**CLIA WAIVED**

**Cannabinoids Urine Test**

Catalog No. See Pouch Label

Cannabinoids Urine Test is a rapid test for the qualitative detection of 11-nor-Δ9-THC-9-COOH (major metabolite of Cannabinoids) in human urine at specified cut-off level. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for prescription use.

**SUMMARY**

Cannabinoids is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabinoids, THC & Cannabinoi, can be metabolized and excreted as 11-nor-9-tetrahydrocannabinol-9-carboxylic acid with a half-life of 24 hours. It can be detected for 1 to 5 days after use. Smoking is the primary method of use of Cannabinoids/cannabis. Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. Tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea.

**THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME**

<table>
<thead>
<tr>
<th>Drug(Identifier)</th>
<th>Cut-off level</th>
<th>Minimum detection time</th>
<th>Maximum detection time</th>
</tr>
</thead>
<tbody>
<tr>
<td>11-nor-Δ9-THC-9-COOH /THC</td>
<td>50 ng/mL</td>
<td>2 hours</td>
<td>Up to 5 days</td>
</tr>
</tbody>
</table>

**PRINCIPLE**

Cannabinoids Urine Test is a competitive immunoassay that is used to screen for the presence of 11-nor-Δ9-THC-9-COOH in urine. It is chromotographic absorbent device in which 11-nor-Δ9-THC-9-COOH in a sample competitively combined to a limited number of anti-11-nor-Δ9-THC-9-COOH monoclonal antibody (mouse) conjugate binding sites.

When the test is activate, the urine is absorbed into the device by capillary action, mixes with the Cannabinoids monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), anti-11-nor-Δ9-THC-9-COOH monoclonal antibody conjugate binds to the Cannabinoids-protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the Cannabinoids monoclonal antibody conjugate preventing the Cannabinoids monoclonal antibody conjugate from binding to the Cannabinoids-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

**WARNINGS AND PRECAUTIONS**

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Do not use test kit beyond expiration date.
6. Do not read after 5 minutes.
7. This kit is for in vitro diagnostic use.

**CONTENT OF THE KIT**

1. Test devices, one test in one pouch. One pouch containing a test and a desiccant. The desiccant is only for storage purposes only, and is not used in the test procedures.
2. Control Region (C).
3. Control line (C).

**STORAGE AND STABILITY**

Store at 4 °C in the sealed pouch up to the expiration date. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE.

**SPECIMEN COLLECTION AND PREPARATION**

Collect a urine sample in the supplied urine cup. Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).

Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well mixed before analysis. Cloudy specimens should be centrifuged before analysis. Use only clear aliquots for testing.

**TEST PROCEDURE**

Test must be in room temperature (18°C to 30°C)
1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample for about 10 seconds. Make sure that the urine level is not above the marker line printed on the front of the device.
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. Do not read after 5 minutes.

**Note:** Results are not reliable at other fluid levels

**READING THE RESULT**

Preliminary positive
A rose-pink band will appear in the test region (T) if 11-nor-Δ9-THC-9-COOH is present.

Negative (-)
A rose-pink band indicates the test has been performed properly.

Invalid
If a color band is not visible in the test region, the test must be repeated using a new test kit.

**QUALITY CONTROL**

Users should follow the QC procedures when using the materials.

Though there is an internal Control region, the user must verify proper test performance. After the expected control, the same test kit should be used.

**PERFORMANCE**

Accuracy

Eighty clinical urine samples were tested with the Cannabinoids Urine Test.
**READING THE RESULTS**

**Preliminary positive (+)**
A rose-pink band is visible in the control region. No color band appears in the test region. It indicates a preliminary positive result for the 11-nor-Δ9-THC-9-COOH.

**Negative (-)**
A rose-pink band is visible in the control region and the test region. It indicates that the concentration of 11-nor-Δ9-THC-9-COOH is zero or below the detection limit of the test.

**Invalid**
If a color band is not visible in the control region or a color band is only visible in the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.

