SpecCheck One Step Fentanyl Test Panel for Surfaces, Solids and Liquids
Package Insert

A rapid, one step test for the qualitative detection of Fentanyl on surfaces, solids and in liquids.

Introduction

The SpecCheck Fentanyl (FYL) Surface Test is a lateral flow chromatographic immunoassay for the qualitative detection of Fentanyl/Norfentanyl in liquid and powder substances at the cut-off concentration of 200 ng/mL.
The SpecCheck Fentanyl (FYL) Surace Test Kit is able to detect Fentanyl and many other Fentanyl analogues such as Carfentanil, Acetyl Fentanyl, Butyryl Fentanyl, Remifentanil, Ocfentanil, Sufentanil, p-Fluoro Fentanyl, Furanyl Fentanyl, Valeryl Fentanyl, and 3-Methyl Fentanyl.

Test	Calibrator	Cut-off
Fentanyl (FEN / FYL)	Fentanyl	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 used. It is intended for laboratory or professional use only.

Fentanyl

Fentanyl is a synthetic opiate used to manage severe pain and post-surgery pain in medicine. It is 100 times more powerful than morphine at the equivalent dose by weight. Fentanyl and its analogues pose a potential hazard to a variety of responders who could come into contact with these drugs in the course of their work. Possible exposure routes to fentanyl can vary based on the source and form of the drug. Responders are most likely to encounter illicitly manufactured fentanyl and its analogues in powder, tablet, and liquid form. Potential exposure routes of greatest concern include inhalation, mucous membrane contact, ingestion, and percutaneous exposure (e.g., needlestick). Any of these exposure routes can potentially result in a variety of symptoms that can include the rapid onset of life-threatening respiratory depression. Initial safe standard operating procedures involve responders assessing the risk for hazards, and determining whether fentanyl or other drugs are suspected to be present. The SpecCheck surface screen can be used to assist responders determine risk and possible exposure to the Fentanyl compound.

Principle

The specimen migrates up the test strip by capillary action. If the drug compound is present below the cut off level, the antibody will bind with the drug protein conjugate and a visible coloured line will form in the test region. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody and a 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 Panel contains mouse monoclonal anti-Fentanyl antibody-coupled particles and Fentanyl-protein conjugate. A goat antibody is employed in the control line system.

Precautions

- For in vitro diagnostic use only. Do not use after the expiration date.
- The test Panel should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test Panel should be discarded according to federal, state and local regulations.

Storage

The kit can be stored at room temperature or refrigerated (2-30°C). The test Panel is stable through the expiration date printed on the sealed pouch. The test Panel must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Materials

Materials Provided

- Test strip / panel
- Buffer solution
- Package insert
- Plastic specimen container
- Plastic tubes
- Tube Rack

Materials Required But Not Provided

- Timer

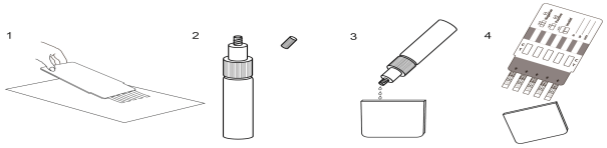
Specimen Collection and Preparation

The test strip and buffer solution should be brought to room temperature (15-30°C) prior to screening. Do not open pouches until ready to perform the test.

FOR SURFACES:

1. Remove the test device from the foil pouch.
2. Using the test strip (pad facing down), gently swipe across the surface to be screened.
3. Add one vial of buffer solution to a plastic tube and place tube In the rack provided.
4. Insert the test strip into the tube containing the buffer solution and hold for approximately 10-15 seconds (until the pad is completely saturated). An immediate reaction will start to take place.
5. Remove the test strip from the sample cup and place on a non-absorbent surface.
6. Visually examine the strip under bright, direct lighting in order to avoid missing fainter bands. The result can normally be read off the strip immediately, but if colour is slow to develop, you may need to wait up to two minutes for well-defined bands to appear.
7. Wait for lines to appear on the membrane and read the results after 5 minutes.

DO NOT INTERPRET RESULT AFTER 10 MINUTES.



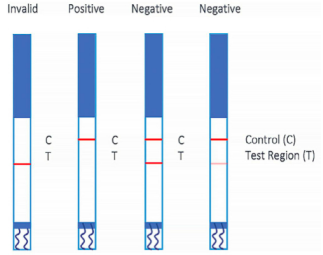
FOR SOLIDS:

1. Add approximately 1mg of the substance in question to the buffer solution vial.
2. Place the cap onto the tube and shake for 5-10 seconds. Wait for 30 sec.
3. Remove the cap from the tube.
4. Pour the buffer solution (containing the specimen) into the plastic container provided.
5. Insert the test strip into the specimen and hold for 10-15 seconds until the pad is completely saturated. An immediate reaction will start to take place.
6. Remove the test strip from the sample cup and place on a non-absorbent surface.
7. Visually examine the strip under bright, direct lighting in order to avoid missing fainter bands. The result can normally be read off the strip immediately, but if colour is slow to develop, you may need to wait up to two minutes for well-defined bands to appear.
8. Wait for lines to appear on the membrane and read the results after 5 minutes.

