Fentanyl Rapid Test Dip Card

English

This package insert is for testing of Fentanyl.
For professional and in vitro diagnostic use only.

[INTENDED USE]

The Fentanyl Rapid Test Dip Card is a lateral flow chromatographic immunoassay for the qualitative detection of Fentanyl in urine at the cut-off concentrations of 200ng/mL.
This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

[SUMMARY]

Fentanyl is a synthetic opioid. It has the brand names of Sublimaze, Actiq, Durogestic, Fentora and others. The Fentanyl drug is approximately 100 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. The Fentanyl drug is a potent narcotic analgesic with rapid onset and short duration of action. Historically, the fentanyl drug has been used to treat chronic breakthrough pain and is commonly used pre-procedures. Illicit use of pharmaceutical Fentanyl drugs first appeared in the mid-1970s. Because the effects of the Fentanyl drug last for only a very short time, it is even more addictive than heroin. Regular users may become addicted very quickly. The Fentanyl drug is much more potent than heroin, and tends to produce significantly worse respiratory depression, making it somewhat more dangerous than heroin to users. Overdose of the Fentanyl drug has caused death. In the United States, the Fentanyl drug is classified as a Schedule II controlled substance.
The Fentanyl Rapid Test Dip Card yields a positive result when the concentration of Fentanyl in urine exceeds 200ng/mL.

[PRINCIPLE]

The Fentanyl Rapid Test Dip Card is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.
During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen 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 cassette. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.
A drug-positive urine specimen will not generate a colored line in the specific test line region of the cassette because of drug competition, while a drug-negative urine specimen 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.

[WARNINGS AND PRECAUTIONS]

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test dip card emain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

Each test contains Fentanyl anti-coupled particles and corresponding Fentanyl protein conjugates. A goat antibody is employed in each control line. The quantity of tests was printed on the labeling.

Materials Provided

• Test Dip Card •Package insert

Materials Required But Not Provided

•Specimen collection container •Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30°C or 40-86°F). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

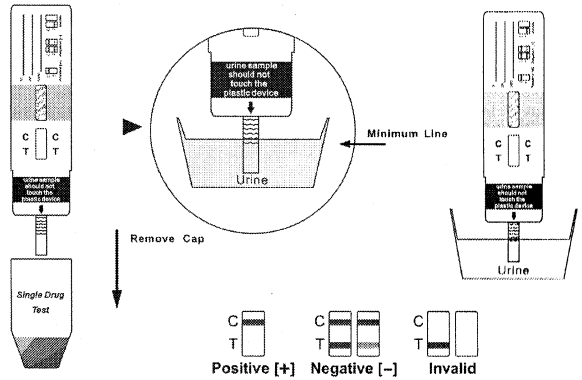
[SPECIMEN]

- The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.
- Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

[TEST PROCEDURE]

Allow the test and urine samples to equilibrate to temperature (15-30°C or 59-86°F) prior to testing.

1. Remove the test dip card from the sealed pouch and use it as soon as possible.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test dip card vertically in the urine specimen for at least 10 to 15 seconds. Immerse the dipstick to at least the level of the wavy lines, but not above the arrow on the test dip card.
4. Replace the cap and place the test dip card on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. Interpret the test results at 3-5 minutes. Do not read results after 10 minutes.



(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

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 the colored line in the test line region (T) may 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 cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

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

[LIMITATIONS]

- The Fentanyl Rapid Test Dip Card provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography and mass spectrometry (GC/MS) is the preferred confirmatory method.
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A Positive result does not indicate level or intoxication, administration route or concentration in urine.
- A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.

[PERFORMANCE CHARACTERISTICS]

Accuracy

A side-by-side comparison was conducted using the The Fentanyl Rapid Test and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributed to the Totals of GC/MS
FYL	Fentanyl

The following results are tabulated from these clinical studies:

%Agreement with Commercial Kit			%Agreement with GC/MS	
	FYL			FYL
Positive Agreement	94%		Positive Agreement	97%
Negative Agreement	100%		Negative Agreement	100%
Total Results	97%		Total Results	98%

Forty (40) clinical samples were run using the Fentanyl Rapid Test by an untrained operator at a Professional Point of Care site. Based on GC/MS data, the operator obtained statistically similar Positive Agreement, Negative Agreement and Overall Agreement rates as trained Laboratory personnel.

