D. Interference testing

The AccuTest™ THC test strip performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.5 to 9.0 and 1.005 to 1.035.

The following substances were tested and confirmed did not interfere with the AccuTest™ THC test strip at the listed concentrations.

Glucose	2000 mg/dl
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/dl

E. Specificity

The specificity for adding various drugs, drug metabolites tested the AccuTest™ THC test strip, and other compounds that are likely to be present in urine. All compounds were prepared in drug -free normal human urine.

The following table lists compounds that are detected by the AccuTest™ THC test strip, which produced positive results when tested at levels equal or greater than the concentrations listed below:

Test	Compounds	Cut-off(ng/ml)
THC	11-nor-△9-THC-9-COOH	50
	11-nor-△8-THC-9-COOH	37.5
	11-hydroxy-△9-THC	5000
	△8-Tetrahydrocannabinol	15000
	△9-Tetrahydrocannabinol	25000

The following compounds show no cross-reactivity at concentration up to 100 µg/ml unless specified.

4-Acetamidophenol
Acetaminophen
Acetylsalicylic acid
Amikacin
Amitriptyline
Arterenol
Ascorbic acid
Aspartame
Atrophine
Caffeine
Camphor
Chlopheniramine
Chloroquine
Cortisone
Deoxyephedrine
Dextromethorphan
Digitoxin
Digoxin
Diphenhydramine
Ecgonine
Ecgonine methylester
Ephedrine
Epinephrine
Gentisic acid
Guaiacol glycerester
Histamine
Homatrophine
Hydrochlorothiazide
Ibuprofen
Imipramine
Isoproterenol
Ketamine
Lamine
Lidocaine
Meperidine
Methaqualon
Methylphenidate
Neomycin
Niacinamide
Penicillin G
Perphenazine
Phenylethylamine-a
Phenylpropano-
Promethazine
Pseudoephedrine
Quinine antidine
Salicyclic acid
Tetracycline
Tetrahydrozoline
Theophyline
Thioridazine
Trifluoperazine
Tryptophan

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AccuTest™ THC Test Cassette

FOR THE QUALITATIVE ASSESSMENT OFTHCL AND THE METABOLITES IN HUMAN URINE

For in vitro Diagnostic and Forensic Use

INTENDED USE

The AccuTest™ THC test strip is an immunochromatography based one step in vitro test. It is designed for qualitative determination of drug substances in human urine specimens. This assay may be used in the point of care setting. The cut-off concentration using our test is as follows;

Cannabinoid (THC) 50 ng/ml of 11-nor-△9-THC-9-COOH

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. The Substance Abuse Mental Health Services Administration (SAMHSA) has established gas chromatography/ mass spectrometry (GC/MS) as 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 indicated.

Note: ***It is not for use in diagnosing disease or illness; it is for investigational use only.***

SUMMARY AND EXPLANATION

THC The agents of Marijuana that cause various biological effects in humans are called cannabinoid. Cannabinoid is a central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short term memory, and produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increased heart rate. Large doses of cannabinoid could cause the development of tolerances and physiological dependency and lead to abuse. A tolerance to the cardiac and psychotropic effects can occur and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea. □9-THC is the primary active ingredient in cannabinoids. The main metabolite excreted in the urine is 11-nor -□9-THC-9-COOH, which are found within hours of exposure and remain detectable in the urine for 3- 10 days after smoking.

PRINCIPLE

The test strip is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze particular compound in human urine specimen. The assay relies on the competition for binding antibody. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored

band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result. A control line is present in the test window to work

as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

MATERIAL PROVIDED

1. An AccuTest™ THC test cassette.
   The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti- mouse IgG antibody.
   Test zone: contains drug bovine protein antigen conjugates
   Control zone: contains Goat anti-mouse IgG antibody
   Conjugate pad: contains mice monoclonal anti-drug antibody.
2. Dropper
3. Instruction for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection container.
2. Timer or clock.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic and professional use only.
2. Do not use the test strip beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
4. Visually inspect the foil package to insure it is intact. If the package is not intact, the integrity of the device might be compromised.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

STORAGE AND STABILITY

The test device should be stored at 2°C to 28°C; **do not freeze** and will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

SPECIMEN COLLECTION AND PREPARATION

Fresh urine does not require any special handling or pretreatment. Specimen should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2- 8 °C or frozen up to 7 days. Specimens should be brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good Laboratory practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 25% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials that are not provided with this test kit are commercially available.

The Rapid Drugs of Abuse Test provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless

the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test cassette and pipette from sealed foil pouch.
3. Place the cassette kit onto a flat surface, face up.
4. Suck up the urine specimen with the pipette.
5. Holding the dropper vertically, dispense 3 drops (110µL) into the sample well

6. Read the result after 3 minutes but within 10 minutes.

Do not interpret the result after 10 minutes. Waiting more than ten minutes may cause the reading to be inaccurate. To avoid confusion, discard the test cassette after interpreting the result.

INTERPRETATION OF RESULTS

Negative:

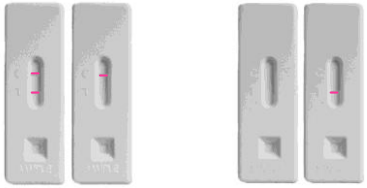
Two colored bands form on any strip of the card. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative result for that particular test(s). The negative result does not indicate the absence of drug in the specimen; it only indicates the level of tested drug in the specimen is less than cut-off level**.**

Positive:

One colored band appears in control line zone. No coloured band is found in test line zone. This is an indication the level of tested drug(s) in the specimen is above the cut- off level.

Invalid:

If there is no colored band in control line zone of any strip, the test result is invalid. Retest the sample with a new device.



NEG POS INVALID

Note: A borderline (+/-) in test line zone should be considered negative result.

LIMITATION OF PROCEDURE

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication. There is a possibility that technical or processed urine error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer “SPECIFICITY” section for lists of substances that will produce either positive results, or that do not interfere with test performance. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

EXPECTED RESULTS

The AccuTest™ THC test strip is a qualitative assay. It identifies the drug in human urine at its cut-off concentration or higher. The concentration of the drug cannot be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the AccuTest™ THC test strip was evaluated in comparison to GC/MS method at the following concentration: 11-nor-9-THC-9-COOH 50ng/ml (THC). The results of the component strip is listed as follows:

THC The accuracy of the THC test was evaluated in comparison to GC/MS at a cut-off of 50 ng/ml of 11-nor-?9-THC-9-COOH. Eighty-eight (88) urine specimens with GC/MS confirmed 11-nor-?9-THC-9-COOH concentration were evaluated in this study. The results are summarized and presented below:

Positive % agreement: 95, Negative % agreement: 100

Two specimens were found discrepant between the Rapid THC and GC/MS method. When compared those data, 50% (1 out of 2) of the discrepancy specimens were found between –25% and cut-off concentration (37.5 – 50 ng/ml).

B. Sensitivity

The cut-off concentrations (sensitivity level) of AccuTest™ THC test strip is determined to be:

THC 50 ng/ml.

C. Precision

The precision of the AccuTest™ THC test strip was determined by conducting the test with spiked controls and interpreted the results by three individuals to verify the random error of visual interpretation. The results of 50% above and 50% below cut-off specimens are 100% agreed by three observers:

Tested Drug	Concentration (ng/ml)	Number Tested	Corrected Result	% Corrected Result
THC	25	40	40	100
	75	40	40	100