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ONE STEP DRUGS OF ABUSE TEST STRIP - CANNABINOIDS (THC)TM

NAME AND INTENDED USE

HCD's **One Step Drugs of Abuse Test strip - Cannabinoids (THC)TM** is a rapid, qualitative, competitive binding immunoassay for the determination of Cannabinoids and their metabolites (THC) in urine/saliva in a convenient one step test strip format. Both the testing and the results are intended to be used by professionals (medical & legal) only. The assay should not be used without appropriate supervision and this test is not intended for Over the Counter (OTC) sale to lay persons.

EXPLANATION OF THE TEST

HCD's **One Step Drugs of Abuse Test strip - Cannabinoids (THC)TM** assay is a rapid, qualitative, competitive binding immunoassay for the determination of Cannabinoids and its metabolites (THC) in urine/saliva. The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrophotometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated³. This test is not intended to be used in monitoring Cannabinoid levels.

Urine/saliva screening for drugs of abuse usually detects the presence of the parent compounds and metabolites of the drug⁹.

The method employs unique polyclonal antibodies to selectively identify Cannabinoids in test samples with a high degree of sensitivity. Cannabinoids are central nervous system stimulants that alter mood and sensory perceptions, can produce losses of coordination, impair short term memory, produce symptoms of anxiety, paranoia, depression, confusion, hallucination, and increased heart rate. Large doses of Cannabinoids could develop tolerances and physiological dependency and lead to its abuse.

A tolerance to the cardiac and psychotropic effects can occur and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea. All forms of Cannabinoids (Marijuana, Hashish) are controlled substances, and NIDA has recommended cutoff level for Cannabinoids screening tests to be set at 100 ng/ml in urine/saliva by the National Institute on Drug Abuse⁶.

The **One Step Drugs of Abuse Test strip - Cannabinoids (THC)TM** is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need of instrumentation.

PRINCIPLE OF THE PROCEDURE

One Step Drugs of Abuse Test strip - Cannabinoids (THC)TM consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye

conjugate binds to the free drug in the specimen forming an antibody antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 50 ng/ml. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

A NEGATIVE specimen produces two distinct color bands in both the test line and control area. **A POSITIVE** specimen produces only one color band in the control area.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers.
2. Clock or timer.
3. 13 x 100mm Test Tube.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional medical & legal use only.
3. Avoid cross contamination of urine/saliva samples by using a new urine/saliva specimen cup for each urine/saliva sample.
4. Do not use a test strip beyond the expiration date imprinted on the outside of the foil pouch.
5. Urine/saliva specimens may be infectious. Upon completion of **All Testing** dispose of residual urine/saliva in an approved manner. Properly handle and dispose of all reaction devices in an approved biohazard container.

STORAGE AND STABILITY

The reagents supplied can be stored under refrigeration (2°-8°C) (35°-46°F) (**DO NOT FREEZE**) or at room temperature (18°-30°C) (64°-86°F) and will be stable for 12 months.

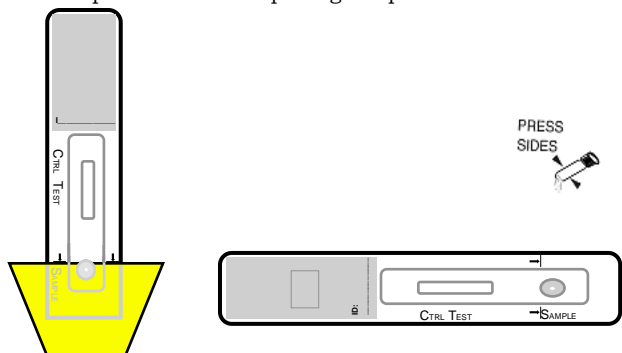
SAMPLE COLLECTION AND PREPARATION

Using **Saliva** as a sample: The test is specifically designed to utilize a saliva sample collected with a Sani-SalTM saliva collector. Saliva collected by any other means may not yield accurate results. Urine/saliva (1.0 ml) - The sample must be collected in a clean, dry container, either plastic or glass, without any preservatives. Urine/saliva specimens may be refrigerated (2°-8°C) (and stored up to 48 hours, or frozen (-20°C or colder) prior to assaying. If samples are refrigerated or frozen, they should be allowed to come to room temperature before testing. Urine/saliva samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be obtained for testing.

ASSAY PROCEDURE

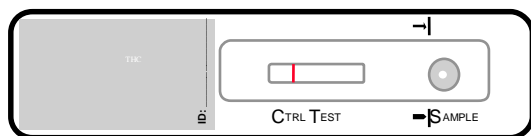
1. Remove the HCD **One Step Drugs of Abuse Test strip - Cannabinoids (THC)TM strip** from its protective foil wrapper by tearing along the notch.

- Add 3-4 drops of urine or saliva to the sample well of the slide. Alternatively, dip the strip into the sample to be tested, up to the sample well, for 30 seconds. The urine/saliva level should not be higher than the maximum fill line indicated on the slide.
 - Read the results after 3 minutes. Test results should not be interpreted after 10 minutes.
- NOTES:** Refrigerated slides should be allowed to come to room temperature before opening the pouch.



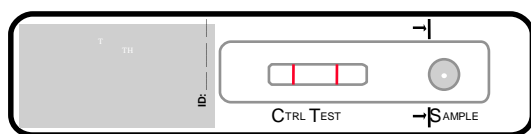
READING THE TEST RESULTS

- POSITIVE:** One magenta band appears on the control region. No visible band on the test region (lower portion of the read area). This is an indication that the Cannabinoids level is above the detection sensitivity level of 50 ng/ml.



