First Romanian rapid tests manufacturer !

rev1

e-mail : sales@campmedica.ro
http:// www.campmedica.ro

"See Now" THC (marijuana) Strip/Cassette Test Urine

CE

For in vitro Diagnosis Use
Product Code: SN 7.11

INTRODUCTION

The *"See Now"* Marijuana (THC) Test is intended for the qualitative detection of the presence of cannabinoids and its metabolites (THC) in urine at or above the cutoff level of 50 ng/ml. The device is designed for laboratory use only.
This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed.

SUMMARY OF THE TEST

Cannabis (Marijuana) is one of the most widely abused drugs in the world, second only to alcohol and is often involved in accidents and other mishaps of operations that require skill [1]. Cannabis is a generic term used to denote the several psychoactive preparations of the plant *Cannabis sativa*. The major psychoactive constituent in cannabis is Δ-9 tetrahydrocannabinol (THC). Compounds which are structurally similar to THC are referred to as cannabinoids[2]. This cannabinoid acts on the cannabinoid receptors located on the surface of nerve cells in the brain[3,4,5]. Most cannabinoid receptors are located in the brain region responsible for pleasure, memory and sense. The binding of THC to the receptors leads to euphoria and pleasure that abusers like to experience. Withdrawal from marijuana would lead to heightened stress, anxiety, depression and personality disturbances. Large doses of Cannabinoids could develop tolerances and physiological dependency and lead to its abuse.
The main metabolite of THC is 11-nor-Δ^9-THC-9-COOH, which is present in excreted urine. This metabolite is usually targeted by test systems to determine whether or not a person has ingested marijuana[6]. Urine screening for drugs of abuse usually detects the presence of the parent compounds and metabolites of the drug. All forms of Cannabinoids (Marijuana, Hashish) are controlled substances where the recommended cutoff level for Cannabinoids screening tests is set at 50 ng/ml 11-nor-Δ^9-THC-9-COOH in urine.
The *"See Now"* THC Test device contains mouse monoclonal anti-THC antibody colloidal gold conjugate predried on a pad. THC-BSA conjugates antigen (on test region) and goat anti mouse IgG (on control region) are coated and immobilized on a reaction membrane.
The principal of the *"See Now"* THC Test is a solid phase, competitive inhibition immuno-chromatographic assay, in which a chemically labeled drug (drug conjugate) competes with the drug that may be present in urine, for limited antibody binding sites. When the absorbent pad is soaked with urine, the urine will migrate via capillary action toward the test window where the test reaction occurs. A negative specimen produces two distinct color bands, one in the test zone and one in the control zone; A positive specimen produces only one color band in the control zone.
To serve as an internal process control, a control band was designed to indicate that the test is performed properly. By utilizing the different antigen/antibody reaction, this control line should always be seen after test is completed. Absence of a colored control line in the control region is an indication of an invalid result.

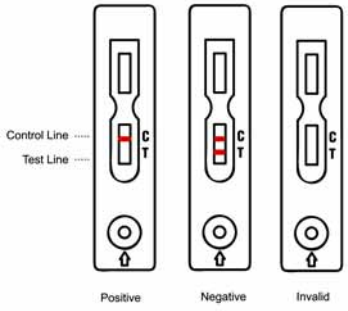
SPECIMEN COLLECTIONAND STORAGE

- Urine specimen may be collected at any time in a clean, dry container without preservatives.
- If specimen cannot be assayed immediately, they can be stored at 2-8°C for up to 72 hours prior to testing or frozen at –20ºC for longer period of time.
- Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.
- Urine specimens exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle so that clear aliquots can be obtained for testing.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Holding the sample dropper vertically, add 5 drops (0.2 ml) of specimen without air bubbles into the sample well.
- For strip test, immerse the strip into the urine cup and take out the strip after 10 sec. Lay the strip on a flat, clean, dry, non-absorbent surface
- Read the results at 10 minutes. Ensure that the background of the test area is white before interpreting the result

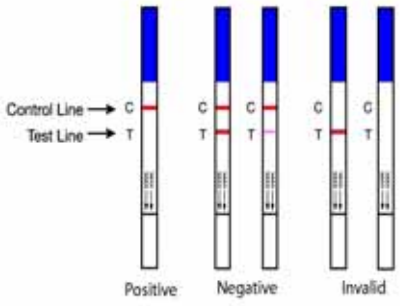
INTERPRETATION OF RESULTS



Positive
Only one color band appears at the control region. No apparent band at the test region. This indicates that drug presence is above the cutoff concentration.

Negative
Two distinct color bands appear at the control and test regions. This indicates that there is no drug in the sample or drug presence is below the cutoff concentration.

Invalid
No visible band at the control region. Repeat with a new test kit. If test still fails, please contact the distributor with the lot number.



