Fentanyl Urine Test Cassette

-CLIA Waived

User Instruction

REF DFY-A102C | English

A rapid test for the qualitative detection of FYL (Fentanyl) in human urine.
Medical and other professional in vitro diagnostic use labeling.

【INTENDED USE】

Alltest Fentanyl Urine Test Cassette is an immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. For *in vitro* diagnostic use only.

【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 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]

The Fentanyl Urine Test Cassette is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Fentanyl in urine. The Fentanyl Urine Test Cassette yields a positive result when Fentanyl in urine exceeds 1 ng/mL.

【PRINCIPLE】

The Fentanyl Urine Test Cassette is an 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. Fentanyl, if present in the urine specimen below 1 ng/mL, will not saturate the binding sites of antibody-coated particles in the test device. The antibody-coated particles will then be captured by immobilized FYL 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 FYL level exceeds 1 ng/mL because it will saturate all the binding sites of anti-FYL 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 Cassette contains mouse monoclonal anti-FYL antibody-coupled particles and FYL-protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test 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 should be discarded according to local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 35.6-86°F (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The Test Cups 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.

Specimen Storage

Urine specimens may be stored at 35.6-46.4°F (2-8°C) for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -4°F (-20°C). Frozen specimens should be thawed and mixed before testing.

【MATERIALS】

Materials Provided

- Test cassettes and droppers (sealed in foil pouch with a desiccant)
- User Instruction

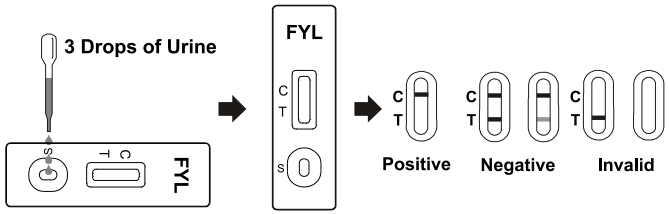
Materials Required But Not Provided

- Specimen Collection Containers
- Timer

【DIRECTIONS FOR USE】

Allow the test, urine specimen and/or controls to reach room temperature 59-86ºF (15-30ºC) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 120 μL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.
4. If preliminary positive results are observed, please send the urine sample to the laboratory for confirmation.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). A negative result indicates that the Fentanyl concentration is below the detectable level (1 ng/mL).

***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). A positive result indicates that the Fentanyl concentration exceeds the detectable level (1 ng/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. 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 line 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. Our recommended quality control material available to users is Fentanyl Cerilliant F-013 at 1.0 mg/mL, which is same QC material used for our performance studies. User should follow federal, state and local guidelines for testing quality control materials.

Laboratories should comply with all federal state, and local laws, as well as all guidelines and regulations.

【LIMITATIONS】

1. The Fentanyl Urine Test Cassette provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. GC/MS or LC/MS is the preferred confirmatory method.
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. A confirmed positive result indicates presence of the drug but does not indicate level of intoxication, administration route or concentration in urine.
4. 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.
5. Test does not distinguish between drugs of abuse and certain medications.

【PERFORMANCE CHARACTERISTICS】

Accuracy

About 80 clinical urine specimens fentanyl with known LC/MS values and tested by Fentanyl Urine Test Cassette. Each test was performed by three operators. Results were as follows:

Site	Alltest Device Result	Concentration by LC/MS (ng/mL)			
		≤ -50% Cut-off	-50%Cut-off to the cut-off	Cut-off to +50% cut-off	≥ +50% Cut-off
Site1	Positive	0	3	22	16
	Negative	25	12	2	0
	Total Results	100%	80.0%	91.7%	100%
Site2	Positive	0	3	22	16
	Negative	25	12	2	0
	Total Results	100%	80.0%	91.7%	100%
Site3	Positive	0	2	21	16
	Negative	25	13	3	0
	Total Results	100%	86.7%	87.5%	100%

Analytical Specificity

The following table list compounds that are positively detected in urine by Fentanyl Urine Test Cassette.

