# For Forensic Use Only
# One Step Fentanyl Test Dipcard(FEN) Package Insert

*A rapid, one step test for the qualitative detection of Fentanyl in human urine. For Forensic use only.*

## INTENDED USE

The One Step Fentanyl Test Dipcard is a lateral flow chromatographic immunoassay for the detection of Fentanyl in human urine.

| Test | Calibrator | Cut-off |
|---|---|---|
| Fentanyl (FEN) | Fentanyl | 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, 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 pain1. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc2,3, 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

## PRINCIPLE

The One Step Fentanyl Test Dipcard is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Norfentanyl, if present in the urine specimen below 20ng/mL, will not saturate the binding sites of the antibody coated particles in the test Dipcard. The antibody coated particles will then be captured by immobilized Fentanyl 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 Norfentanyl level exceeds 20ng/mL because it will saturate all the binding sites of anti-Fentanyl antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen 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 Dipcard contains mouse monoclonal anti-Fentanyl antibody-coupled particles and Fentanyl-protein conjugate. A goat antibody is employed in the control line system.

## PRECAUTIONS

For *Forensic use* only. Do not use after the expiration date.

The test Dipcard should remain 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 Dipcard should be discarded according to federal, state and local regulations.

## STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test Dipcard is stable through the expiration date printed on the sealed pouch. The test Dipcard must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

## SPECIMEN COLLECTION AND PREPARATION

### Urine Assay

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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

### Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

## MATERIALS

### Materials Provided

Test strips
Package insert

### Materials Required But Not Provided

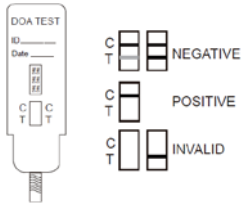
Specimen collection container
Timer

## DIRECTIONS FOR USE

**Allow the test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.**

1) Remove the test device from the foil pouch.
2) Remove the cap from the test device. Label the device with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic device.
4) Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface.
5) Read results at 5 minutes.

**DO NOT INTERPRET RESULT AFTER 5 MINUTES.**




## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE:* Two lines appear**. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Fentanyl concentration is below the detectable level (200ng/mL).

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

**POSITIVE: One red line appears in the control region (C).** No line appears in the test region (T). This positive result indicates that the Fentanyl concentration exceeds the detectable level (200ng/mL).

**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 Dipcard. 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 red 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 testing practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS

1. The One Step Fentanyl Test Dipcard 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) is the preferred confirmatory method.1,2
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. 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.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. 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.
6. Test does not distinguish between drugs of abuse and certain medications.

## PERFORMANCE CHARACTERISTICS

### Reproducibility

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

| Fentanyl conc.(ng/mL) | Total number of Determinations | Result | Precision |
|---|---|---|---|
| No drug present | 40 | 40 negative | >99% |
| 100 | 40 | 40 negative | >99% |
| 300 | 40 | 40 positive | >99% |
| 400 | 40 | 40 positive | >99% |

### Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

| FEN Concentration (ng/mL) | Percent of Cut-off | n | Visual Result | |
|---|---|---|---|---|
| | | | Negative | Positive |
| 0 | 0 | 30 | 30 | 0 |
| 100 | -50% | 30 | 30 | 0 |
| 150 | -25% | 30 | 29 | 1 |
| 200 | Cut-off | 30 | 16 | 14 |
| 250 | +25% | 30 | 3 | 27 |
| 300 | +50% | 30 | 0 | 30 |

## Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by The One Step Fentanyl Test Dipcard (Urine) at a read time of 5 minutes.

| Drug | Concentration (ng/ml) |
|---|---|
| Norfentanyl | 40 |
| Fentanyl | 200 |
| Buspirone | 30,000 |
| Sufentanyl | 50,000 |
| Fenfluramine | 50,000 |

## Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.030) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Fentanyl Test Dipcard was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

## Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with The One Step Fentanyl Test Dipcard. The results demonstrate that varying ranges of pH do 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 One Step Fentanyl Test Dipcard (Urine) at a concentration of 100 μg/mL.

## Non Cross Reacting Compounds

| | | | |
|---|---|---|---|
| Acetophenetidin | l-Cotinine | Cortisone | d-Pseudoephedrine |
| N-Acetylprocainamide | Creatinine | Ketoprofen | Quinidine |
| Acetylsalicylic acid | Deoxycorticosterone | Labetalol | Quinine |
| Aminopyrine | Dextromethorphan | Loperamide | Salicylic acid |
| Amoxicillin | Diclofenac | Meprobamate | Serotonin |
| Ampicillin | Diflunisal | Methoxyphenamine | Sulfamethazine |
| l-Ascorbic acid | Digoxin | Methylphenidate | Sulindac |
| Apomorphine | Diphenhydramine | Nalidixic acid | Tetracycline |
| Aspartame | Ethyl-p-aminobenzoate | Naproxen | Tetrahydrocortisone, |
| Atropine | β-Estradiol | Niacinamide | 3-Acetate |
| Benzilic acid | Estrone-3-sulfate | Nifedipine | Tetrahydrocortisone |
| Benzoic acid | Erythromycin | Norethindrone | Tetrahydrozoline |
| Bilirubin | Fenoprofen | Noscapine | Thiamine |
| d,l-Brompheniramine | Furosemide | d,l-Octopamine | Thioridazine |
| Caffeine | Gentisic acid | Oxalic acid | d,l-Tyrosine |
| Cannabidiol | Hemoglobin | Oxolinic acid | Tolbutamide |
| Chloralhydrate | Hydralazine | Oxymetazoline | Triamterene |
| Chloramphenicol | Hydrochlorothiazide | Papaverine | Trifluoperazine |
| Chlorothiazide | Hydrocortisone | Penicillin-G | Trimethoprim |
| d,l-Chlorpheniramine | o-Hydroxyhippuric acid | Perphenazine | d,l-Tryptophan |
| Chlorpromazine | 3-Hydroxytyramine | Phenelzine | Uric acid |
| Cholesterol | d,l-Isoproterenol | Prednisone | Verapamil |
| Clonidine | Isoxsuprine | d,l-Propanolol | Zomepirac |

## BIBLIOGRAPHY


*1. Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.*

*2. Ambre J. J. Anal. Toxicol. 1985; 9:241.*

*3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.*

*4. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.*

*5. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.*

*6. Robert DeCresce. Drug Testing in the workplace, 114.*

*7. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA 1982; 487.*