Fentanyl - Single Drug Urine Test Panel

Catalogue No. See Box label

For in vitro diagnostic use

The Fentanyl Urine Test Panel is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Fentanyl in human urine at a specified cutoff level ***for use in employment and insurance testing.***

The test provides only preliminary test results. A more specific alternative analytical method should be used in order to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods.

The test is not intended to distinguish between prescription drug or illicit drug use.

Professional judgment should be exercised with any drug test result, particularly when the preliminary result is positive.

WHAT IS FENTANYL URINE TEST PANEL?

The Fentanyl Urine Test Panel is an immunochromatographic assay for the qualitative determination of Fentanyl in human urine.

WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

Drug (Identifier)	Calibrator	Cut-off level	Minimum detection time	Maximum detection time
Fentanyl (FTY)	Fentanyl	200 ng/mL	1-4 hours	1-3 days

WARNINGS AND PRECAUTIONS

1. Not to be used for clinical diagnosis.
2. This kit is for external use only. Do not swallow.
3. Discard after first use. The test cannot be used more than once.
4. Do not use test kit beyond expiry date.
5. Do not use the kit if the pouch is punctured or not sealed.
6. Keep out of the reach of children.
7. Do not read after 5 minutes.

CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch contains a test and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Leaflet with instructions for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection cup
2. Timer or clock

STORAGE AND STABILITY

Store at 4ºC-30ºC (40ºF-86ºF) in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

SPECIMEN COLLECTION

WHEN TO COLLECT URINE FOR THE TEST?

The minimum detection time is 1-4 hours, urine samples may be collected 1-4 hours after the suspected drug use.

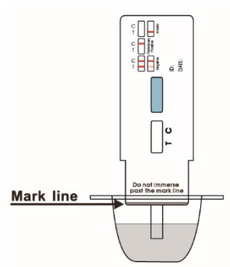
HOW TO COLLECT URINE?

1. Urinate directly into the urine collection cup. Urine samples may be refrigerated at 2ºC-8°C (36ºF-47ºF) and stored up to forty-eight hours. For longer storage, freeze the samples at -20°C (-4ºF) or below.
2. Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well-mixed before analysis. Cloudy specimens should be centrifuged before analysis
3. Use only clear aliquots for testing.

TEST PROCEDURE

Test should be in room temperature 18ºC-30ºC (65ºF-86ºF)

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample for approximately 10 seconds. **Make sure that the urine level is not above the marked line printed on the front of the device.**
4. Re-cap the device and lay it flat on a clean, dry, non-absorbent surface.
5. Read the drug test results at 5 minutes. **Do not read results after 5 minutes.**



Note: *Results after more than 5 minutes may be not accurate and should not be read.*

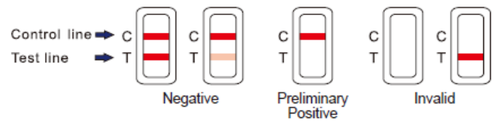
READING THE RESULTS

Negative (-)
A colored band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Preliminary positive (+)
A colored band is visible in each control region. No color band appears in the appropriate test region. It indicates a preliminary positive result for the corresponding drug of that specific test zone.

Invalid
If a colored band is not visible in each of the control region or a color band is only visible in each of the test region, the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor with the lot number.

Note: There is no meaning attributed to line color intensity or width.



A preliminary positive test result does not always mean a person took drugs and a negative test result does not always mean a person did not take drugs. There are a number of factors that influence the reliability of drug tests.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample should be tested by a laboratory in order to determine if a drug is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by the Fentanyl Urine Test Panel. 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 the Fentanyl Urine Test Panel. If the sample is diluted, or the sample is adulterated that may cause 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 anything but urine.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

Note: The test provides only preliminary test results. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods. Professional judgment should be exercised with any drug test result, particularly when the preliminary result is positive.

SUMMARY

Fentanyl is a potent, synthetic narcotic analgesic with a rapid onset and short duration of action. It was first synthesized by Janssen Pharmaceutica (Belgium) in the late 1950s, and it is approximately 100 times more potent than morphine. Fentanyl 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. Fentanyl is frequently given intrathecally as part of spinal anesthesia or epidurally for epidural anesthesia and analgesia.

PRINCIPLE

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

When the absorbent end is immersed into urine specimen, the urine is absorbed into the device by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), respective drug monoclonal antibody conjugate binds to the respective drug-protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, 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 potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials.

Even though there is an internal procedural control line in the test device in the Control Region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of test received, each new shipment, each new operator and monthly to determine that tests are working properly. This will ensure that the end user has clear understanding of when to perform quality control testing.

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty clinical urine specimens were analyzed by GC-MS and by the Fentanyl Urine Test Panel. Each test was read by three viewers. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug test	Result		Drug-free	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	%Agreement with GC/MS (95%CI)
FTY	Viewer A	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)

Precision and Sensitivity

To investigate the precision and sensitivity, each drug sample was analyzed at the following concentrations: cutoff - 100%, cutoff - 75%, cutoff - 50%, cutoff - 25%, cutoff, cutoff +25%, cutoff + 50%, cutoff + 75%and the cutoff + 100%. All concentrations were confirmed with GC-MS. The study was performed 2 runs /day and lasted 25 days using three different lots of the Fentanyl Urine Test Panel. Totally 3 operators participated in the study of the Fentanyl Urine Test Panel. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day), for a total of 50 determinations per concentration per lot of the Fentanyl Urine Test Panel.

