MDPV Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF DMDP-402	English

A rapid test for the qualitative detection 3, 4-methylenedioxypyrovalerone in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

【INTENDED USE】

The MDPV Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection 3, 4-methylenedioxypyrovalerone in whole blood or serum or plasma at a cut-off concentration of 500ng/ml. This test will detect other related compounds, please refer to the analytical Specificity table in this package insert.
This assay provides only a qualitative, 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.

【SUMMARY】

3, 4-methylenedioxypyrovalerone (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 BoehringerIngelheim. 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 methylenedioxyphenylalkylamine 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 whole blood or serum or plasma.
The MDPV Rapid Test Cassette (Whole blood / Serum / Plasma) is a rapid whole blood or serum/plasma 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-methylenedioxypyrovalerone in whole blood or serum or plasma. The MDPV Rapid Test Cassette (Whole blood / Serum / Plasma) yields a positive result when 3, 4-methylenedioxypyrovalerone in whole blood or serum or plasma exceeds 500ng/mL.

【PRINCIPLE】

The MDPV Rapid Test Cassette (Whole blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the specimen compete against the drug conjugate for binding sites on the antibody. During testing, a specimen migrates upward by capillary action. 3, 4-methylenedioxypyrovalerone, if present in the specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized 3, 4-methylenedioxypyrovalerone-protein 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-methylenedioxypyrovalerone level exceeds the cut-off level because it will saturate all the binding sites of anti-3, 4-methylenedioxypyrovalerone antibodies.
A drug-positive specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative specimen or a specimen containing a drug concentration less 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 at 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-methylenedioxypyrovalerone antibody coupled particles and 3, 4-methylenedioxypyrovalerone-protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch 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.

【SPECIMEN COLLECTION AND PREPARATION】

- The MDPV Rapid Test Cassette can be performed using whole blood (from venipuncture or fingerstick).
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 40 μl. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. For long term storage, specimens should be kept below -20°C. Whole blood/serum/plasma collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood or serum or plasma specimens. Whole blood/serum/plasma collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials Provided

• Test cassettes • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature (15-30°C) before opening it. Remove the cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface.

For serum or plasma specimen:

•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40ul), then add **2 drops of buffer** (approximately 80 μl) to the specimen well(S) of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

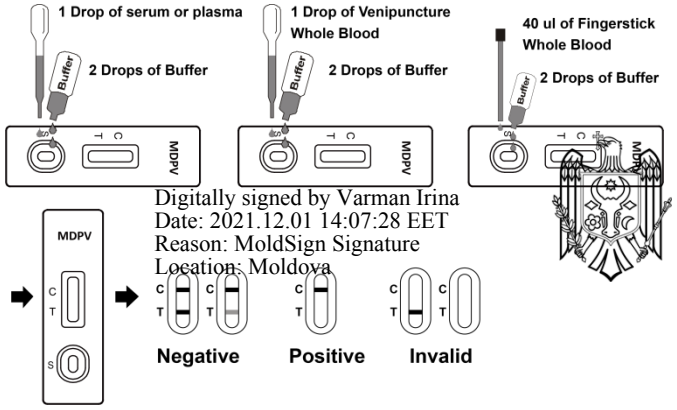
For Venipuncture Whole blood specimen:

•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μl) to the specimen well(S), then **add 2 drops of buffer** (approximately 80 μl), and start the timer. See illustration below.

For Fingerstick Whole blood specimen:

•To use a capillary tube: Fill the capillary tube and **transfer approximately 40μl of fingerstick whole blood specimen** to the specimen well(S) of test cassette, then add **2 drops of buffer**(approximately 80 μl) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result at 5 minutes.** Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the 3, 4-methylenedioxypyrovalerone concentration is below the detectable cut-off level.

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the 3, 4-methylenedioxypyrovalerone concentration exceeds the detectable cut-off 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 with a new test. If the problem persists, discontinue using the test kit 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 the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The MDPV Rapid Test Cassette (Whole blood/Serum/Plasma) 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. It is possible that technical or procedural errors, as well as other interfering substances in the specimen may cause erroneous results.
3. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in whole blood or serum or plasma.
4. A negative result may not necessarily indicate drug-free whole blood/serum/plasma. Negative results can be obtained when drug is present but below the cut-off level of the test.
5. Test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】

This negative result indicates that the 3, 4-methylenedioxypyrovalerone concentration is below the detectable level of 500ng/ml. Positive result means the concentration of 3, 4-methylenedioxypyrovalerone is above the level of 500ng/ml. The 3, 4-methylenedioxypyrovalerone Rapid Test Cassette has a sensitivity of 500ng/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 500ng/ml. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
MDPV Rapid Test Cassette	Results	Positive	Negative	
	Positive	28	2	30
	Negative	2	68	70
Total Results		30	70	100
% Agreement		93.3%	97.1%	96.0%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
MDPV Rapid Test Cassette	Results	Positive	Negative	
	Positive	28	2	30
	Negative	2	68	70
Total Results		30	70	100
% Agreement		93.3%	97.1%	96.0%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with 3, 4-methylenedioxypyrovalerone at the following concentrations of negative ±50%cut off and 3x cut off, the data are summarized below:

MDPV Concentration (ng/ml)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
250	-50%	30	30	0
500	Cut-off	30	15	15
750	+50%	30	0	30
1,500	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the MDPV Rapid Test Cassette (Whole blood/Serum/Plasma) at 5 minutes.

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

Precision

A study was conducted at three hospitals by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing no MDPV and 50% MDPV above and below the 500ng/ml cut-off was provided to each site. The following results were tabulated:

MDPV Concentration (ng/ml)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	9	1	9	1	9	1
750	10	1	9	1	9	2	8

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free whole blood or determine positive whole blood/serum/plasma. The following

compounds show no cross-reactivity when tested with the MDPV Rapid Test Cassette (Whole blood/Serum/Plasma) at a concentration of 100 μg/ml.

Non Cross-Reacting Compounds

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

Interfering Substances

The MDPV Rapid Test Cassette (Whole blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dl hemoglobin;up to 100 mg/dl bilirubin; and up to 200 mg/dl human serum albumin.

【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.

Index of Symbols

	Consult Instructions For Use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

Hangzhou AllTest Biotech Co., Ltd.
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