FYL Rapid Test Dipstick (Powder)
Package Insert

A rapid, test for the detection of Fentanyl on surfaces and in solids.
Test intended to be used as analytical device to detect drugs on surface. For forensic use only.

【INTENDED USE】

The Fentanyl Rapid Test Dipstick is a rapid chromatographic immunoassay for the qualitative detection of Fentanyl a cut-off 200ng/mL.

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 indicated.

【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 etc, 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.

The Fentanyl contained within the FYL Rapid Test Dipstick yields a positive result when the FYL concentration exceeds 200ng/mL.

【PRINCIPLE】

During testing, Fentanyl migrates upward by capillary action. A drug, if present in the specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains membrane strips coated with Fentanyl -protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Fentanyl

【PRECAUTIONS】

- Use only once. For forensic use only.
- Do not touch the free endings of the strips to avoid contamination.
- Do not dip the cassette above the maximum deepness level mark.
- Dip the test into buffer until one or two red lines appear at the reaction zone (~15 seconds).
- Do not spill the samples into the reaction zone.
- Specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Do not use the Multi Drug Test Dipstick after expiration date.
- Do not use the test after damage of the packaging foil.
- Use test right after unwrapping.
- Please take the specificity and the cross reactivity into account for evaluation.
- Store and transport the test device always at 2-30°C.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test Dipstick must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【MATERIALS】

Materials Provided

- Dipsticks
- Package insert
- Buffer
- Tubes
- Swabs
- Workstation

Materials Required But Not Provided

- Timer

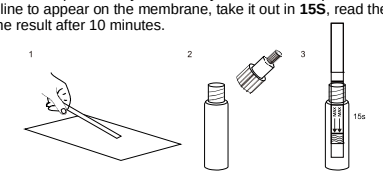
【DIRECTIONS FOR USE】

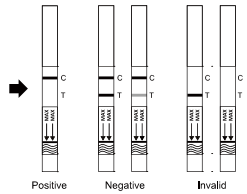
Test device (in closed pouches), samples, and controls should be brought to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.

Remove the test device from its protective pouch and label the device with patient's identification or control label.

FOR SURFACES

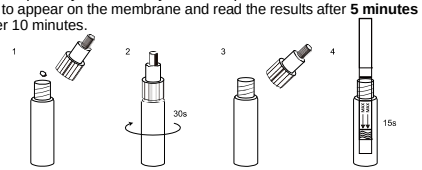
1. Dip a sample of powder with a test strip.
2. Remove the buffer cap and slowly and carefully insert the test strip into the extraction tube with the buffer.
3. Wait for a line to appear on the membrane, take it out in **15S**, read the result after **5 minutes**, do not read the result after 10 minutes.

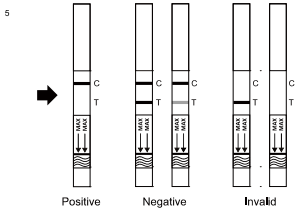




FOR SOLIDS

1. Open the tube and put the solid in to the buffer.
2. Close the tube with dropper and cap. Shake it a short time. Wait for **30 sec.**
3. Take off the cap of supplied tube;
4. Insert the test strip slowly and carefully into the tape buffer.
5. Wait for lines to appear on the membrane and read the results after **5 minutes** and do not interpret the result after 10 minutes.





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* A colored line appears in the Control region (C) and colored lines appear in the Test region (T). This negative result means that the concentrations in the sample are below the designated cut-off levels for a particular drug tested.
***NOTE:** The shade of the colored lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

【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.

【LIMITATIONS】

1. The FYL Rapid Test Dipstick 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. A negative result may not necessarily indicate drug-free sample. Negative results can be obtained when drug is present but below the cut-off level of the test.
3. This test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】

The negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A comparison was conducted using the FYL Rapid Test Dipstick Power) and GC/MS. The following results were tabulated:

Method		GC/MS		Total Results
FYL Rapid Test Dipstick	Results	Positive	Negative	
	Positive	79	1	80
	Negative	2	168	170
Total Results		80	81	179
% Agreement		98.8%	96.3%	99.4%

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 card of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

Fentanyl conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
200	10	1	9	1	9	1	9
250	10	0	10	0	10	0	10

Analytical Sensitivity

The following table lists compounds that are positively detected in DOA Buffer by The FYL Rapid Test Dipstick at 5 minutes.

Drug Conc. (Cut-off Range)	n	FYL	
		-	+
0% Cut-off	30	30	0
-50% Cut-off	30	30	0
-25% Cut-off	30	27	3
Cut-off	30	15	15
+25% Cut-off	30	3	27
+50% Cut-off	30	0	30
+300% Cut-off	30	0	30

Analytical Specificity

The following table lists compounds that were positively detected in buffer by the FYL Rapid Test Strip at 5 minutes.

Compound	Concentration (ng/mL)
Alfentanyl	>600,000
Fenfluramine	100,000
Buspirone	30,000
Fentanyl	200
Sufentanyl	100,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free buffer or Fentanyl positive buffer. The following compounds show no cross-reactivity when tested with the FYL Rapid Test Dipstick (Powder) at a concentration of 100μg/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-	Quinacrine
Amoxicillin	l-Ephedrine	methamphetamine	Quinidine
Ampicillin	l-Epinephrine	Methylphenidate	Quinine
Ascorbic acid	(±)-Epinephrine	Mephentermine	Ranitidine
Aminopyrine	Erythromycin	Metoprolol	Riboflavin
Apomorphine	β-Estradiol	Morphine-3-β-D-glucuronide	Salicylic acid
Aspartame	Estrone-3-sulfate	Morphine sulfate	Secobarbital
Atropine	Ethanol (Ethyl alcohol)	Methyprylon	Serotonin
Benzilic acid	Ethyl-p-aminobenzoate	Nalidixic acid	(5-Hydroxytryptamine)
Benzoic acid	Etodolac	Nalorphine	Sodium chloride
Benzphetamine	Famprofazone	Naloxone	Sulfamethazine
Bilirubin	Fenoprofen	Naltrexone	Sulindac
Brompheniramine	Fluoxetine	α-Naphthaleneacetic acid	Sustiva (Efavirenz)
Caffeine	Furosemide	Naproxen	Temazepam
Cannabidiol	Gentisic acid	Niacinamide	Tetracycline
Cannabinol	d-Glucose	Nifedipine	Tetrahydrocortexolone
Cimetidine	Guaiacol glyceryl ether	Nimesulide	Tetrahydrocortisone,
Chloral hydrate	Hemoglobin	Norcodeine	3-acetate
Chloramphenicol	Hydralazine	Normorphine	Tetrahydrozoline
Chlordiazepoxide	Hydrochlorothiazide	Norethindrone	Thebaine
Chloroquine	Hydrocodone	d-Norpropoxyphene	Theophylline
Chlorothiazide	Hydrocortisone	Noscapine	Thiamine
(+)-Chlorpheniramine	o-Hydroxyhippuric acid	d,l-Octopamine	Thioridazine
(±)-Chlorpheniramine	p-Hydroxymethamphetamine	Orphenadrine	l-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	Iproniazide	Papaverine	Triamterene
(-)-Cotinine	(-)-Isoproterenol	Pemoline	Trifluoperazine
Creatinine	Isoxsuprine	Penicillin-G	Trimethoprim
Cyclobarbital	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
			l-Phenylephrine

【BIBLIOGRAPHY】

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Manufactured for:
American Screening Corp
9742 St Vincent Ave Ste 100
Shreveport, LA 71106
318-798-3306
sales@americanscreeningcorp.com

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