute for heroin. Appropriately so, it was called anesthesia de caballo (horse anesthesia) on the street. Since it has many of the same effects as opioids, it could be substituted for the opioid or the two together have additive effects. Since then, the drug has shown up intermittently with the National Forensic Lab Information System and between 2006-2018; the Philadelphia Medical Examiners Office recorded increasing incidence of cases.[5, 6]

【PRINCIPLE】

The Multi-Drug Rapid Test Dipcard (Powder) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the sample compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the sample migrates upward by capillary action. A drug, if present in the sample below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the sample will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive sample will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative sample will generate a line in the test line region because of the absence of drug competition.

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】

Each test line contains anti-drug antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

【PRECAUTIONS】

- People who use Multi-Drug test accept all responsibility for any injury, or death that could occur after taking drugs, whether they have been tested or not tested for fentanyl or Xylazine.
- 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 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test cassettes must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SAMPLE COLLECTION AND PREPARATION】

The specimen should be collected using the collector provided with the kit. Follow the detailed Directions for Use below. No other collection cassettes should be used with this assay.

【MATERIALS】

Materials Provided

- Test Dipcard
- Package insert
- Scoop
- Container for Water
- Water

Materials Required but Not Provided

- Timer

【DIRECTIONS FOR USE】

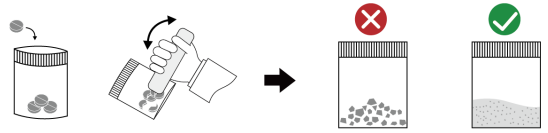
1. Allow the test, water, and/or controls to equilibrate to room temperature (15-30□C) prior to testing.
2. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.

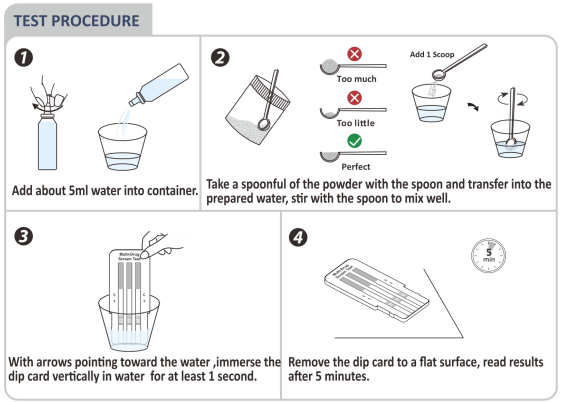
Preparation of drug specimen

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

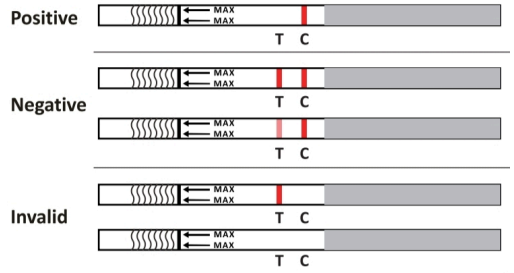
Dipcard

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. Immerse the dip card in the water for a minimum of 1 second. If the volume of the water is less than the sampling window, immerse the dip card in the specimen for at least 20 seconds.
4. Replace the cap and place the card on a flat surface, read the results after 5 minutes. Do not interpret the result after 10 minutes.





【INTERPRETATION OF RESULTS】



(Please refer to the previous illustration)

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

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

POSITIVE: One colored line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable 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 using a new test. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

【QUALITY CONTROL】

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

【LIMITATIONS】

1. The Multi-Drug Rapid Test Dipcard (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), gas chromatography/tandem mass spectrometry (GC/MS/MS), liquid chromatography/mass spectrometry (LC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods.
2. This test dipcard is NOT intended to determine the purity, composition, or if the substance being examined is safe to use.
3. 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.
4. 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.
5. A positive result indicates the presence of drugs only and does not indicate quantity.
6. 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.
7. Not for testing Cocaine, methamphetamine, ketamine or any other nonopioid substances.
8. This test dipcard does not distinguish between illicit drugs and certain medications.
9. Do not use after the expiration date. Do not use if test dipcard pouch has been punctured or damaged. Do not reuse test dipcard.
10. It is possible that technical or procedural errors, as well as other interfering substances in the sample may cause erroneous results

