

MDPV Rapid Test Cassette

(Urine)

Package Insert

A rapid test for the qualitative detection of 3, 4-methylenedioxypropyvalerone in human urine.
For medical and other professional *in vitro* diagnostic use only.

【INTENDED USE】
The MDPV Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of 3, 4-methylenedioxypropyvalerone in human urine at a cut-off concentration of 500 ng/mL.
This assay provides only a qualitative, preliminary 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) or Liquid Chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

【SUMMARY】
3, 4-methylenedioxypropyvalerone (MDPV) is a psychoactive recreational drug with stimulant properties which acts as a norepinephrine-dopamine reuptake inhibitor (NDRI). It was first developed in the 1960s by a team at Boehringer Ingelheim. MDPV remained an obscure stimulant until around 2004 when it was reportedly sold as a designer drug. Products labeled as bath salts containing MDPV were previously sold as recreational drugs in gas stations and convenience stores in the United States, similar to the marketing for Spice and K2 as incense. MDPV is the 3,4-methylenedioxy ring-substituted analog of the compound pyrovalerone, developed in the 1960s, which has been used for the treatment of chronic fatigue and as an anorectic, but caused problems of abuse and dependence. However, despite its structural similarity, the effects of MDPV bear little resemblance to other methylenedioxy phenylalkylamine derivatives such as 3,4-methylenedioxy-N-methylamphetamine (MDMA), instead producing primarily stimulant effects with only mild entactogenic qualities. MDPV undergoes CYP450 2D6, 2C19, 1A2, and COMT phase 1 metabolism (liver) into methylcatechol and pyrrolidine, which in turn are glucuronated (uridine 5'-diphospho-glucuronosyl-transferase) allowing it to be excreted by the kidneys, with only a small fraction of the metabolites being excreted into the stools. No free pyrrolidine will be detected in the urine. The MDPV Rapid Test Cassette (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of 3,4-methylenedioxypropyvalerone in urine. The MDPV Rapid Test Cassette (Urine) yields a positive result when 3,4-methylenedioxypropyvalerone in urine exceeds 500 ng/mL.

【PRINCIPLE】
The MDPV Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a urine specimen migrates upward by capillary action. 3,4-methylenedioxypropyvalerone, if present in the urine specimen below 500 ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody-coated particles will then be captured by immobilized 3, 4-methylenedioxypropyvalerone conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the 3, 4-methylenedioxypropyvalerone level exceeds 500 ng/mL because it will saturate all the binding sites of anti-3, 4-methylenedioxypropyvalerone antibodies.
A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration lower than the cut-off will generate a line in the test line region. 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 added and membrane wicking has occurred.

【REAGENTS】
The test contains mouse monoclonal anti-3, 4-methylenedioxypropyvalerone antibody-coupled particles and 3, 4-methylenedioxypropyvalerone-protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】
• For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
• The test 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 should be discarded according to local regulations.

【STORAGE AND STABILITY】
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Cross-Reactivity
A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or 3, 4-methylenedioxypropyvalerone positive urine. The following compounds show no cross-reactivity when tested with the MDPV Rapid Test Cassette (Urine) at a concentration of 100 µg/mL.

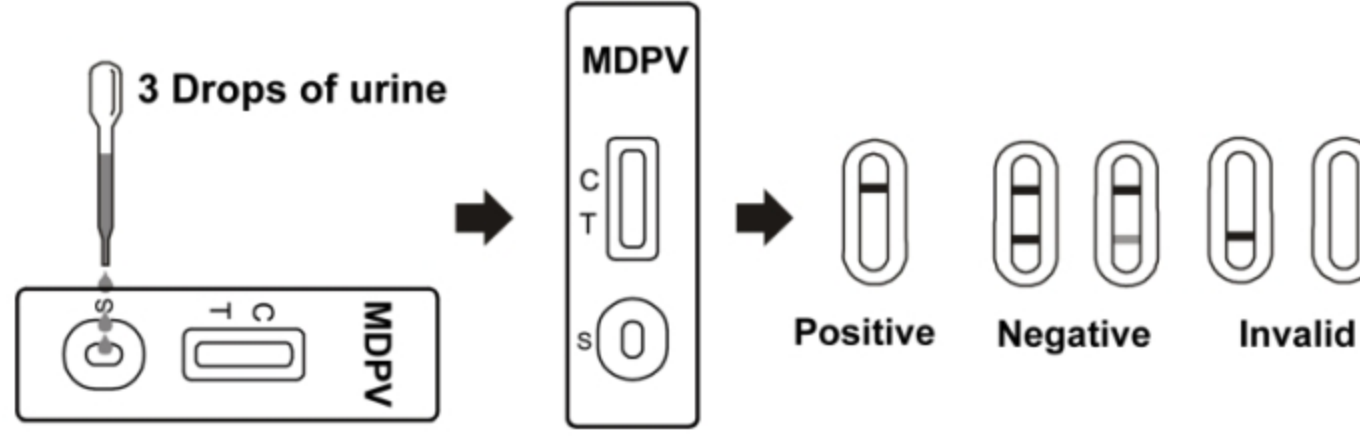
Non Cross-Reacting Compounds			
Acetone	(+/-)-Chlorpheniramine	Hemoglobin	Pheniramine
Albumin	Creatine	Ibuprofen	Phenothiazine
Ampicillin	Dextrompheniramine	(+/-)-Isoproterenol	L-Phenylephrine
Ascorbic	Dextromethorphan	Ketamine	β-Phenylethylamine
Aspartame	Diphenhydramine	Levorphanol	Procaine
Aspirin	Dopamine	Lidocaine	Quinidine
Atropine	(+/-)-Epinephrine	(+)-Naproxen	Ranitidine
Benzocaine	Erythromycin	Niacinamide	Riboflavin
Bilirubin	Acid Ethanol	Nicotine	Sodium Chloride
Caffeine	Furosemide	(+/-)-Norephedrine	Sulindac
Chloroquine	Glucose	Oxalic Acid	Tyramine
(+)-Chlorpheniramine	Guaiacol	Glyceryl Ether	Penicillin-G
(1R,2S)-(-)-N-Methyl-Ephedrine			4-Dimethylaminoantipyrine