Note: A faint line at the test region indicates the drug in sample is near the cut-off level for the test. These samples should be re-tested or confirmed with a more specific method before a clinical determination is made.

STORAGE AND STABILITY

The test kit can be stored at temperature (2 to 30°C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

- *FOR IN VITRO DIAGNOSTIC USE ONLY.*
- Don't use it after the expiration date.
- The test device should not be reused.

PERFORMANCE CHARACTERISTICS

- Sensitivity

The *"See Now"* THC Urinary Test detects THC and its metabolites in urine at concentrations equal to or greater than 50 ng/ml.

- Specificity

A study was conducted with the *"See Now"* THC Test to determine the cross-reactivity of THC-related compounds with the test device (Table I).

Table-I Concentration of THC-related compounds showing a positive response approximately equivalent to the THC cut off set for the test.

Structurally related compounds	ng/ml
11-Nor-Δ^8-Tetrahydrocannabinol carboxylic acid	50
11-Nor-Δ^9-Tetrahydrocannabinol carboxylic acid	50
11-Hydroxy-Δ^9-Tetrahydrocannabinol	5000
Δ^8-Tetrahydrocannabinol	10000
Δ^9 -Tetrahydrocannabinol	10000
Cannabinol	10000
Cannabidiol	50000

A separate study was conducted to determine the cross-reactivity of non-THC related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross-reactivity was detected with the substances listed in Table II.

Table- II Compounds tested and found not to cross-react with the test at a 1000 µg/ml concentration in urine

Amobartital	Pseudophedrine	Doxepin
Butabarbital	3,4-Methylenedioxyethylamphetamine (MDEA)	Imipramine
Hexobarbital	d,l-3,4-Methylenedioxymethamphetamine (MDMA)	Maprotiline
Pentobarbital	l-methamphetamine	Nortriptyline
Phenobarbital	l-amphetamine	Promazine
secobarbital	Methadone	Promethazine
Alprazolam	Diphenhydromine	Protriptyline
Bromazepam	Dextromethorpham	Trimipramine
Clonazepam	Doxylamine	Acetaminophen
Diazepam	Morphine	Acetylsalicylic Acid
Estazolam	Morphine-3-β-D-Glucuronide	Amikacin
Flunitrazepam	Codeine	Ascorbic acid
Flurazepam	6-monoacetylmorphine	Aspartame
Lorazepam	Ethylmorphine	Atropine Sulfate
Nitrazepam	Nalorphine	Benzoic Acid
Nordiazepam	Hydrocodone	Caffeine
Oxazepam	Hydromorphone	Deoxyephedrine
Prazepam	Heroin	Dextromethorphan
Temazepam	Oxycodone	Gentesic acid
Trazolam	Levorphanol	Histamine
Benzoylecgonine	Naloxone	Methaqualone
Cocaine HCl	Thebaine	Pendimetrazine
Cocaethylene	Norcodeine	Penicillin G
Ecgonine	Phencyclidine	Quinine
d-Amphetamine	Phencyclidine Morpholine	Ranitidine
3,4-Methylenedioxymethamphetamine (MDA)	4hydroxyphencyclidine	Sodium Salicylate
d,l-Amphetamine	Amitryptyline	Tryptophan
Phentermine	Clomipramine	Tetracycline
d-methamphetamine	Cyclobenzaprine	Tetrahydrozoline
Ephedrine	Desipramine	

- Interference Testing

The following conditions were found not to interfere with the test.

Ethanol	1%
Methanol	1%
EDTA	80 mg/dl
Albumin	2,000 mg/dl
Glucose	2,000 mg/dl
Bilirubin	1,000 µg/dl
Hemoglobin	1,000 µg/dl
Urinary Test pH:	pH 3 –pH 9
Specific Gravity:	1.003 – 1.040

- Accuracy

Accuracy of the *"See Now"* THC Urinary Test Device has been evaluated. A total of 80 clinic samples tested (40 negative and 40 positive), The two assays gave an overall of 95% .

Conc. of Sample (ng/ml)	No. of test	Results (# Neg/ #Pos)			
		Lot 1	Lot 2	Lot 3	Total
< 25	35	35 / 0	35 / 0	35 / 0	105/ 0
25 - 49	5	5 / 0	5 / 0	5 / 0	15 / 0
50 - 75	5	2 / 3	2 / 3	2 / 3	6/ 9
> 75	35	2 / 33	2/ 33	2 / 33	6 / 99
% of Negative					100 %
% of Positive					90 %
% of overall					95 %

- Reproducibility

The precision was determined by replicate assays of both positive and negative urine samples with devices from three different production lots. The resultant data indicated no appreciable inter lot variation when testing both positive and negative samples across three different lots of devices.