FYL Rapid Test Panel（Urine）

Package Insert

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 (Fentanyl) Rapid Test Panel (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 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 4.

The FYL Rapid Test Panel (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 Panel (Urine) yields a positive result when Norfentanyl in urine exceeds 20 ng/mL.

【PRINCIPLE】

The FYL Rapid Test Panel (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 Panel 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 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 Panels
- Package insert

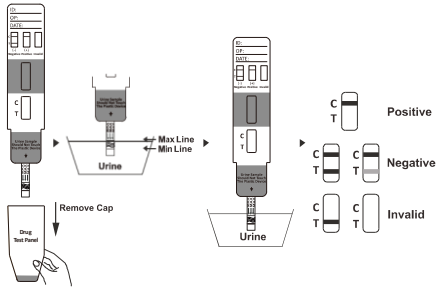
Materials Required But Not Provided

- Specimen collection container
- Timer

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10 to 15 seconds. **Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.**



4. Replace the cap and place the test panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another apparent 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】

1. The FYL Rapid Test Panel (Urine) 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.
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.

【EXPECTED VALUES】

This negative result indicates that the Norfentanyl concentration is below the detectable level of 20ng/ml. Positive result means the concentration of Norfentanyl is above the level of 20ng/ml. The FYL Rapid Test Panel has a sensitivity of 20ng/ml.

【PERFORMANCE CHARACTERISTICS】

Accuracy

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

Method		GC/MS		Total Results
FYL Rapid Test Panel	Results	Positive	Negative	
	Positive	79	1	80
	Negative	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 Panel (Urine) at 5 minutes.

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

Precision

A study was conducted at three hospitals by laypersons 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 Panel (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 Panel (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 Panel (Urine) at a concentration of 100 μg/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	Ecgonine	Methaqualone	l-Propoxyphene
Amitriptyline	Ecgonine methylester	Methadone	d,l-Propranolol
Amobarbital	EMDP	Methoxyphenamine	d-Pseudoephedrine
Amoxapine	Ephedrine	(+)-3,4-Methylendioxy-methamphetamine	Quinacrine
Amoxicillin	l-Ephedrine	Methylphenidate	Quinidine
Ampicillin	l-Epinephrine	Mephentermine	Quinine
Ascorbic acid	(±)-Epinephrine	Metoprolol	Ranitidine
Aminopyrine	Erythromycin	Morphine-3-β-D-glucuronide	Riboflavin
Apomorphine	β-Estradiol	Morphine sulfate	Salicylic acid
Aspartame	Estrone-3-sulfate	Methyprylon	Secobarbital
Atropine	Ethanol (Ethyl alcohol)	Nalidixic acid	Serotonin (5-Hydroxytryptamine)
Benzilic acid	Ethyl-p-aminobenzoate	Nalorphine	Sodium chloride
Benzoic acid	Etodolac	Naloxone	Sulfamethazine
Benzphetamine	Famprofazone	Naltrexone	Sulindac
Bilirubin	Fenoprofen	α-Naphthaleneacetic acid	Sustiva (Efavirenz)
Brompheniramine	Fluoxetine	Naproxen	Temazepam
Caffeine	Furosemide	Niacinamide	Tetracycline
Cannabidiol	Gentisic acid	Nifedipine	Tetrahydrocortexolone
Cannabinol	d-Glucose	Nimesulide	Tetrahydrocortisone, 3-acetate
Cimetidine	Guaiacol glyceryl ether	Norcodeine	Tetrahydrozoline
Chloral hydrate	Hemoglobin	Normorphine	Thebaine
Chloramphenicol	Hydralazine	Norethindrone	Theophylline
Chlordiazepoxide	Hydrochlorothiazide	d-Norpropoxyphene	Thiamine
Chloroquine	Hydrocodone	Noscapine	Thioridazine
Chlorothiazide	Hydrocortisone	d,l-Octopamine	l-Thyroxine
(+)-Chlorpheniramine	o-Hydroxyhippuric acid	Orphenadrine	Tolbutamide
(±)-Chlorpheniramine	p-Hydroxymethamphetamine	Oxalic acid	cis-Tramadol
Chlorpromazine	Hydromorphone	Oxazepam	trans-2-Phenylcyclopropylamine
Chlorprothixene	3-Hydroxytyramine (Dopamine)	Oxolinic acid	Trazodone
Cholesterol	Hydroxyzine	Oxycodone	Trimethobenzamide
Clomipramine	Ibuprofen	Oxymetazoline	Triamterene
Clonidine	Imipramine	Oxymorphone	Trifluoperazine
Codeine	Iproniazide	Papaverine	Trimethoprim
Cortisone	(-)-Isoproterenol	Pemoline	Trimipramine
(-)-Cotinine	Isoxsuprine	Penicillin-G	Tryptamine
Creatinine	Kanamycin	Pentazocine	d,l-Tryptophan
Cyclobarbital	Ketamine	Pentobarbital	Tyramine
Cyclobenzaprine	Ketoprofen	Perphenazine	d,l-Tyrosine
Deoxycorticosterone	Labetalol	Phencyclidine	Uric acid
R (-)Deprenyl	Levorphanol	Phenelzine	Verapamil
Dextromethorphan	Lidocaine	Pheniramine	Digoxin
Diazepam	Lindane (Hexachlorocyclohexane)	Phenobarbital	Lithium carbonate
Diclofenac	Loperamide	Phenothiazine	l-Phenylephrine
Dicyclomine		Phentermine	
Diflunisal			

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