Precision

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical cassette of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Fentanyl conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
100	15	15	0	15	0	15	0
150	15	14	1	13	2	12	3
250	15	3	12	0	15	1	14
300	15	0	15	0	15	0	15

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below:

Drug concentration Cut-off Range	n	FYL	
		-	+
0% Cut-off	30	30	0
-50% Cut-off	30	30	0
-25% Cut-off	30	30	0
Cut-off	30	13	17
25% Cut-off	30	0	30
50% Cut-off	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the Fentanyl Rapid Test at 3-5 minutes.

Fentanyl (FYL)	Concentration(ng/mL)
Fentanyl	200
Norfentanyl	375

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Fentanyl Rapid Test was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Fentanyl Rapid Test. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Fentanyl positive urine. The following compounds show no cross-reactivity when tested with the Fentanyl Rapid Test at a concentration of 100µg/mL.

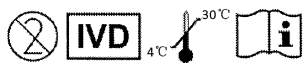
Non Cross-Reacting Compounds

Acetaminophen	Acetophenetidin
N-Acetylprocainamide	Acetylsalicylic acid
Aminopyrine	Amoxicillin
Ampicillin	L-Ascorbic acid
Apomorphine	Aspartame
Atropine	Benzilic acid
Benzoic acid	Benzphetamine*
Bilirubin	D/L-Brompheniramine
Caffeine	Cannabidol
Chloralhydrate	Chloramphenicol
Chlorothiazide	D/L-Chloropheniramine
Chlorpromazine	Chloroquine
Cholesterol	Clonidine
Cortisone	L-Cotinine
Creatinine	Deoxycorticosterone
Dextromethorphan	Diclofenac
Diflunisal	Digoxin
Diphenhydramine	Ecgonine methyl ester
L -Ψ-Ephedrine	β-Estradiol
Estrone-3-sulfate	Ethyl-p-aminobenzoate
[1R,2S] (-) Ephedrine	L(−)-Epinephrine
Erythromycin	Fenoprofen
Furosemide	Gentisic acid
Hemoglobin	Hydralazine
Hydrochlorothiazide	Hydrocortisone
O-Hydorxyhippuric acid	p-Hydroxyamphetamine
p-Hydroxytyramine	Ibuprofen
Iproniazid	D/L-Isoproterenol
Isoxsuprine	Ketamine
Ketoprofen	Labetalol
Loperamide	Meperidine
Meprobamate	Methoxyphenamine
Methylphenidate	Nalidixic acid
Naloxone	Naltrexone
Naproxen	Niacinamide
Nifedipine	Norethindrone
D-Norpropoxyphene	Noscapine
D/L-Octopamine	Oxalic acid
Oxolinic acid	Oxymetazoline
Papaverine	Penicillin-G
Pentazocine hydrochloride	Perphenazine
Phenelzine	Trans-2-phenylcyclo-propylamine hydrochloride
L-Phenylephrine	β-Phenylethylamine
Phenylpropanolamine	Prednisolone
Prednisone	D/L-Propranolol
D-Propoxyphene	D-Pseudoephedrine
Quinacrine	Quinine
Quindine	Ranitidine
Salicylic acid	Serotonin
Sulfamethazine	Sulindac
Tetracycline	Tetrahydrocortisone 3-acetate
Tetrahydrozoline	Tetrahydrocortisone 3 (β-D-glucuronide)
Thiamine	Thioridazine
D/L-Tyrosine	Tolbutamide
Triamterene	Trifluoperazine
Trimethoprim	Tryptamine
D/L-Tryptophan	Tyramine
Uric acid	Verapamil
Zomepirac	

*Parent compound only; metabolizes amphetamine and methamphetamine in urine.

[Bibliography]

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Davis, CA. 2002; 129.
2. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.
3. A Handbook of Drug and Alcohol Abuse, Gail Winger, Third Edition, Oxford Press, 1992, page 146.
4. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
5. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.



Index of Symbol

Do not reuse	For in vitro diagnostic use only
Store between 4-30°C	Consult instructions for use
Caution	Lot number
Use by	Contains sufficient for <n> tests
Keep away from sunlight	Keep dry
Manufacturer	Do not use if package is damaged

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