D-FYL-11

Fentanyl FYL
Rapid Test Strip

INTENDED USE

The FYL Rapid Test Strip (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of Fentanyl in human urine specimens at the cut-off concentrations listed below:

Parameter	Calibrator	Cut-off (ng/mL)
FYL (Fentanyl)	Fentanyl	200

INTRODUCTION

Fentanyl is a synthetic opioid related to the phenylpiperidines.Fentanyl is approximately 100 times more potent than morphine. This agent is highly lipid soluble and rapidly cross the blood-brain barrier. This is reflected in the half-life for equilibration between the plasma and cerebrospinal fluid of approximately 5 minutes for fentanyl. The levels in plasma and cerebrospinal fluid decline rapidly owing to redistribution of fentanyl from highly perfused tissue groups to other tissues, such as muscle and fat. As saturation of less well-perfused tissue occurs, the duration of effect of fentanyl and sufentanil approaches the length of their elimination half-lives of between 3 and 4 hours. Fentanyl undergoes hepatic metabolism and renal excretion. Therefore, with the use of higher doses or prolonged infusions, fentanyl becomes longer acting.

PRINCIPLE

The FYL Rapid Test Strip (Urine) detects Fentanyl through visual interpretation of color development on the strip. Drug conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with antibodies conjugated to colored particles and precoated on the sample pad. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are insufficient drug molecules in the specimen, the antibody-colored particle conjugate will bind to the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the drug. If drug molecules are present in the urine above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent attachment of the antibody-colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test consists of a reagent strip. The amount of each antigen and/or antibody coated on the strip is less than 0.001 mg for antigen conjugates and goat anti-rabbit IgG antibodies, and less than 0.0015 mg for antibody components.
The control zone of each test contains goat anti-rabbit IgG antibody. The test zone of each test contains drug-bovine protein antigen conjugate, and the conjugate pad of each test contains monoclonal anti-drug antibody and rabbit antibody-colored particle complex.

MATERIALS

Materials Provided

- Test strips (individually pouched or in canisters
- Package insert

Materials Required but Not provided

- Positive and negative controls
- Timer
- Centrifuge

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch or canister is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30℃ until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch or closed canister until use.
- **Do not freeze.**
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The FYL Rapid Test Strip (Urine) is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8℃ for up to 2 days. For long term storage, specimens should be kept below -20℃.
- 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.

PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, or remove one strip from the canister, and use it as soon as possible. For best results, the assay should be performed within one hour. Canisters should be closed tightly after removing strips.
2. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane.
3. Holding the strip vertically, dip the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip.
4. After the test has finished running, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 8 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. 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 should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The FYL Rapid Test Strip (Urine) is for professional *in vitro* diagnostic use, and should be only used for the qualitative detection of Fentanyl.
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) has 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. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a Fentanyl only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of Fentanyl in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between Fentanyl and certain medications.

PERFORMANCE CHARACTERISTICS

A. Accuracy
The accuracy of the FYL Rapid Test Strip (Urine) was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99.9% in agreement.

B. Reproducibility
The reproducibility of the FYL Rapid Test Strip (Urine) was verified by blind tests performed at four different locations. Samples with Fentanyl concentrations at 50% of the cut-off were all determined to be negative, while samples with Fentanyl concentrations at 200% of the cut-off were all determined to be positive.

C. Precision
Test precision was determined by blind tests with control solutions. Controls with Fentanyl concentrations at 50% of the cut-off yielded negative results, and controls with Fentanyl concentrations at 150% of the cut-off yielded positive results.

D. Specificity
The following tables list the concentrations of compounds (ng/mL) above which the FYL Rapid Test Strip (Urine) identified positive results at 5 minutes.

Fentanyl related compounds	Concentration (ng/ml)
Fentanyl	200
Norfentanyl	375

The following compounds yielded negative results up to a concentration of 100 µg/mL:

Acetaminophen	Dihydrocodeine	Nifedipine
Acetophenetidine	(+)-cis-Diltiazem	Nimesulide
Acetylcodeine	Dimenhydrinate	Nitrazepam
Acetylsalicylic acid	4-Dimethylaminoantipyrine	Olanzapine
Alprazolam	Diphenhydramine	Opipramol
Amikacin	DL-Tryptophan	Oxalic acid
Aminopyrine	DL-Tyrosine	Oxazepam
Amitriptyline	Dopamine	Oxycodone
Amoxicilline	Doxepin	Oxymetazoline
Amphetamine	Doxylamine	Pennicilline G
Ampicilline	d-Propoxyphene	Perphenazine
Apomorphine	Ecgonine HCl	Pheniramine
Ascorbic acid	Ecgonine methylester	Phenothiazine
Aspartame	Ephedrine	Phentermine
Atropine	(+/-)Epinephrine	(+/-) Phenylpropanolamine
Baclofen	Erythromycine	beta-phenylethylamine
Benzocaine	Estron 3 sulfate	Prednisolone
Bilirubin	Ethylmorphine	Prednisone
Bromazepam	Etodolac	Phencyclidine
Buprenorphine	Fenfluramine	Procaine
Caffeine	Flupentixol	Promazine
Cannabidiol	Fluoxetine	Promethazine
Cannabinol	Furosemide	Prothipendyl
Carbamazepine	Gastrozepin	Protriptyline
Chloramphenicol	Gentamicin	Quetiapine
Chlordiazepoxide	Gentisic acid	Quinidine
Chloroquine	Guaiacol Glyceryl Ether	Ranitidine
Chlorpheniramine	Hemoglobin	Rifampicine
Chlorprothixene	Hydralazine	Risperidone
Cholesterol	Hydrochlorothiazide	Salbutamol
Chorptothixene	Hydrocodone	Salicylic acid
Cimetidine	Hydrocortisone	Secobarbital
Ciprofloxacin	Ibuprofen	Sertraline
Citalopram	Imipramine	Spironolactone
Clindamycin	(-)Isoproterenol	Sulfamethoxazole
Clobazam	Ketamine	Sulindac
Clomipramine	Ketoprofen	Temazepam
Clonazepam	L - Thyroxine	Thebaine
Clonidine	Lincomycin	Theophylline
Clorazepate	Lidocaine	Thiamine
Clozapine	Loperamide	Thioridazine
Cocain	L-Phenylephrine	Tobramycin
Codein	Maprotiline	Triamterene
(-)Cotinine	Meperidine	Trimethoprim
Creatinine	Mephentermine hemisulfate salt	Trimipramine
Cyclobenzaprine	Methadone	Tyramine
Delorazepam	Methamphetamine	Vancomycin
Desipramine HCl	3,4-Methylenedioxyamphetamine	Venlafaxine

Dexamethasone	3,4-Methylenedioxy-methamphetamine	Verapamil
Dextromethorphan	N-Methylephedrine	Zolpidem
Diacetylmorphine	Metoclopramide	
Diazepam	Metoprolol	
Diclofenac	Metronidazole	
Dicumarol	MOR-3-Beta-D Glucuronide	
Diflunisal	Nalorphine	
DL-Propanolol	Naloxone	
Digoxin	(+)-Naproxen	

LITERATURE REFERENCES

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE making according to IVD Medical Directive 98/97/EC		