

# MDPV

## One Step Methylenedioxypropylvalerone Test Dip card (Urine)

### Package Insert

This Instruction Sheet is for testing of Methylenedioxypropylvalerone (MDPV). A rapid, one step test for the qualitative detection of single drug and its metabolites in human urine.

For forensic use only.

#### INTENDED USE

The One Step Methylenedioxypropylvalerone Test Dip card (Urine) is a lateral flow chromatographic immunoassay for the detection of single drug and its metabolites in human urine.

Test	Calibrator	Cut-off
Methylenedioxypropylvalerone (MDPV)	3,4-Methylenedioxypropylvalerone	1,000 ng/mL

This assay provides only a 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

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 at 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, Methylo, 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, Methylo and Mephedrone, making testing for these substances more vital than ever.

The One Step Methylenedioxypropylvalerone Test Dipcard yields a positive result when the concentration of opiate exceeds the 1,000ng/mL cut-off level.

#### PRINCIPLE

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

During testing, a 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 Dipcard. 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 Dip card 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 at the control line region,

indicating that proper volume of specimen has been added and membrane wicking has occurred.

#### REAGENTS

The test contains a membrane Dipcard coated with drug-protein conjugate (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 MDPV antibody.

#### PRECAUTIONS

- For Forensic Use Only. Do not use after the expiration date.
- The test Dip card 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 Dip card should be discarded according to federal, state and local regulations.

#### STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test Dip card is stable through the expiration date printed on the sealed pouch. The test Dip card must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

#### 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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

##### Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

#### MATERIALS

##### Materials Provided

- Test device
- Desiccants
- Package insert
- Urine cups

##### Materials Required But Not Provided

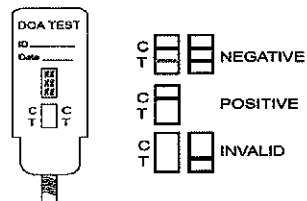
- Specimen collection container
- Timer

#### DIRECTIONS FOR USE

Allow the test device, and urine specimen to come to room temperature (15-30°C (59-86°F)) prior to testing.

- Remove the test device from the foil pouch.
- Remove the cap from the test device. Label the device with patient or control identifications.
- Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic device.
- Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface.
- Read results at 5 minutes.

**DO NOT INTERPRET RESULT AFTER 10 MINUTES.**



#### Test Results

##### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

\*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 distinguishable color line.

**POSITIVE:** One color 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 red 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 testing practice to confirm the test procedure and to verify proper test performance.

#### LIMITATIONS

- The One Step Methylenedioxypropylvalerone Test Dip card (Urine) 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.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.

#### PERFORMANCE CHARACTERISTICS

##### Reproducibility

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

3,4-Methylenedioxypropylvalerone conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

##### Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at  $\pm 50\%$  cut-off and  $\pm 25\%$  cut-off. The results are summarized below.

MDPV Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
150	-50%	30	30	0
225	-25%	30	27	3
300	Cut-off	30	20	10
375	+25%	30	4	26
450	+50%	30	0	30

##### Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the One Step Methylenedioxypropylvalerone Test Dip card (Urine) at a read time of 5 minutes.

Compound	Concentration (ng/mL)
3,4-Methylenedioxypropylvalerone	1,000
Ethylone HCl	1,200
Methylo	50,000
Pyrovalerone	50,000

##### Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.030) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Methylenedioxypropylvalerone Test Dip card was tested in duplicate using ten 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 aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked,