DrugCheck® Dip Drug Test

The **DrugCheck® Dip Drug Test** is an immunochromatographic assay for the qualitative detection of Fentanyl in human urine at a cutoff concentration indicated in the table below.

The test may yield preliminary positive results when prescription drugs are ingested at prescribed doses. It is not intended to distinguish between prescription use and abuse of any drug. There are no uniformly recognized cutoff concentration levels for any drug in urine. The test provides only preliminary test results. A more specific alternative 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 exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use and for professional testing use only.

WHAT IS DRUGCHECK® DIP DRUG TEST?

The **DrugCheck® Dip Drug Test** is a rapid test for qualitative detection of Fentanyl in human urine. The **DrugCheck® Dip Drug Test** yields a positive result when drug and/or its metabolite in urine is at or exceeds its cutoff concentration.

WHAT IS THE CUT-OFF VALUE?

Drug Test	Drug (Identifier)	Cut-off
Fentanyl (FYL)	Fentanyl	10 ng/mL

PRINCIPLE

The **DrugCheck® Dip Drug Test** is an immunoassay. During testing, a urine specimen migrates upward on the test strip. A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip, while a drug-negative urine specimen will generate a line in the test line region. A colored line will always appear at the control line region, indicating that proper volume of specimen has been added.

The test contains a membrane strip coated with drug-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 individual drug on the list indicated in the table above.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use and for professional testing use only.
2. For external use only.
3. For single use. Discard after first use.
4. Do not use the test if the pouch is punctured or not well sealed.
5. Do not use after expiration date.
6. Keep out of the reach of children.
7. The used dip test and urine specimen should be discarded according to federal, state and local regulations.

CONTENT OF THE PACKAGE

Included in package:
- User Instruction
- Dip Test (inside foil pouch)

Not included in package:
- Watch, Timer or Clock
- Collection Cup

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4°C - 30°C. The test is stable through the expiration date printed on the sealed pouch. The dip test must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE. Do not use beyond the expiration date.

WHEN TO COLLECT URINE FOR THE TEST?

You can use urine from any time of the day. The minimum detection time varies for different drugs.

HOW TO COLLECT URINE?

1. When you are ready to begin, remove the dip test from the sealed foil pouch.
2. Notice the colored tape on each strip indicates the name of the drug you are testing for.
3. Fill the collection cup with a fresh urine sample. Do not over-fill.

HOW TO DO THE TEST?

For Single Dip Strip

1. Insert the test strip into the urine sample for 10 to 15 seconds. DO NOT let the urine sample touch the conjugate pad on the strip, this could cause inconclusive drug test results. Place the test on a flat surface.
2. Wait for 5 minutes (start timing immediately after dip is taken out of the urine sample). Read result at 5 minutes. DO NOT READ RESULT AFTER 5 MINUTES.

For Single Dip Cassette

1. Remove the cap from the dip test. Insert the exposed test strip into the urine sample for 10 to 15 seconds. DO NOT let the urine sample touch the plastic device, this could cause inconclusive drug test results.
2. Insert the cap firmly back onto the dip test and lay it on a flat surface.
3. Wait for 5 minutes (start timing immediately after dip test is taken out of the urine sample). Read result at 5 minutes. DO NOT READ RESULT AFTER 5 MINUTES.

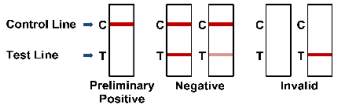
Note: Results after more than 5 minutes may not be accurate and should not be read.

READING THE RESULTS

Preliminary Positive (+): If a line appears in the C - Control area but NO line appears in the T - Test area, then it indicates a Preliminary Positive result for the corresponding drug.

Negative (-): If a line appears in both the C - Control and T - Test area, then it indicates a Negative result for the corresponding drug regardless of how dark or light the line may appear.

Invalid: If at 5 minutes, NO line appears in the C - Control area, then the results are Invalid. In such case, retest with a new dip test.



Note: Each test strip needs to be looked at individually. Each line may vary in color and darkness or the rate at which the line appears. (DO NOT compare lines within the same test strip or between different test strips).

A positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by a laboratory in order to determine if a drug of abuse is actually present.

WHAT IS A FALSE POSITIVE TEST?

The definition of a false positive test would be an instance where the test result from the **DrugCheck® Dip Drug Test** is positive, even though the initial target drug is not present in the sample. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may also 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 target drug is present but is not detected by the **DrugCheck® Dip Drug Test**. If the sample is diluted, or if the sample is tainted or contaminated with a substance this could cause false negative results.

