

Rapid Fentanyl (FYL) Test Strip Instruction Insert

Please read all the information in this Insert before performing the test.

Instruction of use for testing of Fentanyl (FYL).

Rapid Fentanyl (FYL) Test Strip is a rapid, screening test for the qualitative detection of Fentanyl (FYL) in human urine at the cut off of 200 ng/ml.

For *in vitro* diagnostic use only.

For Forensic use only.

INTENDED USE

Rapid Fentanyl (FYL) Test Strip is an immuno-chromatographic assay for the qualitative determination of the presence of Fentanyl (FYL) at the cut off of 200 ng/ml.

This assay provides only a preliminary analytical test 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 indicated.

SUMMARY

Fentanyl (FYL)

Fentanyl is a potent, synthetic narcotic analgesic with a rapid onset and short duration of action. It is a strong agonist at the μ -opioid receptors. Historically it has been used to treat breakthrough pain and is commonly used in pre-procedures as a pain reliever as well as an anesthetic in combination with a benzodiazepine. It is approximately 80 to 100 times more potent than morphine and roughly 15 to 20 times more potent than heroin.

PRINCIPLE

Rapid Fentanyl (FYL) Test Strip is a competitive immunoassay that is used to screen for the presence of Fentanyl (FYL) in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the strip. This produces a colored Test line in the Test Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.

When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), of each strip, if the test has been performed properly.

WARNINGS AND PRECAUTIONS

- Immunoassay for *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test Strip should remain in the sealed pouch until use.
- The used test Strip should be discarded according to local regulations.

CONTENTS OF THE KITS

- Drug Test Strip.
- Desiccant .
- Leaflet with instruction for use.

ADDITIONAL REQUIREMENTS

- A clean, dry, plastic or glass container to collect the urine.
- Timer (watch or clock)
- External controls

STORAGE AND STABILITY

- Store at 39 ~ 86 °F (4 ~ 30 °C) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

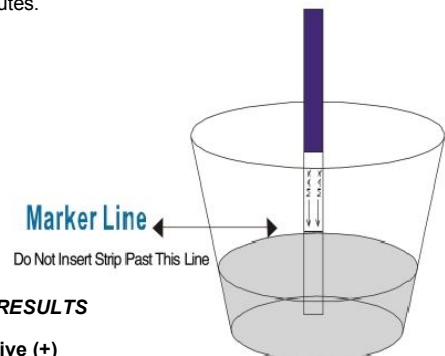
SPECIMEN COLLECTION AND PREPARATION

- Collect urine sample with a clean, dry container. Urine collected at any time of the day may be used.
- For best results, test specimens immediately following collection.
- Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).
- Bring frozen or refrigerated samples to room temperature before testing.

HOW TO PERFORM THE TEST?

Test must be in room temperature (15°C to 30°C)

1. Open the sealed pouch by tearing along the notch. Remove the test strip from the pouch.
2. Immerse the absorbent end into the urine sample for about 10 seconds. **IMPORTANT: Do not allow the urine level to exceed the MAX (marker line), otherwise the test will not perform correctly.**
3. Lay the strip flat on a clean, dry, non-absorbent surface.
4. Read the results at 5 minutes. The drug test results remain stable for up to thirty minutes.



READING THE RESULTS

Preliminary positive (+)

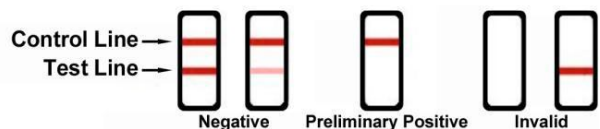
A rose-pink band is visible in each control region. If no color band appears in the appropriate test "T" region, a preliminary positive result is indicated for the corresponding drug of that specific test zone.

Negative (-)

If a rose-pink band is visible in each control region and the appropriate test "T" region, it indicates that the concentration of the corresponding drug of that specific test zone is absent or below the detection limit of the test.

Invalid

If a color band is not visible in the control "C" region or a color band is only visible in the test "T" region, the test is invalid. Another test should be opened and run to re-evaluate the specimen. If test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number for the test.



Note: There is no meaning attributed to line color intensity or width. Any visible line is considered to be a line.

Certain lines may appear lighter or thinner than other lines. ANY COLORED LINE VISIBLE IN THE TEST "T" REGION, NO MATTER HOW DARK OR FAINT, SHOULD BE INTERPRETED AS A NEGATIVE RESULT.

