Single-Drug Test Strips (Liquid & Powder) Product Insert

For Forensic Use Only

INTENDED USE

The Rapid Response™ FYL Test Strips (Liquid, Powder) is a rapid visual immunoassay for the qualitative, presumptive detection of drugs in suspicious substance on from surfaces and liquids from suspicious receptacles. By means of this test strip, you can determine whether or not your sample contains fentanyl. The detection limit of this test is below 200 ng.

INTRODUCTION

Fentanyl belongs to powerful narcotic analgesics and is a special opiates receptor stimulant. Fentanyl is one of the varieties that have been listed in management of United Nations "Single Convention of Narcotic Drug in 1961". Among the opiates agents that are under international control, Fentanyl is one of the most commonly used to cure moderate to severe pain. After continuous injection of fentanyl, the sufferer may experience protracted opioid abstinence syndromes, such as ataxia and irritability etc. after prolong use of the drug. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have the possibility of higher infection rate of HIV, more dangerous injection behavior, and more lifelong medication overdose.

PRINCIPLE

The Rapid Response™ single-drug tests are competitive immunoassay tests, during which drug molecules affixed to the test strip and drug molecules possibly contained in the extraction buffer, in liquid compete against each other for a limited number of binding sites. The membrane strips are pre-coated with immobilized drug molecules (drug conjugate) in the test result line region (T-region). The pink colored pad at the left end of the membrane contains complexes of a dye and monoclonal antibodies against the drug.

The buffer, liquid flows up the test strip after immersion of the test strip into the sample. The liquid transports the antibodies from the pink pad to the test region. If the sample does not contain drug molecules, the antibody-dye complexes from the pink pad are bound to the drug conjugates affixed there to the membrane and form a distinct line. Hence the appearance of a line in the test region means that the sample is drug-free (negative result), or that the drug concentration is below the cut-off value.

However, if the sample does contain drug molecules, these will compete against the drug conjugates in the test region for the binding sites on the antibodies. Occupancy of the binding sites will increase with an increase of the drug concentration in the sample and coloration of the test result line will become increasingly weak. If the drug concentration attains values equal to or above the cut-off, binding of antibodies to the drug conjugate in the test region is suppressed and the line gradually disappears. I.e. if a line does not appear in the test region, the result is positive.

A control line (control region C), generated by a different antigen-antibody reaction that indicates correct test procedure, is also present on the test strip. Appearance of the red line in the control region confirms that the sample volume was sufficient and that the test was performed as intended. This control line should appear at all times, regardless of the presence of the drug to be examined.

This means that two colored lines (test and control line) appear in the event of a negative result and only one colored line appears in the event of a positive result.

MATERIALS

Materials Provided

Test strips	Swabs
Bottle containing extraction buffer solution	Plastic test tubes for the extraction
Test tube holder	Product Insert

Materials Required but Not provided

Timer

Specimen collection container

PRECAUTIONS

- Forensic Use Only devices are intended for use only in drug of abuse testing for law enforcement purposes. Appropriate users of such device include, for example, court systems, police departments, probation offices, juvenile detention centers, prisons, correction centers, military and other similar law enforcement/ government agencies, laboratories or other establishments performing forensic testing for these entities.
- Forensic Use Only devices are not designed, tested, or labeled for use in other settings, such as clinical diagnostic or workplace settings.
- The test device is not intended to be used with urine specimens or for in vitro diagnostic uses.
- The test device is not intended for drug users to determine the purity, composition, or if the substance being examined is safe to use.
- Open the foil pouch containing the test strip just before you wish to immerse it into a liquid, otherwise it will become invalid since test strips absorb moisture when exposed to air.
- The pouch containing the test strip should be sealed. Discard the test strip if package is ripped or torn.
- Do not reuse
- Use a new test set (test tube, swab, test strip) for each new sample
- Only touch the test strip at the handle with the drug abbreviation (FYL) intended for this purpose
- Please strictly adhere to the instructions. The following text contains a precise procedural method for each sample type.
- Protect yourself from the unknown substances you are examining by wearing gloves.
- Only use the test strips until the specified date of expiry.
- The test can be refrigerated or stored at room temperature (2°C to 30°C).
- No danger emanates from the components contained in the test (e.g. antibodies or chemicals) by appropriate handling.
- Only use the test to examine substances that are dissolved in the buffer itself. The test is designed for buffers. E.g. If tap water is used as solvent, the test may lead to false or invalid results.