【BIBLIOGRAPHY】
1. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991, 216
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Davis, CA.,129, 2002
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

【SPECIMEN COLLECTION AND PREPARATION】
Urine Assay
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 centrifuged, filtered, or allowed settle to obtain a clear specimen for testing.
Specimen Collection
Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.
【MATERIALS】

- Materials Provided
- Package Insert • Droppers
- Materials Required But Not Provided
- Specimen Collection Containers • Timer

【DIRECTIONS FOR USE】
Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (Approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】
(Please refer to the illustration above)

NEGATIVE: * **Two colored lines appear.** One colored line should be in the control line region (C) and another colored line should be in the test line region (T). This negative result indicates that the 3, 4-methylenedioxypropyvalerone concentrations are below the detectable level (500 ng/mL).
***NOTE:** The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint colored line.
POSITIVE: **One colored line appears in the control region (C).** No line appears in the test line region (T). This positive result indicates that the 3, 4-methylenedioxypropyvalerone concentration exceeds the detectable level (500 ng/mL).
INVALID: **Control line (C) 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. If the problem persists, discontinue using the lot immediately and contact your local distributor.

【QUALITY CONTROL】
A procedural control is included in the test. A colored 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.

【LIMITATIONS】
1. The MDPV Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.^{2,3}
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.

5. 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.
6. Test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】
This negative result indicates that the 3, 4-methylenedioxypropyvalerone concentration is below the detectable level of 500 ng/mL. Positive result means the concentration of 3, 4-methylenedioxypropyvalerone is above the level of 500 ng/mL. The MDPV Rapid Test Cassette (Urine) has a sensitivity of 500 ng/mL.

【PERFORMANCE CHARACTERISTICS】
Accuracy
A side-by-side comparison was conducted using the MDPV Rapid Test Cassette and GC/MS at the cut-off of 500 ng/mL. Testing was performed on 89 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

MDPV Rapid Test Cassette	Method	GC/MS		Total Results
	Results	Positive	Negative	
Positive		27	1	28
Negative		2	59	61
Total Results		29	60	89
% Agreement		93.1%	98.3%	96.6%

Analytical Sensitivity
A drug-free urine pool was spiked with 3, 4-methylenedioxypropyvalerone at the following concentrations: 0 ng/mL, 250 ng/mL, 375 ng/mL, 500 ng/mL, 625 ng/mL, 750 ng/mL and 1,500 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

3, 4-methylenedioxypropyvalerone Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
250	-50%	30	30	0
375	-25%	30	25	5
500	Cut-off	30	15	15
625	+25%	30	3	27
750	+50%	30	0	30
1,500	3X	30	0	30

Analytical Specificity
The following table lists compounds that are positively detected in urine by the MDPV Rapid Test Cassette (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
3, 4-methylenedioxypropyvalerone	500

Precision
A study was conducted at 3 hospitals using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no 3, 4-methylenedioxypropyvalerone, 25% 3, 4-methylenedioxypropyvalerone above and below the cutoff and 50% 3, 4-methylenedioxypropyvalerone above and below the 500 ng/mL cutoff were provided to each site. The following results were tabulated:

3, 4-methylenedioxypropyvalerone Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	8	2
625	10	2	8	1	9	1	9
750	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity
Fifteen urine samples with specific gravities ranging from 1.004 to 1.034 were spiked with 3, 4-methylenedioxypropyvalerone to the concentrations of 250 ng/mL, and 750 ng/mL. The MDPV Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of the Urinary pH
The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with 3, 4-methylenedioxypropyvalerone to 250 ng/mL and 750 ng/mL. The spiked, pH-adjusted urine was tested with the MDPV Rapid Test Cassette (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.



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