**Note:** There is no meaning attributed to line color intensity or width. A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

**TEST LIMITATIONS**
1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test anything but urine.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

**QUALITY CONTROL**
Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials.

Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

**PERFORMANCE CHARACTERISTICS**

**Accuracy**
Eighty clinical urine specimens were analyzed by GC-MS and by the Cannabinoids Urine Test dip card. Each test was read by three viewers. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

**Viewer A:**

<table>
<thead>
<tr>
<th>Result</th>
<th>Drug-free</th>
<th>Less than half the cutoff concentration by GC/MS analysis</th>
<th>Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)</th>
<th>Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)</th>
<th>High Positive (greater than 50% above the cutoff concentration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>18</td>
<td>22</td>
</tr>
<tr>
<td>Negative</td>
<td>10</td>
<td>12</td>
<td>17</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

% agreement among positives is 100% (95% Confidence Interval 91.24% - 100%)
% agreement among negatives is 97.5% (95% Confidence Interval 87.12% - 99.56%)

**Viewer B:**

<table>
<thead>
<tr>
<th>Result</th>
<th>Drug-free</th>
<th>Less than half the cutoff concentration by GC/MS analysis</th>
<th>Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)</th>
<th>Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)</th>
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</tr>
</thead>
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<tr>
<td>Positive</td>
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<td>0</td>
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% agreement among positives is 100% (95% Confidence Interval 91.24% - 100%)
% agreement among negatives is 97.5% (95% Confidence Interval 87.12% - 99.56%)

**Viewer C:**

<table>
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<tr>
<th>Result</th>
<th>Drug-free</th>
<th>Less than half the cutoff concentration by GC/MS analysis</th>
<th>Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)</th>
<th>Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)</th>
<th>High Positive (greater than 50% above the cutoff concentration)</th>
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</thead>
<tbody>
<tr>
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<td>0</td>
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</tr>
<tr>
<td>Negative</td>
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</tbody>
</table>

% agreement among positives is 100% (95% Confidence Interval 91.24% - 100%)
% agreement among negatives is 97.5% (95% Confidence Interval 87.12% - 99.56%)

From the results of the above tables, the total results are shown as below:
The average positive agreement is 100%
The average negative agreement is 97.5%.

**Precision and Sensitivity**
To investigate the precision and sensitivity, samples were analyzed at the following concentrations: +100%, +75%, +50%, +25%, cutoff, -25%, -50%, -75%, and -100% of cutoff. All concentrations were confirmed with GC-MS. The study was performed 2 runs/day and lasted 25 days using three different lots. Totally 3 operators participated in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day), for a total of 50 determinations per concentration per lot.
Lot 1

<table>
<thead>
<tr>
<th>Approximate concentration of sample (ng/mL)</th>
<th>Number of determinations</th>
<th>Results Negative Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>50</td>
<td>50/0</td>
</tr>
<tr>
<td>12.5</td>
<td>50</td>
<td>50/0</td>
</tr>
<tr>
<td>25.0</td>
<td>50</td>
<td>50/0</td>
</tr>
<tr>
<td>37.5</td>
<td>50</td>
<td>50/0</td>
</tr>
<tr>
<td>50.0</td>
<td>50</td>
<td>50/0</td>
</tr>
<tr>
<td>75.0</td>
<td>50</td>
<td>50/0</td>
</tr>
<tr>
<td>97.5</td>
<td>50</td>
<td>50/0</td>
</tr>
<tr>
<td>100.0</td>
<td>50</td>
<td>50/0</td>
</tr>
</tbody>
</table>

Effect of Urinary Specific Gravity

12 urine samples with density ranges (1.000-1.035) are collected and spiked with 11-nor-Δ9-THC-9-COOH at 25% below and 25% above cutoff levels. Each sample was tested by three batches of Cannabinoids Urine Test dip card. Three laboratory assistants read the result per batch. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with 11-nor-Δ9-THC-9-COOH at 25% below and 25% above cutoff levels. Each sample was tested by three batches of Cannabinoids Urine Test dip card. Three laboratory assistants read the result per batch. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Interfering substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a 11-nor-Δ9-THC-9-COOH concentration 25% below the cutoff, and urine with a 11-nor-Δ9-THC-9-COOH concentration 25% above the cutoff. All potential interferents were added at a concentration of 100 ng/mL. None of the urine samples showed any deviation from the expected results.