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Results Negative/ Positive		
			Lot 1	Lot 2	Lot 3
FTY	0	50	50/0	50/0	50/0
	5	50	50/0	50/0	50/0
	10	50	50/0	50/0	50/0
	15	50	50/0	50/0	50/0
	20	50	4/46	5/45	5/45
	25	50	0/50	0/50	0/50
	30	50	0/50	0/50	0/50
	35	50	0/50	0/50	0/50
	40	50	0/50	0/50	0/50

Specificity and Cross Reactivity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present 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.

Items	Concentration (ng/mL)
Fentanyl (FTY)	
Norfentanyl	20
Fentanyl	200

Effect of Urinary Specific Gravity

12 urine samples with density ranges (1.005-1.025) were collected and spiked with Fentanyl at 25% below and 25% above cutoff levels. Each sample was tested by three batches of the Fentanyl Urine Test Panel. Three laboratory assistants read the result per batch of the Fentanyl Urine Test Panel. 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 of negative urine pool was adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with Fentanyl at 25% below and 25% above cutoff levels. Each sample was tested by three batches of the Fentanyl Urine Test Panel. Three laboratory assistants read the result per batch of the Fentanyl Urine Test Panel. The result demonstrates that varying range of pH do not interfere with the performance of the test.

Interfering Substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a drug concentration 25% below the cutoff, and urine with a drug concentration 25% above the cutoff for Fentanyl. All potential interferents were added at a concentration of 100 μg/mL. None of the urine samples tested showed any deviation from the expected results.

3-Acetylmorphine
Acetaminophen
Acetylcodeine
Aciclovir
Acid Reducer
Adrenalin Hydrochloride
Airshield
Alprazolam
Aminophylline
Amiodarone Hydrochloride
Amitriptyline
Amlodipine Mesylate
Amoxicillin
Amphetamine
Ampicillin
Aripiprazole
Aspirin
Atomoxetine
Atorvastatin
Atropine
Barbital
Benzoylecgonine
Caffeine
Captopril
Carbamazepine
Cefaclor
Cefalexin
Cefradine
Ciprofloxacin Hydrochloride
Citalopram
Clarithromycin
Clomipramine
Clonazepam
Clopidogrel Bisulfate
Clozapine
Cocaine Hydrochloride
Codeine Phosphate
Cortisone
CVS
Dayquil
Dextromethorphan Hydrobromide
Dextropropoxyphene Napsylate
Diazepam
Diclofenac Sodium
Digoxin
Diphenoxylate Hydrochloride
Dirithromycin
Domperidone
Dopamine Hydrochloride
Doxepin
Doxylamine
Duloxetine
Ecstasy Hydrochloride
Enalapril Maleate
Ephedrine Hydrochloride
Esomeprazole
Estrogen
Estroven
Extenze
Fenofibrate
Flunitrazepam
Fluoxetine Hydrochloride
Fluvoxamine
Fuel
Furosemide
Gabapentin
Glibenclamide
Gliclazide
Glipizide
Glucosamine Chondroitin
Glucose
Haloperidol
Heartburn Relief
Hydrochlorothiazide
I Caps
Ibuprofen
Isosorbide Dinitrate
Ketamine
Ketoconazole
Lamotrigine
Lansoprazole
Levofloxacin
Levonorgestrel
Levothyroxine Sodium
Lidocaine Hydrochloride
Lisinopril
Lithium Carbonate
Liverite
Lofexidine Hydrochloride
Loperamide
Loratadine
Magnesium
Mega-T Plus
Methadone
Methylamphetamine
Metoprolol Tartrate
Mifepristone
Mirtazapine
Montelukast
Morphine
Mosapride
Naloxone Hydrochloride
Naltrexone Hydrochloride
Naproxen
Nifedipine
Nikethamide
Nimetazepam
Nimodipine
Nitrazepam
Nitroglycerin
Noscapine
Olanzapine
Omeprazole
Oxazepam
Oxycodone Acetaminophen
Pantoprazole
Papaverine
Penfluridol
Penicillin V Potassium
Pethidine Hydrochloride
Phenobarbital
Phentolamine
Phenytoin Sodium
Pholcodine
Pioglitazone Hydrochloride
Piracetam
Pravastatin Sodium
Prednisone Acetate
Procaine Hydrochloride
Propranolol Hydrochloride
Propylthiouracil
Pseudoephedrine Hydrochloride
Pseudoephedrine Hydrochloride
Quetiapine
Ranitidine Hydrochloride
Rifampin
Secobarbital
Sertraline Hydrochloride
Sildenafil Citrate
Simvastatin
Sinus&Allergy
Spironolactone
Tetracycline
Thebaine
Topiramate
Tramadol Hydrochloride
Trazodone
Triamterene
Valproate Sodium
Venlafaxine Hydrochloride
Vitamin B1
Vitamin B2
Vitamin C
Zencore Plus2

BIBLIOGRAPHY OF SUGGESTED READING

Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.
Ellenhorn, M.J. and Barceloux, D. G Medical Toxicology. Elservier Science Publishing Company, Inc., New York, 1988
Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring – Verlag, 1977.
Harvey, R.A., Champe, P.C. Lippincotts Illustrated Reviews. Pharmacology. 91-95, 1992.
Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986
Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

INDEX OF SYMBOLS


Keep away from sunlight

Store between 4ºC - 30ºC (40ºF - 86ºF)


Keep dry


Do not re-use

In vitro diagnostic use

Distributed by:
Alere Toxicology Services
Portsmouth, VA 23704 USA

Rev. A2

Rel.: 2017/12/14