TEST LIMITATIONS

1. The **DrugCheck® Dip Drug Test** 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. There is a possibility that interfering substances in the urine specimen may cause erroneous results.
3. Substances, such as bleach and/or alum, in urine specimens may produce erroneous results.
4. A positive result does not indicate intoxication, the concentration of drug in the urine, or the route of drug administration.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

QUALITY CONTROL

If you work in a laboratory, you should perform quality control testing and you should read this section.

A procedural control is included in the test. A color 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. Quality control testing should be done with each new lot and each new shipment. It should be done every thirty days to check storage. Please contact our Technical Support at 507-526-3951 for controls that work with the dip test.

PERFORMANCE CHARACTERISTICS

Accuracy

In the comparison study, the **DrugCheck® Dip Drug Test** was compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for Fentanyl. Clinical specimens were quantified by GC/MS analysis before testing. The following results are tabulated from these clinical studies:

	Positive	Negative
Negative Samples	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19
Near Cut-off Positive Samples [between cut-off and 150% of cut-off]	20	0
Positive Samples [>150% of cut-off]	20	0
Agreement with GC/MS	97.5%	100%

Overall Agreement with GC/MS is 99%.

Reproducibility

Reproducibility studies were carried out using commercially available stock solutions of the drug analyte listed. Dilutions were made from the stock solution of Fentanyl to the concentrations specified in the following table. The results are listed in the following table.

Fentanyl Concentration (ng/mL)	Total Number of Determinations	Result	Precision
No Drug Present	60	60 negative	>99%
5	60	60 negative	>99%
15	60	60 positive	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug concentration Cut-off Range	n	Fentanyl	
		-	+
0% Cut-off	30	30	0
-50% Cut-off	30	30	0
-25% Cut-off	30	30	0
Cut-off	30	4	26
+25% Cut-off	30	0	30
+50% Cut-off	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the **DrugCheck® Dip Drug Test** at a read time of 5 minutes.

Drug	Concentration
Fentanyl	10 ng/mL
Valeryl fentanyl HCl	5,000 ng/mL
Butyryl fentanyl	50 ng/mL
Furanyl fentanyl HCl	250 ng/mL
Norfentanyl oxalate	25 ng/mL
Ocfentanil	5,000 ng/mL
Para-Fluorofentanyl	25 ng/mL
(±)-cis-3-Methylfentanyl HCL	250 ng/mL
Acetyl fentanyl	1,000 ng/mL

EFFECT OF URINARY SPECIFIC GRAVITY

Urine samples of normal, high, and low specific gravity ranges (1.000-1.035) were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **DrugCheck® Dip Drug Test** was tested using twelve drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

EFFECT OF URINARY PH

The pH of an aliquot of negative urine pool was adjusted to pH ranges of 4.0 - 9.0 and spiked with drugs at 25% below and 25% above cut-off levels. The spiked, pH-adjusted urine was tested with the **DrugCheck® Dip Drug Test**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

INTERFERENCE

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Fentanyl. The following compounds show no cross-reactivity when tested with the **DrugCheck® Dip Drug Test** at concentrations of 100 µg/mL.

Non Cross-Reacting Compounds – Fentanyl		
Acebutolol Hydrochloride	Chlorpromazine Hydrochloride Tablets	Hippuric Acid
Acepromazine-d6 hydrochloride		Hydralazine hydrochloride
	Chloramphenicol	Hydromorphone
Acetaminophen	ChloralHydrate	Hydrocodone
N-Acetylprocainamide	Cholesterol	α-Hydroxyhippuric acid
Acetophenetidin	Chlorothiazide	21-Hydroxy progesterone
Alprazolam	Clomipramine	p-Hydroxymethamphetamine
Alphenal	Clonazepam	
Amoxicillin	Clonidine hydrochloride	Hydrocortisone
Ampicillin	Clozapine	Hydrochlorothiazide
Amitriptyline Hydrochloride Tablets	(-) Cotinine	-4-Hydroxyamphetamine HCL
	Cocaethylene	
S(+)Amphetamine	Cocaine Hydrochloride	Ibuprofen
R(-)-Amphetamine	Codeine	Imipramine
Amobarbital	Cortisone	Iprazid
(±)Amphetamine	Creatinine	Isoxsuprine hydrochloride
R-(-)-Apomorphine Hydrochloride	Cyclopentobarbital	Isoproterenol Hydrochloride Injection
	Citalopram hydrobromide	
Aprobarbital	Dextromethorphan	Ketamine hydrochloride
Aspirin	Desipramine	Ketoprofen
Aspartame	Diazepam	Emetine dihydrochloride hydrate
L-Ascorbic Acid	Diclofenac Sodium salt	
Atropine	Dicyclomine	Ephedrine-(+/-) hydrochloride
6-Acetylmorphine	Digoxin	
Acetylsalicylic acid	4-Dimethylaminoantipyrine	(-)-Ephedrine HCL
Benzphetamine	Dihydrocodeine HCL	[1R,2S] (-) Ephedrine
Benzilic acid	5,5-Diphenylhydantoin	Erythromycin
Benzoylecgonine	Diphenhydramine	Eserine
SS Benzoic Acid	Dopamine	Estazolam
Bilirubin, Mixed Isomers	Doxylamine	β-Estradiol
Brompheniramine maleate	Ecgonine methylester	(±)-EDDP
Buprenorphine	Ecgonine HCL	Ethyl-p-aminobenzoate
Buspirone hydrochloride	Efavirenz	JWH-018 pantanoic acid
Butalbital	Ethylone	JWH-073 butanoic acid
Butabarbital	EthylMorphine	Labetalol Hydrochloride
Cannabidiol	Fenoprofen	Levorphanol
Cannabinol	Furosemide	Loperamide Hydrochloride
Caffeine	Gentisic acid	Lorazepam
Cetirizine Hydrochloride	D-Glucuronic acid	Maprotiline hydrochloride
Chlordiazepoxide HCL	Glutethimide	(±)-MDEA
Chlorothiazide	Guaifenesin	(±)-MDA
Chloroquine	Hemoglobin porcine	Meperidine
Chlorpheniramine Maleate	Heroin hydrochloride	Meprobamate

