

One Step Methylenedioxypyrovalerone Drug of Abuse Test

(Dip Card)

For Forensic Use Only

INTENDED USE

The **One Step Methylenedioxypyrovalerone Drug of Abuse Test** is a lateral flow chromatographic immunoassay for the qualitative detection of Methylenedioxypyrovalerone (MDPV) in human urine specimen at the cut-off level of 1,000ng/mL. This assay is intended for forensic use only.

This assay provides only a preliminary qualitative test result. A more specific confirmatory reference method, such as Liquid chromatography tandem mass spectrometry (LC/MS/MS) or gas chromatography/mass spectrometry (GC/MS) must be use in order to obtain a confirmed analytical result.

BACKGROUND

'Bath salts', a form of designer drugs, also promoted as 'plant food' or 'research chemicals', is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised a'legal' highs. The technical term for 'bath salts' is substituted cathinone. Substituted cathinone is synthetic, concentrated version of the stimulant chemical in Khat. Khat is a plant that is cultivated and used in East Africa and the Middle East. It has a stimulant effect on the user and can be quite dangerous. The white crystals resemble legal bathing salts, thus the name of 'bath salts'. In 2009 and 2010 there was a significant rise in the abuse of synthetic cathinone, initially in the United Kingdom and the rest of Europe, and subsequently in the US and Canada. Established as one of the main ingredients for 'bath salts', among other synthetic stimulants like Mephedrone, Methylone, Butylone and Methedrone, MDPV started appearing around 2004 when it was popularized as a club drug, often used in combination with alcohol, GHB, cannabis and other abused drugs, for its desired effects such as euphoria, alertness, talkativeness, and sexual arousal. There are currently no prescribed used for the synthetic stimulants.

While synthetic stimulants appear to affect users in ways similar to amphetamines, ecstasy and cocaine, reports concerning aggression, tachycardia, paranoia and suicide suggest that they may be more acutely toxic. These negative effects have resulted in an increase of ER visits and hospitalizations, severe psychotic and violent episodes, self-inflicted wounds, suicide and an alarming increase in abuse-related deaths. U.S. Poison Control and National Drug Intelligence have all issued health warnings, noting nationwide emergency room visits related to these drugs. In October 2011, the DEA announced an emergency ban on MDPV, Methylone and Mephedrone, making testing for these substances more vital than ever.

The **One Step Methylenedioxypyrovalerone Drug of Abuse Test** is a rapid and convenient assay to perform before any further confirmatory lab testing can be order. It offers a competitive edge as an alternative method considering the limited number of the labs which have the testing capacity and the cost associated. The **One Step Methylenedioxypyrovalerone Drug of Abuse Test** yields a positive result when the concentration of Methylenedioxypyrovalerone in urine exceeds 1,000ng/mL.

PRINCIPLE

The **One Step Methylenedioxypyrovalerone Drug of Abuse Test** is an immunoassay based on the principle of competitive binding. Drug analyte, which may be present in the urine specimen, compete against its respective drug conjugate for binding sites on its specific antibody.

During testing, urine specimen migrates upward by capillary action. A drug, if present in the urine 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 line 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 line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been applied and membrane wicking has occurred.

REAGENTS

The device contains a membrane strip coated with drug-protein conjugate (purified bovine albumin) at 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 Methylenedioxypyrovalerone.

PRECAUTIONS

- For Forensic Use Only.
- For single use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until ready to use.
- Use of gloves is recommended to avoid unnecessary contact with the specimen.
- The used device and urine specimen should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store in original package at 2 °C - 30 °C (36 °F - 86 °F). DO NOT FREEZE. The test is stable through the expiration date printed on the labels.

SPECIMEN COLLECTION AND PREPARATION

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be allow settling to obtain a clear specimen for testing.

SPECIMEN STORAGE

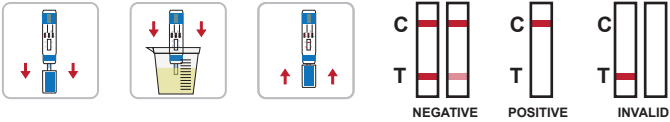
Urine specimen collected for later testing may be stored at 2 °C - 8 °C (36 °F - 46 °F) for up to 48 hours. For prolonged storage, specimens may be frozen and stored at below -20 C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

- Materials Provided:**
- Dip cards
  - Desiccants
  - Package insert
- Materials Required But Not Provided:**
- Specimen collection container
  - Disposable gloves
  - Timer