Fentanyl (Cut-off=1 ng/mL)	Concentration (ng/mL)	Cross-Reactivity (%)
Acetyl fentanyl	1	100%
Acrylfentanyl	1	100%
ω-1-Hydroxyfentanyl	20,000	0.005%
Isobutyryl fentanyl	1	100%
Ocfentanil	2.5	40%
Butyryl fentanyl	2.5	40%
Furanyl fentanyl	5	20%
Valeryl fentanyl	10	10%
(±) β-hydroxythiofentanyl	2	50%
4-Fluoro-isobutyrylfentanyl	50	2%
Para-fluorobutyryl fentanyl	4	25%
Para-fluoro fentanyl	3	33.3%
(±)-3-cis-methyl fentanyl	50	2%
Carfentanil	2	50%
Sufentanil	7.5	13.3%
Alfentanil	5,000	0.02%
Despropionyl fentanyl (4-ANPP)	2,500	0.04%
Trazodone	1,000	0.1%
Remifentanil	>100μg/mL	< 0.001%
Norfentanyl	>100μg/mL	< 0.001%
Acetyl norfentanyl	>100μg/mL	< 0.001%
Norcarfentanil	>100μg/mL	< 0.001%

The following opioids compounds were tested at a concentration of 100 μg/ml. Negative results were obtained for all these compounds. There is no cross-reactivity for these compounds using the AllTest Fentanyl Urine Test Cassette.

6-Acetyl morphine	Ketamine	Noroxycodone
Amphetamine	Levorphanol	Oxycodone
Buprenorphine	Meperidine	Oxymorphone
Buprenorphineglucuronide	Methadone	Pentazocine (Talwin)
Codeine	Morphine	Pipamperone
Dextromethorphan	Morphine-3-glucuronide	Risperidone
Dihydrocodeine	Naloxone	Tapentadol
EDDP	Naltrexone	Thioridazine
EMDP	Norbuprenorphine	Tilidine
Fluoxetine	Norcodeine	Tramadol
Heroin	Norketamine	Tramadol-O-Desmethyl

Hydrocodone	Normeperidine	Tramadol-N-Desmethyl
Hydromorphone	Normorphine	

Precision

This study is performed by three POC personnel who don't know the sample number system participate in the study, at 3 POC site. Three lots were run in consecutive business days at each concentration for each lot per day. The results as follows:

Concentration	n	Lot 1		Lot 2		Lot 3	
		+	-	+	-	+	-
0 ng/mL	60	0	60	0	60	0	60
0.25 ng/mL	60	0	60	0	60	0	60
0.5 ng/mL	60	0	60	0	60	0	60
0.75 ng/mL	60	2	58	1	59	0	60
1 ng/mL	60	35	25	28	32	26	34
1.25 ng/mL	60	60	0	60	0	60	0
1.5 ng/mL	60	60	0	60	0	60	0
1.75 ng/mL	60	60	0	60	0	60	0
2 ng/mL	60	60	0	60	0	60	0

Effect of Urinary Specific Gravity

Total 12 urine samples of specific gravities (SG) ranging from 1.000-1.035 were collected. Values of SG levels were determined by a refractometer. Target drugs were spiked to these urine samples at +50% cut-off and -50% cut-off concentrations. 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 a pH range of 4 to 9 in 1 pH unit increments and spiked with Fentanyl to 0.5 ng/mL and 1.5 ng/mL. The spiked, pH-adjusted urine was tested with the Fentanyl Urine Test Cassette in duplicate. The results demonstrated that varying ranges of pH do not interfere with the performance of the test.

Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drug fentanyl urine with concentrations at 50% below and 50% above cut-off levels. There urine samples were tested using three batches of each device. Compounds that showed no interference at a concentration of 100 μg/mL or specified concentrations are summarized in the following tables.