PROCEDURE

EXAMINATION OF SUSPICIOUS SUBSTANCES FROM SURFACES

a. Prepare the desired number of test tubes by placing them in the test tube holder.

b. Transfer entire bottle of the extraction buffer solution into a test tube. If the extraction buffer has been cooled, wait until it has acquired room temperature.

c. Remove the swab from its packaging. Dip the swab into the test tube containing the extraction buffer for 3 seconds in order to moisten the swab.

d. Wipe the tip of the swab across the suspicious surface several times. The more often the swab is wiped across the surface, the more of the drug can be absorbed.

e. Dip the swab into the filled tube a second time and leave it there for 1 to 2 minutes. Stir the swab in the buffer during this period, in order to quicken drug extraction. Remove the swab from the buffer and squeeze it out by pressing it against the upper, dry part of the test tube in order to obtain as much liquid as possible in the test tube.

f. Allow the sealed packaging of the test strip to acquire room temperature (15-30°C), in case it has been cooled. Open the packaging and remove the strip by the handle with the drug abbreviation (FYL). Once opened, the test strip must be used immediately.

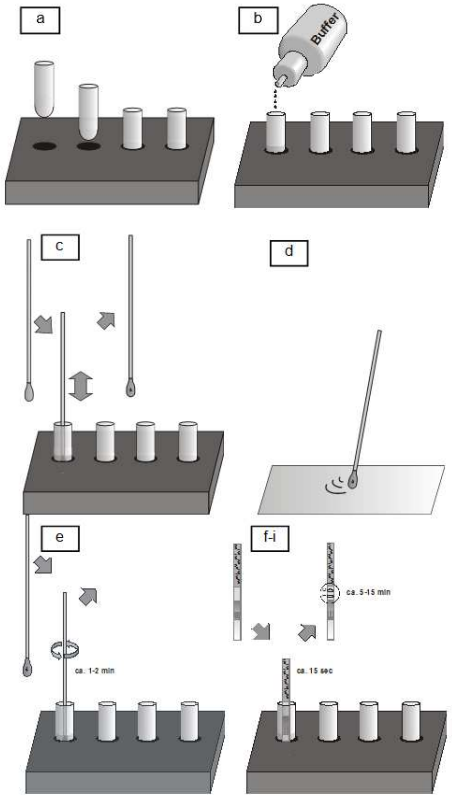
g. Now hold the test strip by the handle with the drug abbreviation (FYL) and immerse it up to the MAX-mark into the liquid in the tube for 10-15 sec. Caution: Contact between the reaction zone and the buffer solution will render the test useless!

h. The test process can be observed from a pink colored front moving across the reaction zone. Depending on the sample, it can take 10 to 15 seconds until this front appears.

i. Remove the strip from the test tube and place it horizontally on a flat surface.

j. Read the result after 5 minutes, but no later than 10 minutes after the strip has been dipped into the solution. Refer to chapter "Interpretation of results" for advice relating to interpretation.

k. Repeat the procedure for the next suspicious surface using a new test set.



EXAMINATION OF SOLID MATTER

a. Prepare the desired number of test tubes by placing them in the test tube holder.

b. Transfer entire bottle of the extraction buffer solution into a test tube. If the extraction buffer has been cooled, wait until it has acquired room temperature.

c. Remove a swab from its packaging

d. Using the tip of the swab, just touch the solid substance to be examined. If the solid to be examined is a coated tablet, crush the tablet before sampling using the swab.

e. Dip the swab into the filled tube and leave it there for 1 to 2 minutes. Stir the swab in the buffer during this period, in order to quicken drug extraction. Remove the swab from the buffer and squeeze it out by pressing it against the upper, dry part of the test tube in order to obtain as much liquid as possible in the test tube.