DO NOT INTERPRET RESULT AFTER 10 MINUTES.

Interpretation of Results

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Fentanyl concentration is below the detectable level (200ng/mL).
***NOTE:** The shade of red in the test line region (T) may vary, but it should be considered negative whenever there is even a faint pink line.
POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Fentanyl concentration exceeds the detectable level (200ng/mL).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test Panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.



Procedural Control

A procedural control is included in the test. A red 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 testing practice to confirm the test procedure and to verify proper test performance.

1. The One Step Fentanyl Test Panel(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.[1,2]
2. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in the sample.
3. 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.
4. Test does not distinguish between drugs of abuse and certain medications.

Reproducibility

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

Fentanyl conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
100	40	40 negative	>99%
300	40	40 positive	>99%
400	40	40 positive	>99%

Analytical Sensitivity

A drug-free buffer pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

FEN Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
100	-50%	30	30	0
150	-25%	30	28	2
200	Cut-off	30	16	14
250	+25%	30	2	28
300	+50%	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in buffer by The One Step Fentanyl Test Panel(Powder) at a read time of 5 minutes.

Drug	Concentration (ng/ml)
Norfentanyl	15
Fentanyl	200
Sufentanyl	50,000
Fenfluramine	50,000

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 One Step Fentanyl Test Panel(Powder) at a concentration of 100 µg/mL.

Acetophenetidin	*l-Cotinine*	*Cortisone*	*d-Pseudoephedrine*
N-Acetylprocainamide	*Creatinine*	*Ketoprofen*	*Quinidine*
Acetylsalicylic acid	*Deoxycorticosterone*	*Labetalol*	*Quinine*
Aminopyrine	*Dextromethorphan*	*Loperamide*	*Salicylic acid*
Amoxicillin	*Diclofenac*	*Meprobamate*	*Serotonin*
Ampicillin	*Diflunisal*	*Methoxyphenamine*	*Sulfamethazine*
l-Ascorbic acid	*Digoxin*	*Methylphenidate*	*Sulindac*
Apomorphine	*Diphenhydramine*	*Nalidixic acid*	*Tetracycline*
Aspartame	*Ethyl-p-aminobenzoate*	*Naproxen*	*Tetrahydrocortisone,*
Atropine	*β-Estradiol*	*Niacinamide*	*3-Acetate*
Benzilic acid	*Estrone-3-sulfate*	*Nifedipine*	*Tetrahydrocortisone*
Benzoic acid	*Erythromycin*	*Norethindrone*	*Tetrahydrozoline*
Bilirubin	*Fenoprofen*	*Noscapine*	*Thiamine*
d,l-Brompheniramine	*Furosemide*	*d,l-Octopamine*	*Thioridazine*
Caffeine	*Gentisic acid*	*Oxalic acid*	*d,l-Tyrosine*
Cannabidiol	*Hemoglobin*	*Oxolinic acid*	*Tolbutamide*
Chloralhydrate	*Hydralazine*	*Oxymetazoline*	*Triamterene*
Chloramphenicol	*Hydrochlorothiazide*	*Papaverine*	*Trifluoperazine*
Chlorothiazide	*Hydrocortisone*	*Penicillin-G*	*Trimethoprim*
d,l-Chlorpheniramine	*o-Hydroxyhippuric acid*	*Perphenazine*	*d,l-Tryptophan*
Chlorpromazine	*3-Hydroxytyramine*	*Phenelzine*	*Uric acid*
Cholesterol	*d,l-Isoproterenol*	*Prednisone*	*Verapamil*
Clonidine	*Isoxsuprine*	*d,l-Propanolol*	*Zomepirac*

1. Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.
2. Ambre J. J. Anal. Toxicol. 1985; 9:241.
3. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
5. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.
6. Robert DeCresce. Drug Testing in the workplace, 114.
7. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA 1982; 487.

ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.
National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686
Center for Substance Abuse Treatment www.health.org 1-800-662-HELP
The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL
American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS


Keep away from sunlight

Store between 4°C and 30°C


Keep dry


Do not re-use

Manufactured By:
Spectrum® medical diagnostics
90 Burnhamthorpe Road West
Suite 1400, 14th floor
Mississauga, ON
L5B 3C3
P: 1-866-287-2425