【PERFORMANCE CHARACTERISTICS】

Analytical Sensitivity

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

Drug conc. (Cut-off range)	n	FEN20		XYL1000	
		-	+	-	+
0% Cut-off	30	30	0	30	0
-50% Cut-off	30	30	0	30	0
-25% Cut-off	30	27	3	27	3
Cut-off	30	16	14	15	15
+25% Cut-off	30	2	28	7	23
+50% Cut-off	30	0	30	0	30
+300% Cut-off	30	0	30	0	30

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 drugs, 50% drugs above and below the cut-off and 25% drugs above and below the cut-off was provided to each site. The following results were tabulated:

Fentanyl (FEN20)

FEN Concentration	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
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

Xylazine(XYL1000)

XYL Concentration	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0% cutoff	10	10	0	10	0	10	0
-50% cutoff	10	10	0	10	0	10	0
-25% cutoff	10	9	1	8	2	9	1
+25% cutoff	10	1	9	1	9	1	9
+50% cutoff	10	0	10	0	10	0	10

Analytical Specificity

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

Fentanyl (FEN20)			
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%)
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%)

Xylazine(XYL1000)			
Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
Xylazine	1000 (100%)	Clonidine	100,000（1.0%）
Benztropine	100,000（1.0%）		
Levomisole	>10,000,000(<0.0002%)	Diphenhydramine	>10,000,000(<0.0002%)
Methamphetamine	>5,000,000(<0.0004%)	Ketamine	>10,000,000(<0.0002%)
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%)

Cross-Reactivity

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

Non-Cross-Reacting Compounds

4-Acetaminophenol	Acetophenetidin	Meperidine	Prednisone
Acetone	Disopyramide	d-Methamphetamine	Promazine
N-Acetylprocainamide	Doxylamine	Methadone	Promethazine
Acetylsalicylic acid	EMDP	Methoxyphenamine	l-Propoxyphene
Albumin	Ephedrine	Metoprolol	d,l-Propranolol
Amitriptyline	(±)-Epinephrine	Morphine-3-β-D-glucuronide	d-Pseudoephedrine
Amoxapine	Erythromycin	Morphine sulfate	Quinidine
Ampicillin	Estrone-3-sulfate	Nalidixic acid	Diflunisal
Ascorbic acid	Ethanol (Ethyl alcohol)	Naloxone	Ranitidine
Aminopyrine	Ethyl-p-aminobenzoate	Naltrexone	Riboflavin
Apomorphine	Etodolac	α-Naphthaleneacetic acid	Salicylic acid
Aspartame	Fenoprofen	Naproxen	Serotonin
Atropine	Furosemide	Niacinamide	(5-Hydroxytryptamine)
Benzilic acid	Gentisic acid	Nifedipine	Sodium chloride
Benzoic acid	d-Glucose	Nimesulide	Sulfamethazine
Bilirubin	Guaiacolglyceryl ether	Norcodeine	Sulindac
Caffeine	Hemoglobin	Normorphine	Sustiva (Efavirenz)
Cimetidine	Hydralazine	Norethindrone	Tetracycline
Chloral hydrate	Hydrochlorothiazide	d-Norpropoxyphene	Tetrahydrozoline
Chloramphenicol	Hydrocodone	Buspirone	Theophylline
Chlordiazepoxide	Hydrocortisone	d,l-Octopamine	Thiamine
Chloroquine	o-Hydroxyhippuric acid	Orphenadrine	Thioridazine
(+)-Chlorpheniramine	p-Hydroxymethamphetamine	Oxalic acid	l-Thyroxine
(±)-Chlorpheniramine	Hydromorphone	Oxazepam	Tolbutamide
Chlorprothixene	3-Hydroxytyramine	Oxolinic acid	Phenylcyclopropylamine
Cholesterol	(Dopamine)	Oxycodone	Trazodone
Clomipramine	Hydroxyzine	Oxymetazoline	Triamterene
Codeine	Ibuprofen	Papaverine	Trimethoprim
Cortisone	Imipramine	Pemoline	Trimipramine
(-)-Cotinine	(-)-Isoproterenol	Penicillin-G	d,l-Tryptophan
Creatinine	Isoxsuprine	l-Phenylephrine	Uric acid
Cyclobenzaprine	Kanamycin	Phenelzine	Verapamil
Deoxycorticosterone	Ketoprofen	Pheniramine	Digoxin
R (-)Deprenyl	Labetalol	Phenobarbital	Lindane
Dextromethorphan	5,5-Diphenylhydantoin	Diazepam	Loperamide
Diclofenac	(Hexachlorocyclohexane)	Dicyclomine	
4-Dimethylaminoantipyrine	Maprotiline	Prednisolone	

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