f. Allow the sealed packaging of the test strip to acquire room temperature (15-30°C), in case it has been cooled. Open the packaging and remove the strip by the handle with the drug abbreviation (FYL). Once opened, the test strip must be used immediately.

g. Now hold the test strip by the handle with the drug abbreviation (FYL) and immerse it up to the MAX-mark into the liquid in the tube for 10-15 sec. Caution: Contact between the reaction zone and the buffer solution will render the test useless!

h. The test process can be observed from a pink coloured front moving across the reaction zone. Depending on the sample, it can take 10 to 15 seconds until this front appears.

i. Now remove the strip from the test tube and place it horizontally on a flat surface.

j. Read the result after 5 minutes, but no later than 10 minutes after the strip has been dipped into the solution. Refer to chapter "Interpretation of results" for advice relating to interpretation.

EXAMINATION OF LIQUIDS

a. Prepare the desired number of test tubes by placing them in the test tube holder.

b. Transfer entire bottle of the extraction buffer solution into a test tube. If the extraction buffer has been cooled, wait until it has acquired room temperature.

c. Add 1 drop of the liquid to be examined to the buffer.

d. Remove a swab from its packaging and use the smooth end to stir the mixture in the tube.

e. Allow the sealed packaging of the test strip to acquire room temperature (15-30°C), in case it has been cooled. Open the packaging and remove the strip by the handle with the drug abbreviation (FYL). Once opened, the test strip must be used immediately.

f. Hold the test strip by the handle with the drug abbreviation (FYL) and immerse it up to the MAX-mark into the liquid in the tube for 10-15 sec. Caution: Contact between the reaction zone and the buffer solution will render the test useless!

g. The test process can be observed from a pink coloured front moving across the reaction zone. Depending on the sample, it can take 10 to 15 seconds until this front appears.

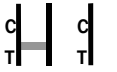
h. Now remove the strip from the sample and place it horizontally on a flat surface.

i. Read the result after 5 minutes, but no later than 10 minutes after the strip has been dipped into the solution. Refer to chapter "Interpretation of results" for advice relating to interpretation.

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: A very faint line in the test region indicates that the drug concentration is very close to the detection limit, in which case the test should be repeated or the sample should be additionally examined via a more specific method before a positive or negative result is determined.

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.

PERFORMANCE CHARACTERISTICS

ACCURACY

Accuracy of the FYL Test Strip was established by running samples against GC/MS specification. The following results were tabulated:

% Agreement with GC/MS

Method		GC/MS		Total Results
Rapid Response™ FYL Test Strips	Results	Positive	Negative	
	Positive	79	1	80
	Negative	1	169	170
Total Results		80	170	250
% Agreement		98.8%	99.4%	99.2%

PRECISION

A Study was conducted at three hospitals by lay persons 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 concentration ±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
250	10	1	9	1	9	1	9
300	10	0	10	0	10	0	10

SENSITIVITY

The sensitivity of the FYL Test Strip was determined by tested GC/MS confirmed controls to the concentration at negative, -75%, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff and 3 times of cutoff. The results are summarized below:

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	14	16
+25% Cut-off	30	4	26
+50% Cut-off	30	0	30
+300% Cut-off	30	0	30

Specificity

The following table lists compounds that are positively detected in oral fluid by the Rapid Response Fentanyl Test Strip (Liquid/ Powder) at 5 minutes.

Fentanyl 200 related compound	
Alfentanyl	>600,000
Dentluramine	100,000
Norfentanyl	40
Buspirone	3000
Fentanyl	200
Sufentanyl	100,000

*The test device is designed to screen for the presence of Fentanyl in suspicious solids or liquids. Other compounds found in illicit drugs may display cross reactivity with the test device.
*Cross reactivity with other fentanyl analogs, such as Carfentanil, Acetylfentanyl, is yet to be determined.

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 Rapid Response™ Fentanyl Test Strips (Powder/Liquid) at a concentration of 100µg/ml.

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

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GLOSSARY OF SYMBOLS

REF	Catalog number		Store between 36ºF to 86ºF (2-30ºC)
	Consult instructions for use		Lot number
	Use by		Do not reuse
	Manufacturer