Non Interference Compounds

Acetaminophen	Creatinine	Ketamine	Perphenazine
Acetone (1000mg/dL)	Cyclobenzaprine	Ketoprofen	Phencyclidine
Acetophenetidin	Deoxycorticosterone	Labetalol	Phenelzine
Acetylsalicylic acid	Desipramine	Lidocaine	Phenobarbital
Albumin (100mg/dL)	Dextromethorphan	Loperamide	Prednisone
Albuterol	Diclofenac	Maprotiline	Propoxyphene (50μg/ml)
Aminopyrine	Diflunisal	Meperidine(50μg/ml)	Propranolol
Amitriptyline	Digoxin	Meprobamate	Pseudoephedrine
Amobarbital	Diphenhydramine	Methapyrilene	Quinine
Amoxicillin	DL-Tryptophan	Methaqualone	Ranitidine
Ampicillin	DL-Tyrosine	Methoxyphenamine	Riboflavin (10mg/dL)
Apomorphine	Doxepin	Metronidazole (300μg/ml)	Salicylic acid
Ascorbic acid	Ecgonine methyl ester	N-Acetylprocainamide	Secobarbital
Aspartame	Ephedrine	NaCl (4000mg/dL)	Serotonin (5-Hydroxytyramine)
Atropine	Erythromycin	Nalidixic acid	Sulfamethazine
Benzilic acid	Ethanol (1%)	Naloxone	Sulindac
Benzoic acid	Fenoprofen	Naltrexone	Tetrahydrocortisone 3-(β-Dglucuronide)
Benzoylecgonine	Fluphenazine	Naproxen	Tetrahydrocortisone 3-acetate
Bilirubin	Furosemide	Niacinamide	Tetrahydrozoline
Boric Acid (1%)	Galactose (10mg/dL)	Nicotine	Thiamine
Bupropion	Gamma Globulin (500mg/dL)	Nifedipine	Thioridazine
Caffeine	Gentisic acid	Norethindrone	Triamterene
Carbamazepine	Glucose (3000mg/dL)	Nortriptyline	Trifluoperazine
Chloral hydrate	Hemoglobin	Noscapine	Trimethoprim
Chloramphenicol	Hydralazine	O-Hydroxyhippuric acid	Tyramine
Chlorothiazide	Hydrochlorothiazide	Octopamine	Urea (2000mg/dL)
Chlorpromazine	Hydrocortisone	Oxalic acid (100 mg/dL)	Uric acid
Cholesterol	Hydroxytyramine	Oxazepam	Valproic acid (250μg/ml)
Clomipramine	Ibuprofen	Oxolinic acid	Venlafaxine
Clonidine	Imipramine	Oxymetazoline	Verapamil
Cortisone	Isoproterenol	Papaverine	Zomepirac
Cotinine	Isoxsuprine(10μg/ml)	Penicillin G	β-Estradiol

【BIBLIOGRAPHY】

1. International Narcotics Control Board. Report of the International Narcotics Control Board for 2009[R].New York：UN，2010
2. Lane JC, Tennison MB, Lawless ST, et al. Movement disorder after withdrawal of fentanyl infusion. J Pediatr, 1991, 119（4）：649-651
3. Dominguez KD, Lomako DM，Katz RW，et al. Opioid withdraw in critically ill neonates.Ann Pharmacotherm，2003，37（4）：473-477
4. European Monitoring Centre for Drugs and Drug Addiction.Annual Report 2009[R].Lisbon：EMCDDA，2010

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Store between 35.6-86°F (2-30°C)
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
	Manufacturer		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use	UDI	Unique device identifier		

Distributed By:
CLIAwaived, Inc.
2721 Loker Avenue W.
Carlsbad, CA 92010

www.cliawaived.com

Toll Free #: 1-888-882-7739
Email: orders@cliawaived.com

Number:14601879601
Date: 2023-12-06