IMPORTANT: This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by Rapid *Fentanyl* (FYL) Test Strip. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial drug is present but isn't detected by Rapid *Fentanyl* (FYL) Test Strip. Diluted or adulterated urine specimens may cause a false negative result.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test substances other than urine.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyte. If a sample is suspected of being adulterated, obtain a new sample in a different, unused, cup.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
5. A positive result does not indicate level or intoxication, administration route or concentration in urine.
6. 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.

QUALITY CONTROL

A procedural control is included in the test. A line appearing in the Control 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 practice to confirm the test procedure and to verify proper test performance. Quality control should be run with each new lot, and every 30 days to check storage stability. Positive and negative control should give the expected results. Users can commercially obtain control materials (For example from Sigma-Aldrich Corporation). The concentration of drug(s) in positive and negative controls are approximately 50% above and below the cutoff concentration of the assay.

PERFORMANCE CHARACTERISTICS

Specificity and cross reactivity

To test the cross reactivity of the test, Rapid *Fentanyl* (FYL) Test Strip was used to test with drug metabolites and drug structurally similar compounds in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

Fentanyl (FYL)	
Fentanyl	200

Interfering substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine or drug positive urine containing FYL with the concentration 50% below the cutoff and the concentration 50% above the cutoff, respectively. All potential interfering substances were added at a concentration of 100µg/mL. The urine specimens were tested with Rapid *Fentanyl* (FYL) Test Strip. None of the urine samples showed any deviation from the expected results.

Acetaminophen	Estrone-3-sulfate	Oxolinic acid
Acetophenetidin	Ethyl-p-aminobenzoate	Oxymetazoline
Amoxicillin	Erythromycin	Oxytetracycline
Ampicillin	Fenoprofen	Papaverine

Aspirin	Flucloxacillin	Penicillin-G
Atenolol	Fluoxetine	Pentazocine
Atorvastatin	Furosemide	Perphenazine
Azocillin	Gentisic acid	Phenelzine
Benzilic acid	Hemoglobin	Prednisolone
Benzylpenicillin	Hydralazine	Prednisone
Benzoic acid	Hydrochlorothiazide	d,l-Propranolol
Bilirubin	Hydrocortisone	d-Pseudoephedrine
Benzylamine	o-Hydroxyhippuric acid	Quinacrine
Caffeine	p-Hydroxytyramine	Quinine
Carbamazepine	Ibuprofen	Quindine
Cephalexin	Indomethacin	Ranitidine
Chloralhydrate	Iproniazid	Salicylic acid
Chloramphenicol	d,l-Isoproterenol	Serotonin
Chlorothiazide	Isoxsuprine	Sulfamethazine
Chlorpheniramine	Ketamine	Sulindac
d,l-Chlorpromazine	Ketoprofen	Tetracycline
Cholesterol	Labetalol	Tetrahydrozoline
Clonidine	Lisinopril	Thiamine
Cimetidine	Loperamide	Thioridazine
Citalopram	Meperidine	d, l-Thyroxine
Cortisone	Meprobamate	Tolbutamine
Creatinine	Methoxyphenamine	Tolbutamide
Deoxycorticosterone	Methylphenidate	Trifluoperazine
Dexamethasone	Nadolol	Tryptamine
Dextromethorphan	Nalidixic acid	Uric acid
Diclofenac	Naproxen	Verapamil
Diffunisal	Niacinamide	Zomepirac
Digoxin	Nifedipine	
Diphenhydramine	Norethindrone	
Ephedrine	d,l-Octopamine	
β -Estradiol	Oxalic acid	

Effect of Urinary Specific Gravity

The specific gravity studies were conducted on different specific gravity including 1.002,1.010, 1.020, 1.030, 1.040 specimens with drug free urine containing FYL at 50% below and 50% above cutoff level. Each sample was tested by Rapid *Fentanyl* (FYL) Test Strip. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 3 to 9 in 1 pH unit increments and spiked with FYL at 50% below and 50% above cutoff levels. Each sample was tested by Rapid *Fentanyl* (FYL) Test Strip. The result demonstrate that varying range of pH do not interfere with the performance of the test.







APPLICABLE STANDARDS

Draft Guidance for Industry and FDA Staff: Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 13612:2002, EN ISO 13640:2002.

MANUFACTURED For

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INDEX OF SYMBOLS

	Consult instructions for use		Keep away from sunlight
	In vitro diagnostic for use		Keep dry
	Store between 4 ~ 30 °C		Do not reuse

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