INSTRUCTIONS FOR USE

- 1) Remove the dip card from the foil pouch.
- 2) Remove the cap from the dip card. Label the device with patient or control identifications.
- 3) Immerse the absorbent tip into the urine sample for 5 seconds. Urine sample should not touch the plastic device.
- 4) Replace the cap over the absorbent tip and lay the dip card on a clean, flat, and non-absorptive surface.
- 5) Read result at 5 minutes. **DO NOT INTERPRET RESULT AFTER 10 MINUTES.**



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

**NEGATIVE:** \*Two colored lines appear, one in the control region (C), and another one in the adjacent test region (T). This negative result indicates that the drug concentration is below the detectable level.

\*NOTE: The shade of color of the line(s) may vary, but it should be considered negative whenever there is even a faint distinguishable color line.

**POSITIVE:** One colored line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

**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 device. If the problem persists, discontinue using the lot immediately and contact your supplier.

QUALITY CONTROL

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.

LIMITATIONS

1. The **One Step Methylenedioxypyrovalerone Drug of Abuse Test** provides only a qualitative, preliminary analytical result. A secondary analytical method must be use to obtain a confirmed result. Liquid chromatography/mass spectrometry (LC/MS) or gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. A positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
4. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
5. If adulteration is suspected, the test should be repeated with a new urine specimen and a new test device.
6. Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive result is obtained.

PERFORMANCE CHARACTERISTICS

Precision							
Methylenedioxypyrovalerone							
Concentration (ng/mL)	Number of Test Samples Per Level	Positive			Negative		
		Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
No Drug Present	60	0	0	0	40	10	10
500	60	0	0	0	40	10	10
1500	60	40	10	10	0	0	0

**Analytical Sensitivity**

The cut-off concentration of the **One Step Methylenedioxypyrovalerone Drug of Abuse Test** is determined to be 1,000ng/mL. Test was run in 30 replicates with negative urine and standard control at ±25% cut-off and ±50% cut-off concentration levels. Test results are summarized below.

Percent of Cut-off Methylenedioxypyrovalerone Concentration in ng/mL	n	Test Result	
		Negative	Positive
0% Cut-off (No Drug Present)	30	30	0
-50% Cut-off (500ng/mL)	30	30	0
-25% Cut-off (750ng/mL)	30	30	0
Cut-off (1000ng/mL)	30	2	28
+25% Cut-off (1250ng/mL)	30	0	30
+50% Cut-off (1500ng/mL)	30	0	30

Analytical Specificity

To evaluate the specificity of the test, drug metabolites and other structurally related compounds, which are likely to be present in the urine specimen, were added to drug-free normal human urine. Then tested with the **One Step Methylenedioxypyrovalerone Drug of Abuse Test**. Positive results were produced when the concentrations are equal to or greater than the levels listed below for each compound.

Compound	Concentration (ng/mL)
Butylone	1,000
Ethylone	1,000
Methylone	10,000
Mephedrone	10,000
Methedrone	10,000
Pyrovalerone	4,000
Naphyrone	>100,000
Flephedrone	>100,000
Brompheniramine	>100,000
Methyprylon	>100,000
Zomepirac	>100,000

INTERFERENCE

Potentially 100µg/mL interfering substances were also added to drug-free urine or drug positive urine containing Methylenedioxypyrovalerone. None of the following substances tested at the concentration interfered with the **One Step Methylenedioxypyrovalerone Drug of Abuse Test**.

(-) Cotinine	(±)-MDA
(-)-Ephedrine HCL	Methylenedioxymethamphetamine-(-+/-)3/4
(-)-Epinephrine	Methaqualone
(±)Amphetamine	Methylphenidate
(±)Methadone	Morphine-3- $\beta$ -D-Glucuronide
[1R,2S] (-)- Ephedrine	Nalorphine
21-Hydroxyprogesterone	Naloxone
3-Hydroxytyramine	Nalidixic Acid
4-Dimethylaminoantipyrine	Naltrexone Hydrochloride
5,5-Diphenylhydantoin	Nicotinamide
Acetaminophen	Morphine Sulfate Salt Solution
Acepromazine—d6 Hydrochloride	Nifedipine
Amitriptyline	Norcodeine
Amobarbital	Norethindrone
Amoxicillin	d-Norpropoxyphene
Ampicillin	Noscapine HCL

