



### 3-CMC Rapid Test Dip Card (Urine)

#### Package Insert

|                 |         |
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| REF DRX152-CE25 | English |
|-----------------|---------|

A rapid test for the qualitative detection of 3-Chloromethcathinone in human urine.

For medical and other professional in vitro diagnostic use only.

#### 【INTENDED USE】

The 3-CMC Rapid Test Dip Card (Urine) is a rapid chromatographic immunoassay for the detection of 3-Chloromethcathinone in urine at a cut-off concentration of 1500ng/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-Chloromethcathinone (3-CMC) is a synthetic stimulant of the cathinone family. 3-CMC is one isomeric form of the drug "chloromethcathinone", in which 2-chloromethcathinone (2-CMC) and 4-chloromethcathinone (4-CMC) are the other two positional isomers. Given its pharmacological profile, 3-CMC appears to present a moderate risk for recreational use, physiological dependence and overdose.<sup>[1][2][3]</sup>

The 3-CMC Rapid Test Dip Card (Urine) is a rapid urine-screening test that can be performed without the use of an instrument. The test utilizes the antibody to selectively detect elevated levels of 3-Chloromethcathinone in urine. The 3-CMC Test Dip card (Urine) yields a positive result when the 3-Chloromethcathinone in urine exceeds the cut-off level.

#### 【PRINCIPLE】

The 3-CMC Rapid Test Dip Card (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-Chloromethcathinone, if present in the urine 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-Chloromethcathinone-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-Chloromethcathinone level exceeds the cut-off level, because it will saturate all the binding sites of anti-3-Chloromethcathinone antibody.

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 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-Chloromethcathinone antibody coupled particles and 3-Chloromethcathinone-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.

#### 【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 a clear specimen for testing.

##### Specimen Storage

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

#### 【MATERIALS】

##### Materials Provided

- 1 second Dip Card

- Package insert

##### Materials Required But Not Provided

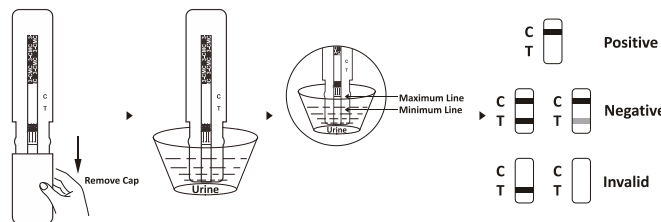
- Specimen collection container
- timer

#### 【DIRECTIONS FOR USE】

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

- Remove the dip card from the sealed pouch. Write the donor name or ID on the dip card in the provided space, then remove the cap.
- Collect urine into clean container.
- Remove the cap, with the arrows pointing downward, dip the card into the urine specimen.

- If the volume of the urine specimen exceeds the sampling window, immerse the dip card into the urine specimen for minimum of 1 second. Replace the cap and place the card on a flat surface.
- If the volume of urine specimen lower than the sampling window, dip the card into the urine specimen for at least 20 seconds. Replace the card and place the card in a flat surface. Alternatively, the dip card can remain in the specimen throughout the testing process.
- Read drug test results at 5 minutes. Results remain stable for 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-Chloromethcathinone 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-Chloromethcathinone 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 line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking.

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 3-CMC Rapid 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.<sup>1,2</sup>
- 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.

#### 【EXPECTED VALUES】

This negative result indicates that the 3-Chloromethcathinone concentration is below the detectable level of 1500ng/ml. Positive result means the concentration of 3-Chloromethcathinone is above the level of 1500ng/ml. The 3-CMC Rapid Test Dip Card has a sensitivity of 1500ng/ml.

#### 【PERFORMANCE CHARACTERISTICS】

##### Accuracy

A side-by-side comparison was conducted using The 3-CMC Rapid Test Dip Card (Urine) and GC/MS at the cut-off of 1500ng/ml. Testing was performed on 150 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| 3-CMC Rapid Test Dip Card | Method   | GC/MS    |          | Total Results |
|---------------------------|----------|----------|----------|---------------|
|                           | Results  | Positive | Negative |               |
|                           |          |          |          |               |
|                           | Positive | 25       | 2        | 27            |
|                           | Negative | 1        | 122      | 123           |
| Total Results             |          | 26       | 124      | 150           |
| % Agreement               |          | 96.2%    | 98.4%    | 98.0%         |

##### Analytical Sensitivity

A drug-free urine pool was spiked with 3-Chloromethcathinone at the following concentrations: 0ng/ml, 750ng/ml, 1125 ng/ml, 1500ng/ml, 1875ng/ml, 2250ng/ml, and 4500ng/ml. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| 3-Chloromethcathinone Concentration (ng/mL) | Percent of Cut-off | n  | Visual Result |          |
|---------------------------------------------|--------------------|----|---------------|----------|
|                                             |                    |    | Negative      | Positive |
| 0                                           | 0                  | 30 | 30            | 0        |
| 750                                         | -50%               | 30 | 30            | 0        |
| 1125                                        | -25%               | 30 | 26            | 4        |
| 1500                                        | Cut-off            | 30 | 14            | 16       |
| 1875                                        | +25%               | 30 | 5             | 25       |
| 2250                                        | +50%               | 30 | 0             | 30       |
| 4500                                        | 3X                 | 30 | 0             | 30       |