Non-Cross-Reacting Compounds

<table>
<thead>
<tr>
<th>Approximate concentration of sample (ng/mL)</th>
<th>Number of determinations</th>
<th>Results Negative Positive</th>
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</thead>
<tbody>
<tr>
<td>0</td>
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<td>50/0</td>
</tr>
<tr>
<td>75.0</td>
<td>50</td>
<td>50/0</td>
</tr>
<tr>
<td>97.5</td>
<td>50</td>
<td>50/0</td>
</tr>
<tr>
<td>100.0</td>
<td>50</td>
<td>50/0</td>
</tr>
</tbody>
</table>

Specificity and cross reactivity

To test the specificity of the test, the test device was used to test Cannabinoids, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11-nor-Δ9-THC-9-COOH</td>
<td>50</td>
</tr>
<tr>
<td>11-nor-Δ9-THC-9-COOH</td>
<td>30</td>
</tr>
<tr>
<td>11-hydroxy-Δ9-Tetrahydrocannabinol</td>
<td>2,500</td>
</tr>
<tr>
<td>Δ8-Tetrahydrocannabinol</td>
<td>7,500</td>
</tr>
<tr>
<td>Δ9-Tetrahydrocannabinol</td>
<td>10,000</td>
</tr>
<tr>
<td>Cannabidiol</td>
<td>100,000</td>
</tr>
</tbody>
</table>

Lot 2

<table>
<thead>
<tr>
<th>Approximate concentration of sample (ng/mL)</th>
<th>Number of determinations</th>
<th>Results Negative Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>50</td>
<td>50/0</td>
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<tr>
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<td>50/0</td>
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<td>50</td>
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</tr>
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Non-Cross-Reacting Compounds

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<td>75.0</td>
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</tr>
<tr>
<td>97.5</td>
<td>50</td>
<td>50/0</td>
</tr>
</tbody>
</table>

Lot 3

Component | Concentration (ng/mL) |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>11-nor-Δ9-THC-9-COOH</td>
<td>50</td>
</tr>
<tr>
<td>11-nor-Δ9-THC-9-COOH</td>
<td>30</td>
</tr>
<tr>
<td>11-hydroxy-Δ9-Tetrahydrocannabinol</td>
<td>2,500</td>
</tr>
<tr>
<td>Δ8-Tetrahydrocannabinol</td>
<td>7,500</td>
</tr>
<tr>
<td>Δ9-Tetrahydrocannabinol</td>
<td>10,000</td>
</tr>
<tr>
<td>Cannabidiol</td>
<td>100,000</td>
</tr>
</tbody>
</table>

BIBLIOGRAPHY


ADDITIONAL INFORMATION

The following list is provided for informational purposes only and is not intended to be exhaustive.

- www.health.org

National Clearinghouse for Drug Information (NIDA)
Codeine
Cortisone
(-) Colchicine
Onalase
Darvoncontosterone
Dexmethorphan
Oxazepam
Diazepam
Diphenhydramine
Dilantin
Doxylamine
Ecgonine hydrochloride
Egocine methylester
(-) Y Ephedrine
Erythromycin
B - Estradiol
Estriol sulfate
Etholano-benzoate
Fenoprofen
Fenamidone
Gentamic acid
Hemoglobin
Hydrazine
Hydrocortisone
Hydrocortisone
Hydroxyacetic acid
Hydroxyzine
Ibuprofen
Iprima
Ipronaizid
(-) Isoprenaline
Iosiprpropionate
Ketamine
Ketoprofen
Labetalol
Lovastatin
Loperamide
Mepropramide
Meprobamate
Methadone
Methamphetamine
N - Phenylpropanolamine
Phenylpropanolamine
Phenylalanine
Phenytoin
Prednisone
Prednisolone
Prednisone
Procaine
Prilocaine
Promazine
Promethazine
(-) Propoxycaine
D - Propanolol
(-) Y Tyramine
N - Tyramine
L - Tyrosine
Tyramine
Tryptamine
Tryptophane
(-) L - Tryptophane
Uric acid
Verapamil
Zomepirac

INDEX OF SYMBOLS

• Keep away from sunlight.

Store between 4°C and 30°C

Keep dry

Do not re-use

BIBLIOGRAPHY OF SUGGESTED READING


ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.

National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686

Center for Substance Abuse Treatment www.health.org 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL

American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG