



FYL Rapid Test Cassette (Urine)

Package Insert

REF DFY-102 English

A rapid test for the qualitative detection of FYL in human urine. For medical and other professional *in vitro* diagnostic use only.

INTENDED USE

The FYL Rapid Test Cassette (Urine) is a rapid immunochromatographic assay for the qualitative detection of Norfentanyl, a metabolite of Fentanyl. It is a potent narcotic analgesic, abuse of which leads to habituation or addiction. It is primarily a mu-opioid agonist. Norfentanyl is also used as adjunct to general anaesthetics, and as an anaesthetic for induction and maintenance.

This assay provides only a preliminary 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 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 FYL Rapid Test Cassette (Urine) 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 Norfentanyl in urine. The FYL Rapid Test Cassette (Urine) yields a positive result when Norfentanyl in urine exceeds 20 ng/mL.

PRINCIPLE

The FYL Rapid Test Cassette (Urine) 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 20 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 20 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 either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test 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 cassettes
- Droppers
- Package insert

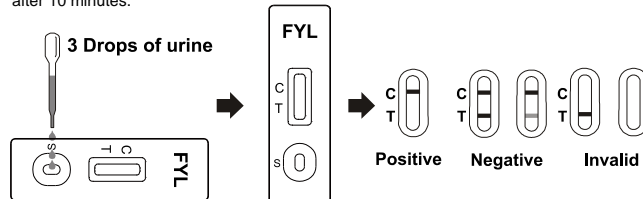
Materials Required But Not Provided

- Specimen collection containers
- Timer

DIRECTIONS FOR USE

Allow test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it within one hour.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer **3 full drops of urine** (approx. 120 μ L) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. **The result should be read at 5 minutes.** It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.



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 Norfentanyl concentration is below the detectable level (20 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 Norfentanyl concentration exceeds the detectable level (20 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.

LIMITATIONS

- The FYL Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- It is possible 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 indicates presence of the drug or its metabolites but does not indicate level of 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.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the FYL Rapid Test Cassette (Urine) and GC/MS. The following results were tabulated:

Method	GC/MS		Total Results
	Positive	Negative	
FYL Rapid Test Cassette	79	1	80
	1	169	170
Total Results	80	170	250
% Agreement	98.8%	99.4%	99.2%

Analytical Sensitivity

A drug-free urine pool was spiked with Norfentanyl at the following concentrations: 0 ng/mL, 10 ng/mL, 15 ng/mL, 20 ng/mL, 25 ng/mL, 30ng/mL and 60 ng/mL. The results demonstrate >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Norfentanyl Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
10	-50%	30	30	0
15	-25%	30	27	3
20	Cut-off	30	15	15
25	+25%	30	3	27
30	+50%	30	0	30
60	+300%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the FYL Rapid Test Cassette (Urine) at 5 minutes.

Compound	Conc. (ng/mL)	Compound	Conc. (ng/mL)
Alfentanil	600,000	Bupirone	15,000
Fenfluramine	50,000	Fentanyl	100
Norfentanyl	20	Sufentanyl	50,000

Precision

A study was conducted at three hospitals using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Norfentanyl, 25% Norfentanyl above and below the cut-off, and 50% Norfentanyl above and below the 20ng/mL cut-off was provided to each site. The following results were tabulated:

Norfentanyl Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
10	10	10	0	10	0	10	0
15	10	9	1	9	1	9	1
25	10	1	9	1	9	1	9
30	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges were spiked with 10ng/mL and 30ng/mL of Norfentanyl. The FYL Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat 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 a pH range of 4 to 9 in 1 pH unit increments and spiked with Norfentanyl to 10ng/mL and 30ng/mL. The spiked, pH-adjusted urine was tested with the FYL Rapid Test Cassette (Urine) in duplicate. The results demonstrated 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 FYL positive urine. The following compounds show no cross-reactivity when tested with the FYL Rapid Test Cassette (Urine) at a concentration of 100 μ g/mL.

