One Step Fentanyl Test Dip Card (Urine) Package Insert

For forensic use only

A rapid, one step test for the qualitative detection of Fentanyl and Norfentanyl in human urine.

INTENDED USE

The One Step Fentanyl Test Dip Card (Urine) is a lateral flow chromatographic immunoassay for the detection of Fentanyl in human urine.

Test	Calibrator	Cut-off
Fentanyl (FEN)	Norfentanyl	10 ng/mL

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) and Liquid chromatography/tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used. This test does not distinguish between drugs of abuse and certain medications.

SUMMARY

Fentanyl belongs to powerful narcotics analgesics and is a special opiates receptor stimulant. Fentanyl is one of the varieties that has been listed in management of United Nations "Single Convention of narcotic drug in 1961". Among the opiates agents that are under international control, fentanyl is one of the most commonly opioids used to treat 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 can lead toaddiction after taking fentanyl over a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl have the possibility of a higher infection rates of HIV, more dangerous injection behavior and lifelong medication overdose.

PRINCIPLE

The One Step Fentanyl Test Dip Card (Urine) 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 10 ng/mL, will not saturate the binding sites of the antibody coated particles in the Test Dip Card. The antibody coated particles will then be captured by immobilized Norfentanyl 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 10 ng/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 Dip Card contains mouse monoclonal anti-Fentanyl antibody-coupled particles and Fentanyl-protein conjugate. Goat antibody is employed in the control line.

PRECAUTIONS

- *For forensic use only.*
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged, Do not reuse the test.
- The Test Dip Card should remain in the sealed pouch until use.
- Avoid cross-contamination of specimen by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Humidity and temperature can adversely affect results.
- The used test Dip Card 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/36-86°F) until the expiry date printed on the pouch.
- The test dip card must remain in the sealed pouch until use.
- The kit should be kept out of direct sunlight.
- **DO NOT FREEZE.**
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents

MATERIALS

Materials Provided

- Individually packaged single dip card
- Package Insert

Materials Required But Not Provided

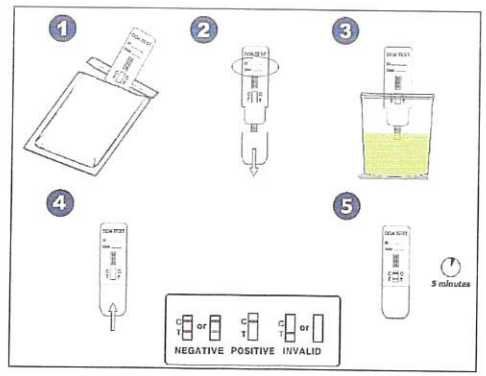
- Specimen Collection Container/Cup
- Timer

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 and use as soon as possible. If needed, label the device with patient or control identifications.
2. Remove the cap from the test device.
3. With the arrows pointing toward the urine specimen, immerse the sample tip vertically in the urine specimen for at least 10 - 15 seconds.
4. Replace the cap back on the device and place the device on a flat surface.
5. Read results at 5 minutes.

DO NOT INTERPRET RESULTS AFTER 10 MINUTES.



INTERPRETATION OF RESULTS

(Please refer to the illustration within "Directions for Use")

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

NOTE: The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. This is a qualitative test only and cannot determine the concentration of analytes in the specimen.

POSITIVE: One color 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 dip card. If the problem persists, discontinue using the lot immediately and contact your 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 Dip Card (Urine) provides only a qualitative, preliminary analytical result.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) and Liquid Chromatography / Mass Spectrometry / Tandem Mass Spectrometry (LC-MS/MS) have been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
4. 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.
5. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
6. 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.
7. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

80 clinical urine samples were analyzed by GC-MS and by the Healgen® One Step Fentanyl Test Dip Card. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cut-off low negative, near cut-off negative, near cut-off positive, and high positive. Results were as follows:

Healgen Test Operator		Drug-free	Low Negative (Less than half the cut-off concentration)	Near Cut-off Negative (Between 50% below the cut-off and the cut-off concentration)	Near Cut-off Positive (Between the cut-off and 50% above the cut-off concentration)	High Positive (greater than 50% above the cut-off concentration)
A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
B	Positive	0	0	0	15	24
	Negative	10	15	15	1	0
C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 95%

% agreement among negatives is 100%

Analytical Sensitivity

A drug-free urine pool was spiked with Norfentanyl at the following concentrations: 0 ng/mL, -50% cut-off, -25% cut-off, cut-off, +25% cut-off and +50% cut-off. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data is summarized below.

Norfentanyl Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
5	-50%	30	30	0
7.5	-25%	30	26	4
10	Cut-off	30	15	15
12.5	+25%	30	3	27
15	+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 Dip Card (Urine) at a read time of 5 minutes.

Drug	Concentration (ng/mL)
Norfentanyl	10
Fentanyl	150

Reproducibility

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

Norfentanyl conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negatives	>99%
5	40	40 negatives	>99%
15	40	40 positives	>99%
20	40	40 positives	>99%

Effect of Urinary Specific Gravity

Twelve (12) 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 Dip Card (Urine) 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 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 Dip Card (Urine). The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Interference

The following compounds were evaluated for potential positive or negative interference with the Fentanyl dip card. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cut-off concentrations and tested with the Fentanyl Dip Card. An unaltered sample was used as control. No interference was found for the following compounds at a concentration of 100 µg/mL.

Non-Interfering Compounds

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

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Revision Date : 2020-08-08
Version : 1.0
B21950-01