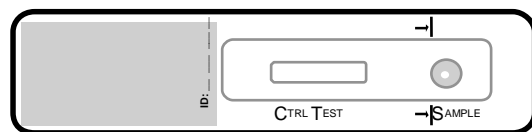
POSITIVE RESULT

- NEGATIVE:** In addition to the control band, a magenta band also appears in the test region (lower portion of the read area). If this is the case, the Cannabinoids level is below the detection sensitivity level of 50 ng/ml.



NEGATIVE RESULT

- INVALID:** If there are no distinct color bands in both the upper and lower portions of the test area, (lower portion of the slide), or no band in the control region (upper portion of the read area), then the test results are invalid. It is recommended that the specimen be retested.



INVALID RESULT

QUALITY CONTROL

- Each reaction strip has its own built-in quality control indicator. If after performing the test no line is visible on the slide, you may have placed the strip into the tube incorrectly or the test device may have been deteriorated. You will have to repeat the assay using new One Step Drugs of Abuse Test strip - Cannabinoids (THC)[™]. Re-read the instructions carefully or call HCD for assistance.

(800 427-2907)

- Good laboratory practice recommends the use of control material to test each product shipment or whenever it is necessary to validate reagent performance and reliability. Commercial controls from BioRad, Utak, and Alltech are available for the validation of device functionality. The NIDA recommended guidelines for drugs of abuse screening indicate that controls should contain the drug of abuse analyte at levels at least 20% above the NIDA cut off values.

AFTER TESTING

Urine/saliva specimens may be infectious. Properly handle and dispose of all used reaction devices in an approved biohazard container. The residual urine/saliva should be disposed of in a medically approved manner after the completion of all testing including the confirmatory testing. Sample disposal may be controlled by legal chain of custody considerations.

PERFORMANCE CHARACTERISTICS

SENSITIVITY:

One Step Drugs of Abuse Test strip - Cannabinoids (THC)[™] has been designed for the detection of Cannabinoids in urine/saliva at the detection sensitivity of 50 ng/ml which is suggested for the immunoassay method. In house testing on a total of 249 samples by both SIA[™], GC/MS, and **One Step Drugs of Abuse Test strip - Cannabinoids (THC)[™]** yield a sensitivity of 1.00%.

SPECIFICITY:

One Step Drugs of Abuse Test strip - Cannabinoids (THC)[™] can specifically detect 11-nor- Δ -9-tetrahydrocannabinol-9-carboxylic acid at levels of 50 ng/ml (0.1ug/ml) or higher.

ACCURACY:

Based on the In House evaluation for 249 individual patient urine/saliva s the HCD's **One Step Drugs of Abuse Test strip - Cannabinoids (THC)[™]** had an accuracy of 100%.

Related compounds giving cross-reactivities at high levels are as follows:

Table 1 - Compounds that give a Positive Reaction

| Compound | Level of Positive Reaction |
|-------------------------------|----------------------------|
| 11-nor- Δ 8-THC-9-COOH | 50 ng/ml |
| 11-nor- Δ 9-THC-9-COOH | 50 ng/ml |
| Δ 8-THC | 1 μ g/ml |
| Δ 9-THC | 4 μ g/ml |
| Cannabinol | 10 μ g/ml |
| 11-hydroxy- Δ 9-THC | 10 μ g/ml |

Table 2 - Compounds that give negative results at concentration up to 100 μ g.ml (Unless Noted)

| | |
|-----------------------|----------------------|
| Acetaminophen | Hydrocodone |
| 4-Acetamidophenol | Hydromorphone |
| Acetylsalicylic acid | Homatropine |
| Amikacin | Imipramine |
| Ampicillin | Isoproterenol |
| d,1-Amphetamine | Ketamine |
| Amitriptyline | Lidocaine |
| Arterenol | d-Methamphetamine |
| Aspartame | Meperidine |
| Atropine sulfate | Methadone |
| Benzoic acid | Methaqualone |
| Benzoylcegonine | Methylphenidate |
| Caffeine | Morphine glucuronide |
| Camphor | Morphine sulfate |
| Chloroquine | Morphine |
| Chlorpheniramine | Naloxone |
| Chlorpromazine HCl | Neomycin |
| Cocaine Hydrochloride | Niacinamide |
| Cocaine | Oxazepam |
| Cimetidine | Perphenazine |

| | |
|--------------------------|---------------------------|
| Cortisone | Penicillin G |
| Deoxyepinophrine | Phencyclidine |
| Dextromethorphan | Phenobarbital |
| Diazepam | Phenyletylamine- α |
| Digitoxin | Phenylpropanolamine |
| Digoxin | Promethazine |
| Ecgonine Hydrochloride | Pseudoephedrine |
| Ecgonine Methyl Esther | Rantidine |
| Ephedrine | Salicyclic acid |
| Epinephrine (\oplus) | Secobarbital r |
| Gentisic acid | Tetracycline |
| Glucose | Tetrahydrozoline |
| Guaiacol | Theophylline |
| Glycerol ether | Thioridazine |
| Histamine | Trifluoperazine |
| Hydrochlorothiazide | Tryptophan |

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of Cannabinoids in human urine/saliva only.
2. Although the HCD's **One Step Drugs of Abuse Test strip - Cannabinoids (THC)[™]** is very accurate in detecting the urine/saliva Cannabinoids level, there is a possibility of false results due to the presence of interfering substances in the urine/saliva.
3. The test is a qualitative screening assay and is not suggested for determining the quantitative Cannabinoids level of urine/saliva.
4. Adulterants, such as bleach or other strong oxidizing agents, when added to urine/saliva specimens, may produce erroneous test results regardless of analysis method used. If adulteration is suspected, obtain another urine/saliva specimen.

BIBLIOGRAPHY

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Manufactured in the USA by:

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FOR USE WITH THE

SANI-SAL® SALIVA COLLECTION DEVICE