PRINCIPLE OF THE ASSAY

Marijuana is a hallucinogenic agent derived from the flowering portion of the hemp plant. Smoking is the primary method of use of marijuana/cannabis Cannabinoids have been proposed for therapy for acute glaucoma and parsea due to chemotherapy. 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. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea. When marijuana is ingested, the drug is metabolized by the liver, the primary urinary metabolite of' marijuana is 11-nor-Δ-9-tetrahydrocannabinol-9-caboxylic acid and its glucuronide. This means that the presence of detected Cannabinoids, including the primary carboxyl metabolite, in the urine indicate marijuana/cannabis use. The THC Rapid Test is a homogeneous immunochromatographic assay based en the principle of highly specific immunochemical reactions of antigens and antibodies, which are used for the analysis of specific c compound in biological fluids. The assay relies on the competition for binding antibody between drug conjugates and drugs, which may be present in the urine being tested. When THC is present in the urine, it competes for limited antibody sites between the drug or its metabolite in the sample and a drug conjugate immobilized on a porous solid phase. When a sufficient amount of drug is present, it will prevent the binding of dye-antibody conjugate to the drug conjugate on the membrane. Therefore, a positive urine sample will not generate a color band on test region indicating a positive result. While the presence of the color band on test region indicates a negative result.

PRECAUTIONS

1. Not for *in vitro* diagnostic use.
2. For research or evaluation use only.
3. Use a new specimen container and dropper for each test to avoid cross contamination of urine samples.
4. Do not use after the expiration date.
5. Test device should remain sealed until ready for use.

STORAGE AND STABILITY

The test should be stored refrigerated or at room temperature (2-25°C), in sealed pouch, under dry condition. The test is stable for 18 months.

SPECIMEN COLLECTION AND STORAGE

Collect a small volume of urine in a clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2-8 degrees C) stored up to 3 days. Bring refrigerated samples to room temperature before testing. Urine specimens exhiiting visible precipitates should be filtered, centrifuged or allowed to settle. Use only clear aliquots for testing.

ASSAY PROCEDURE

1. Collect a small volume of urine for the test (one quarter of the cup’s fill-volume is sufficient).
2. Bring up all reagents and specimens to room temperature. Do not open the pouch until ready to use.
3. Removing the dipstick strip by tearing open the pouch.
4. Carefully place the white end of the reaction strip into the urine sample. A 10-30 seconds dip into the urine is sufficient.
5. Remove end of test strip from urine sample and start the watch or timer.
6. Read the result within 5 minutes, no longer than 10 minutes.

INTERPRETATION OF RESULT

POSITIVE

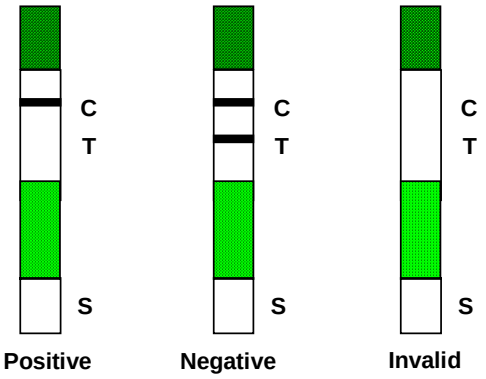
Only one color band appears in the control region.

NEGATIVE

Two color bands appear, one in the control region and another one in the test region.

INVALID

If no bands appear after 10 minutes, the result is invalid. The protocol may not have been followed correctly or the test may be deteriorated. The assay should be repeated using a new test. **Note**: Do not interpret result after 10 minutes.



LIMITATIONS

1. The test is designed for use with human urine only.
2. There is a possibility that factor such as technical or procedural errors, as well as additional substances in the urine sample that are not listed below, may interfere with the test and cause erroneous results.
3. The test detects only the presence of cannabinoids and its metabolites in urine. It does not provide any indication of intoxication.
4. A test result read after 10 minutes may not be consistent with the original reading obtained within the 5 minutes test period.

CHARACTERISTIC AND SPECIFICITY

NIDA has suggested that the screening cutoff for positive samples be 100 ng ml for the qualitative screening of marijuana metabolites. The THC Rapid Test detects an average of 100 ng/ml for Cannabonoid metabolites in urine.

1. Compounds detected

11-nor-Δ-9-tetrahydrocannabinol-9-carboxylicacid: 100 ng/ml

2. Compounds not detected

Acetaminophen	Sodium Salicylate
Acetylsalicylic Acid	Tryptophan
Ampicillin	Meperidine
Benzoic Acid	Morphine Glucuronide
Benzoylecgonine HCl	Morphine Sulfate

Caffeine	Methylphenidate
Chlorpheniramine	Methadone
Chlorpromazine HCl	Methaqualone
Cimetidine	OxycodonePropraanollol
Codeine	d-Propoxyphene Hydrochlorothiazide
Dextromethorphan	Phencyclidine
Diethylpropion	Phenylpropanolamine
Diphenylhydantoin	Pendimetrazine
Doxylamine	Pentobarbital
Ecgonine HCl	Phenobarbital
Ecgonine Methyl Ester	Phentermine
Hydrocodone	Penicillin G
Hydromorphone	L-Phenylephrine
Indomathacin	Quinine
Ketoprofen	Ranitidine
Levorphanol	

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