Non Cross-Reacting Compounds

4-Acetaminophenol	4-Dimethylaminoantipyrine	Maprotiline	Prednisolone
Acetone	Diphenhydramine	Meperidine	Prednisone
Acetophenetidin	5,5-Diphenylhydantoin	Meprobamate	Procaine
N-Acetylprocainamide	Disopyramide	d-Methamphetamine	Promazine
Acetylsalicylic acid	Doxylamine	l-Methamphetamine	Promethazine
Albumin	Ecgoinine	Methaqualone	l-Propoxyphene
Amiriptryline	Ecgoinine methylester	Methadone	d,l-Propranolol
Amobarbital	EMDP	Methoxyphenamine	d-Pseudoephedrine
Amoxapine	Ephedrine	(+)-3,4-Methylenedioxy-methamphetamine	Quinacrine
Amoxicillin	l-Ephedrine		Quinidine
Ampicillin	l-Epinephrine		Quinine
Ascorbic acid	(±)-Epinephrine		Ranitidine
Aminopyrine	Erythromycin		Riflavin
Apomorphine	β -Estradiol		Morphine-3- β -D-glucuronide
Aspartame	Estrone-3-sulfate		Morphine sulfate
Atropine	Ethanol (Ethyl alcohol)		Methypyrrolon
Benzilic acid	Ethyl-p-aminobenzoate		Nalidixic acid
Benzoic acid	Etodolac		Nalorphine
Benzphetamine	Famprofazone		Naloxone
Bilirubin	Fenoprofen		Naltrexone
Brompheniramine	Fluoxetine		α -Naphthaleneacetic acid
Caffeine	Furosemide		Sustiva (Efavirenz)
Cannabidiol	Genticic acid		Acid
Cannabinol	d-Glucose		Niacinamide
Cimetidine	Guaiaicol glyceryl ether		Nifedipine
Chloral hydrate	Hemoglobin		Nimesulide
Chloramphenicol	Hydralazine		Norcocaine
Chlordiazepoxide	Hydrochlorothiazide		Normorphine
Chloroquine	Hydrocodone		Norethindrone
Chlorothiazide	Hydrocortisone		d-Norpropoxyphene
(+)-Chlorpheniramine	o-Hydroxyhippuric acid		Noscapine
			d,l-Octopamine
			Thiamine
			Thioridazine

(±)-Chlorpheniramine	P-Hydroxymethamphetamine	Orphenadrine	I-Thyroxine
Chlorpromazine	Hydromorphone	Oxalic acid	Tolbutamide
Chlorprothixene	3-Hydroxytyramine	Oxazepam	cis-Tramadol
Cholesterol	(Dopamine)	Oxolinic acid	trans-2-
Clomipramine	Hydroxyzine	Oxycodone	Phenylcyclopropylamine
Clonidine	Ibuprofen	Oxymetazoline	Trazodone
Codeine	Imipramine	Oxymorphone	Trimethobenzamide
Cortisone	lproniazide	Papaverine	Triamterene
(-)-Cotinine	(-)-Isoproterenol	Pemoline	Trifluoperazine
Creatinine	Isoxsuprine	Penicillin-G	Trimethoprim
Cyclobarbitol	Kanamycin	Pentazocine	Trimipramine
Cyclobenzaprine	Ketamine	Pentobarbital	Tryptamine
Deoxycorticosterone	Ketoprofen	Perphenazine	d,l-Tryptophan
R (-)Deprenyl	Labetalol	Phencyclidine	Tyramine
Dextromethorphan	Levorphanol	Phenelzine	d,l-Tyrosine
Diazepam	Lidocaine	Pheniramine	Uric acid
Diclofenac	Lindane	Phenobarbital	Verapamil
Dicyclomine	(Hexachlorocyclohexane)	Phenothiazine	Digoxin
Diflunisal	Loperamide	Phentermine	Lithium carbonate
I-Phenylephrine			

【BIBLIOGRAPHY】

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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

	Caution		Tests per kit		Authorized Representative in EU
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use

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