Apomorphine	(±)-Octopamine HCL
Ascorbic Acid	Oxalic Acid
Aspartame	Oxazepam
Aspirin	Oxolinic Acid
Atropine	Oxycodone
Benzilic Acid	Oxymetazoline Hydrochloride
Benzoic Acid	p-Hydroxymethamphetamine
Benzoylcegonine	Papaverine Hydrochloride
Benzphetamine HCL	Penicillin-G
Bilirubin	Pentobarbital
Butabarbital	Perphenazine
Caffeine	Phenelzine
Cannabidiol	PCP
Cannabinol	Phenobarbital
Chloral Hydrate	Acebutolol Hydrochloride
Chloramphenicol	R(-)-Amphetamine
Chlorothiazide	Phentermine HCL
Chlorpheniramine Maleate	(+/-)-4-Hydroxyamphetamine HCL
Chlorpromazine Hydrochloride	Pentazocine
Cholesterol	L-Phenylephrine
Clomipramine Hydrochloride	Phenylpropanolamine Hydrochloride
Clonidine Hydrochloride	2-phenylethylamine HCL
Cocaethylene	Prednisolone
Cocaine Hydrochloride	Prednisone
Codeine	Procaine HCL
Cortisone	Promazine Hydrochloride
Creatinine	Promethazine
Dextromethorphan	Propranolol Hydrochloride
D-Glucuronic Acid	D-Propoxyphene
Diphenhydramine	Pseudoephedrine HCL
D-methamphetamine	Quinacrine
Doxylamine	Quinidine
Ecgonine Hydrochloride	Quinine
Ecgonine Methyl Ester	Ranitidine Hydrochloride
Ephedrine-(+/-) Hydrochloride	Salicylic Acid
Erythromycin	Sertraline HCl
Estradiol	Serotonin HCl
Estrone-3-Sulfate	Secobarbital
Fenoprofen	Sulfamethazine
Furosemide	Sulindac
Gentisic Acid	Temazepam
Glutethimide	Acetophenetidin
Guaiphenesin (Guaiacol Glyceryl Ether)	S(+)-Amphetamine
Hemoglobin Porcine	Tetracycline
Hippuric Acid	Tetrahydrocortisone 3-(B-D-Glucuronide)
Hydralazine hydrochloride	Tetrahydrozoline Hydrochloride
Hydrochlorothiazide	Thebaine
Hydrocodone	Thiamine
Hydrocortisone	Thioridazine
Ibuprofen	D, L-Thyroxine
Imipramine HCL	Tolbutamide
Iprazid	L-Methamphetamine

Isoproterenol Hydrochloride	Triamterene
Isoxsuprine Hydrochloride	Trifluoperazine Dihydrochloride
Ketamine Hydrochloride	Trimethoprim
Ketoprofen	Trimipramine
Labetalol Hydrochloride	Trans-2-Phenylcyclopropylamine Hydrochloride
Levorphanol	Tryptamine
Loperamide Hydrochloride	Chlordiazepoxide HCL
Loxapine Succinate Salt	Trazodone
Maprotiline Hydrochloride	Buspirone Hydrochloride
Meperidine	D, L-Tryptophan
Meprobamate	Tyramine
Methamphetamine Hydrochloride	DL-Tyrosine
Methoxyphenamine Hydrochloride	Uric Acid
N-Acetylprocainamide	Verapamil Hydrochloride
Noroxymorphone HCL	d,l-Metamfepramone HCL
o-Hydroxyhippuric Acid	Naproxen

EFFECT OF SPECIMEN SPECIFIC GRAVITY

The urine samples of normal, high, and low specific gravity ranges from 1.000 - 1.025 were spiked with drug analyte at 50% below and 50% above cut-off level respectively and tested using the **One Step Methylenedioxyprovalerone Drug of Abuse Test**. The results demonstrate that varying ranges of specimen specific gravity do not interfere with the performance of the test.

EFFECT OF SPECIMEN PH

The pH of an aliquot negative urine pool was adjusted to pH ranges of 4.5 - 9.0, and was spiked with drugs at 50% below and 50% above cut-off level. The spiked, pH-adjusted urine was tested with the **One Step Methylenedioxyprovalerone Drug of Abuse Test**. The results demonstrate that varying ranges of specimen pH do not interfere with the performance of the test.

REFERENCES

- [https://www.redwoodtoxicology.com/docs/services/3396\\_designer\\_stimulant\\_sellsheet.pdf](https://www.redwoodtoxicology.com/docs/services/3396_designer_stimulant_sellsheet.pdf)
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