##### Analytical Specificity

The following table lists compounds that are positively detected in urine by the 3-CMC Rapid Test Dip Card (Urine) at 5 minutes.

| Compound              | Concentration (ng/mL) | Compound   | Concentration (ng/mL) |
|-----------------------|-----------------------|------------|-----------------------|
| 3-Chloromethcathinone | 1,500                 | Mephedrone | 200                   |
| MDPV                  | >100,000              | Cathinone  | >100,000              |
| Methcathinone         | 1000                  | Metoprolol | >100,000              |

##### 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 dip card of coded specimens containing, according to GC/MS, no 3-Chloromethcathinone, 25% 3-Chloromethcathinone above and below the cut-off and 50% 3-Chloromethcathinone above and below the 1500ng/ml cut-off was provided to each site. The following results were tabulated:

| 3-Chloromethcathinone Concentration (ng/mL) | n per Site | Site A |    | Site B |    | Site C |    |
|---------------------------------------------|------------|--------|----|--------|----|--------|----|
|                                             |            | -      | +  | -      | +  | -      | +  |
| 0                                           | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 750                                         | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 1125                                        | 10         | 8      | 2  | 9      | 1  | 9      | 1  |
| 1875                                        | 10         | 1      | 9  | 1      | 9  | 2      | 8  |
| 2250                                        | 10         | 0      | 10 | 0      | 10 | 0      | 10 |

##### Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 750ng/ml and 2250ng/ml of 3-Chloromethcathinone. The 3-CMC Rapid Test Dip Card (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 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-Chloromethcathinone to 750ng/ml and 2250ng/ml. The spiked, pH-adjusted urine was tested with the 3-CMC Rapid Test Dip Card (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

##### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or 3-Chloromethcathinone positive urine. The following compounds show no cross-reactivity when tested with the 3-CMC Rapid Test Dip Card (Urine) at a concentration of 100 µg/ml.

##### Non Cross-Reacting Compounds

|                       |                           |                                       |                       |
|-----------------------|---------------------------|---------------------------------------|-----------------------|
| 4-Acetamidophenol     | Creatinine                | Loperamide                            | β-Phenylethylamine    |
| Acetophenetidin       | Deoxycorticosterone       | Maprotiline                           | Phenylpropanolamine   |
| N-Acetylprocainamide  | Dextromethorphan          | Meperidine                            | Prednisone            |
| Acetylsalicylic acid  | Diazepam                  | Meprobamate                           | D,L-Propanolol        |
| Aminopyrine           | Diclofenac                | Methadone                             | D-Propoxyphene        |
| Amitypyline           | Diffunisal                | Methoxyphenamine                      | D-Pseudoephedrine     |
| Amobarbital           | Digoxin                   | (+) 3,4-Methylenedioxy-amphetamine    | Quinidine             |
| Amoxicillin           | Diphenhydramine           | (+) 3,4-Methylenedioxy-metamphetamine | Quinine               |
| Ampicillin            | Doxylamine                | (+) 3,4-Methylenedioxy-metamphetamine | Ranitidine            |
| L-Ascorbic acid       | Ecgonine hydrochloride    | Nalorphine                            | Salicylic acid        |
| D,L-Amphetamine       | Ecgonine methylester      | Nalidixic acid                        | Secobarbital          |
| Apomorphine           | (-)-y-Ephedrine           | Naloxone                              | Serotonin             |
| Aspartame             | Erythromycin              | Naltrexone                            | (5-Hydroxytryptamine) |
| Atropine              | β-Estradiol               | Naproxen                              | Sulfamethazine        |
| Benzilic acid         | Estrone-3-sulfate         | Niacinamide                           | Sulindac              |
| Benzoic acid          | Ethyl-p-aminobenzoate     | Nifedipine                            | Temazepam             |
| Benzoylecgonine       | Fenoprofen                | Norethindrone                         | Tetracycline          |
| Benphetamine          | Furosemide                | D-Norpropoxyphene                     | Tetrahydrocortisone,  |
| Bilirubin             | Gentisic acid             | Oxalic acid                           | 3-Acetate             |
| (±) - Brompheniramine | Hemoglobin                | D,L-Octopamine                        | Tetrahydrocortisone   |
| Caffeine              | Hydralazine               | Oxazepam                              | 3-(β-D glucuronide)   |
| Cannabidiol           | Hydrochlorothiazide       | Oxolinic acid                         | Tetrahydrozoline      |
| Chloralhydrate        | Hydrocortisone            | Oxymetazoline                         | Thiamine              |
| Chloramphenicol       | O-Hydroxyhippuric acid    | Papaverine                            | Thioridazine          |
| Chlordiazepoxide      | p-Hydroxy-methamphetamine | Penicillin-G                          | D, L-Tyrosine         |
| Chlorothiazide        | 3-Hydroxytryptamine       | Imipramine                            | Tolbutamide           |
| (±) Chlorpheniramine  | lbutuprofen               | Imipramine                            | Triamterene           |
| Chlorpromazine        | Imipramine                | Imipramine                            | Trifluoperazine       |
| Chlorquine            | Ipromazine                | Phencyclidine                         | Trimethoprim          |
| Cholesteryl           | Isoproterenol             | Phencyclidine                         | Trimipramine          |
| Clomipramine          |                           |                                       | Tryptamine            |

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