Fentanyl Test Strips (Liquid & Powder) Product Insert

For forensic use only

INTENDED USE

The Rapid Response™ Fentanyl 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/ml.

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 prolonged 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

During testing, the specimen 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 strip. 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 test strip 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.

MATERIALS

Materials Provided

Test strips	Swabs
Extraction buffer solution	Plastic test tubes
Test tube holder	Product Insert

Materials Required but Not provided

Timer

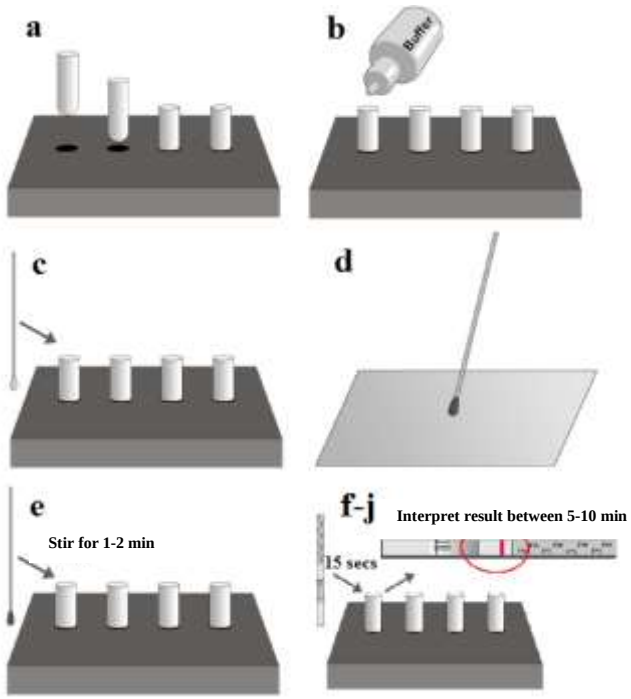
PRECAUTIONS

- There are no direct therapeutic or diagnostic claims being made for this product. These tests are not involved in diagnosing, treating, mitigating, or preventing a disease, disorder or symptom in human being, nor do they restore, modify or correct a body structure, function of the human body
- 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
- A positive or negative test result is NOT an indication that the substance being examined is safe to use. Many factors come into play when examining the samples, including but not limited to mixture of multiple substances, solubility, and pH of the sample.
- BTNX Inc. does not encourage the use, supply, or production of illegal drugs or controlled substances in any way. The device is intended for harm reduction purposes.
- The Rapid Response™ Fentanyl Test Strips (Liquid, Powder) only gives an indication and should be used solely as a presumptive guide to work in conjunction with further analysis such as Gas Chromatography- Mass Spectrometry or High Performance Liquid Chromatography (HPLC). For complete analysis, we recommend all samples should be sent to a professionally certified laboratory.
- Do not reuse
- Do not touch the free endings of the strips to avoid contamination
- Do not dip the test strips above the maximum level mark
- Dip the test into buffer until one or two lines appear at the reaction zone (~15 seconds)
- Do not spill the samples into the reaction zone.
- Specimens may be potentially hazardous. Proper handling and disposal methods should be established.
- Do not use the test strips after the expiration date
- Do not use the test after damage of the packaging foil
- Use the test strips as soon as the test strips are removed from its immediate packaging.
- Store the test device in the sealed pouch at 2-30ºC. The test is stable through the expiration date printed on the sealed pouch. The test strips must remain in the sealed pouch until use. DO NOT FREEZE.

PROCEDURE

EXAMINATIONOF SUSPICIOUS SUBSTANCES FROM SURFACES

1. Prepare the desired number of test tubes by placing them in the test tube holder.
2. Transfer entire bottle of the extraction buffer solution into a test tube. If the extraction buffer has been cooled, wait until it has reached room temperature.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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!
8. 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.
9. Remove the strip from the test tube and place it horizontally on a flat surface.
10. 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 SOLID MATTER

1. Prepare the desired number of test tubes by placing them in the test tube holder.
2. 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.
3. Remove a swab from its packaging. Dip the swab into the test tube containing the extraction buffer for 3 seconds in order to moisten the swab
4. Using the tip of the swab, sample the solid substance to be examined. If the solid to be examined is a coated tablet, crush the tablet before sampling using the swab.
5. 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.
6. 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.
7. 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!

8. 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.
9. Remove the strip from the test tube and place it horizontally on a flat surface.
10. 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

1. Prepare the desired number of test tubes by placing them in the test tube holder.
2. 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.
3. Add 1 drop of the liquid to be examined to the buffer.
4. Remove a swab from its packaging and use the smooth end to stir the mixture in the tube.
5. 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.
6. 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!
7. 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.
8. Remove the strip from the sample and place it horizontally on a flat surface.
9. 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

1. Rapid Response™ Fentanyl Test Strips (Liquid, Powder) 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. The test does not distinguish between different fentanyl analogues and certain medications. Other compounds found in illicit drugs may display cross reactivity with the test device. Cross reactivity with other emerging fentanyl analogs, such as U-47700, cyclopentyl fentanyl, is yet to be determined.

PERFORMANCE CHARACTERISTICS

ACCURACY

Accuracy of the Fentanyl 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	61	0	61
	Negative	2	56	58
Total Results		63	56	119
% Agreement		96.8%	100%	98.3%

SENSITIVITY

The sensitivity of the Fentanyl 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	50	50	0
-50% Cut-off	50	50	0
-25% Cut-off	50	50	0
Cut-off	50	22	28
+25% Cut-off	50	0	50
+50% Cut-off	50	0	50
+300% Cut-off	50	0	50

SPECIFICITY

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

Fentanyl 200 related compound	
Carfentanil	5,000 ng/ml
Butyryl Fentanyl	700 ng/ml
p-Fluoro Fentanyl	200 ng/ml
Acetyl Fentanyl	150 ng/ml
Fentanyl	200 ng/ml
Furanyl Fentanyl	500 ng/ml
Valeryl Fentanyl	700 ng/ml
Ocfentanil	250 ng/ml
3-Methyl Fentanyl	500 ng/ml
Remifentanil	70,000 ng/ml
Sufentanil	100,000 ng/ml

*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

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.

(-)-Ephedrine	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine	Dextromethorphan	Pheniramine
4-Dimethyllaminoantiyrine	Dextrorphan tartrate	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Ibuprofen	Vitamin C (Ascorbic
Bilirubin	Imipramine	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Caffeine	Lidocaine	Ibuprofen
Chloroquine	Methadone	

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GLOSSARY OF SYMBOLS

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

BTNX Inc.
570 Hood Road, Unit 23 Markham, ON, L3R 4G7, Canada Technical Support:1-888-339-9964