FYL One Step Fentanyl Test Device (Urine)
Package Insert

Cat: FYL-102 **Specimens:** Urine

Version: Z **Effective Date:** 2020-9

For professional in vitro diagnostic use only.

INTENDED USE

The FYL One Step Fentanyl Test Device (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 One Step Fentanyl Test Device (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

The test contains drug-bovine protein antigen conjugate on the membrane and the conjugate pad of each test contains monoclonal anti-drug antibody.

MATERIALS

Materials Provided

- Test devices
- Droppers
- 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 4-30°C 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 One Step Fentanyl Test Device (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°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.

PROCEDURE

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

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S).
3. Wait for the colored line(s) to appear. **Read results at 5 minutes**. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:

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

NEGATIVE RESULT:

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 RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be disgarded. 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 negative. 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) considered an internal positive procedural control, confirming sufficient specimen volume and corre 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 One Step Fentanyl Test Device (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

129clinical urine specimens were analyzed by GC-MS and by the FYL One Step Fentanyl Test Device (Urine).Each test was performed by three operators. Samples were divided by concentration into five categories: negative, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Method		GC/MS					
The FYL One Step Fentanyl Test Device		Neg.	Neg.(< –50%cutoff)	Near cutoff neg.(-50% cutoff to cutoff)	Near cutoff pos.(cutoff to +50% cutoff)	Pos. (> +50% cutoff)	% agreement with GC/MS
FYL 200	Positive	0	0	1	20	24	97.78%
	Negative	55	15	13	1	0	98.81%

B.Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The FYL One Step Fentanyl Test Device (Urine) was tested in duplicate using fifteen drug free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

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 One Step Fentanyl Test Device (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	Cocain	Gentisic acid	Pennicilline G
Acetophenetidine	Codein	Guaiacol Glyceryl Ether	Perphenazine

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

LITERATURE REFERENCES

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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.

Index of Symbols

	Consult Instruction for use	Σ	Tests per kit		Do not use if package is damaged
IVD	For in vitro diagnostic use only		Use by date		Do not reuse
2℃ 30℃	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number
	Keep away from sunlight		Keep dry		Manufacturer
	Caution		Date of manufacture	EC REP	Authorized Representative

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