Non Cross-Reacting Compounds – Fentanyl		
Methamphetamine hydrochloride	Phenylethylamine	Terfenadine
	L-phenylephrine	Terbutaline
(±)Methadone	Phenylpropanolamine hydrochloride	Tetraethylthiuram disulfide
S(+)D-methamphetamine		Tetrahydrocannabinol, Delta-8-((-)-delta-8-THC)
L-methamphetamine	Prednisolone	
Methylphenidate	Prednisone Acetate Tablets	Tetracycline
(±)-MDMA		Tetrahydrocortisone 3-(β-D-glucuronide (-)-delta-9-THC)
(±)-MDPV	Procaine HCL	
Methyprylon	Promazine hydrochloride	
Morphine	Promethazine	(+/-)11-Hydroxy-delta-9-THC
Morphine-3β-D-glucuronide	Propoxyphene,d-	
	Propranolol Hydrochloride	(-)-11-nor-9-Carboxy-delta9-THC
Morphine sulfate salt solution	Pseudoephedrine	
	Phendimetrazine	Thebaine
Nalidixic acid	Phenytoin	Theophylline
Nalorphine hydrochloride	Quinine	Thioridazine
Naproxen	Quinidine	Thiamine, (Vitamin B1 Tablets) HCL
Naloxone	Quinacrine	
Naltrexone hydrochloride	Ranitidine Hydrochloride Tablets	DL-Thyroxine
Nicotinamide (vitamin B3)		Tolbutamide
Nimesulide	Nortriptyline Hydrochloride	Tramadol
Nifedipine	Salicylic Acid	Triamterene
Norcodeine	Secobarbital	Trimipramine
Nordoxepin hydrochloride	Serotonin	Tryptamine
Norfloxacin Capsule	Noroxymorphone HCL	Trifluoperazine dihydrochloride
Norethisterone Tablets	Nylidrin hydrochloride	
d-Norpropoxyphene maleate salt	(±)-Octopamine HCL	DL-Tryptophan
	Oxalic Acid	Triazolam
Noscapine	Oxolinic Acid	Trans-2-phenylcyclo-propylamine hydrochlride
PCP	Oxycodone	
Pentobarbital	Oxymetazoline	D/L-Tyrosine
Pentazocine	Papaverine	Tyramine
Perphenazine	(±)-Octopamine HCL	Uric Acid
Penicillin G Sodium salt	Sertraline HCl	Verapamil Hydrochloride
Phenelzine sulfate salt	Sulfamethazine, min 99%	Valproic acid
Phenobarbital	Sulindac	Zomepirac
Phentermine HCL	Temazepam	

BIBLIOGRAPHY OF SUGGESTED READING

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. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

ADDITIONAL INFORMATION AND REFERENCES

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 1-800-729-6686

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

SYMBOLS

	Use-By Date		Manufacturer
	Catalogue Number		Temperature Limit
	Do Not Use if Package is Damaged		Do Not Re-Use
	Keep Away from Sunlight		Consult Instructions for Use
	Keep Dry		Caution
	Batch Code		*In Vitro* Diagnostic Medical Device
	Authorized representative in the European Community		Contains Sufficient for <n> Tests

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