


ADVANCED QUALITY™ ONE STEP Cannabinoids(THC) TEST
(Urine)FOR *IN VITRO* DIAGNOSTIC USE ONLY**INTENDED USE**

THE ADVANCED QUALITY™ ONE STEP CANNABINOID TEST IS A RAPID, QUALITATIVE, COMPETITIVE BINDING IMMUNOASSAY FOR THE DETERMINATION OF CANNABINOID (THC) AND ITS METABOLITES IN HUMAN URINE. THE TEST IS USED TO SCREEN URINE FOR THE PRESENCE OF CANNABINOID AND THEIR METABOLITES AT A CUTOFF CONCENTRATION OF 50 NG/ML. THE TEST IS FOR USE BY HEALTH CARE PROFESSIONALS ONLY.

This test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical considerations and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY AND EXPLANATION OF THE TEST

The agents of Marijuana that cause the various biological effects in humans are called Cannabinoid. Cannabinoid is a central nervous system stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short term memory, 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 its abuse. A tolerance to the cardiac and psychotropic effects can occur and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea. All forms of Cannabinoid including the principle ingredient, Δ^9 -THC, are quickly absorbed by inhalation or from the GI tract. Excretion of urinary metabolites occurs within 72 hours of exposure^{2,6}. Urinary concentrations are dependent on the time of sample collection, frequency of drug use, and the release rate from fatty tissue.

All cannabinoid are controlled substances, and the SAMHSA (NIDA) recommended cutoff level for Cannabinoid screening tests is 50 ng/mL in urine⁴.

The test is a qualitative, visual screening immunoassay. The method employs unique antibodies to selectively identify the drug in the test urine with a high degree of sensitivity and specificity.

PRINCIPLE OF THE PROCEDURE

The test device 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 suggested for the immunoassay method. 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 (2) distinct color bands, one in the test area and one in the control region.

A **positive** specimen produces only one (1) color band in the control region.

REAGENTS AND MATERIALS SUPPLIED

1. Test strips individually foil pouched with a desiccant
2. Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Positive and negative urine controls available from commercial distributors.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Avoid cross contamination of urine samples by using a new urine specimen cup for each sample.
3. Do not use the kit beyond the expiration date printed on the outside of the foil pouch.
4. Do not open the foil pouch until urine specimen is collected and ready to be tested.
5. Urine specimens may be infectious. Handle and dispose of all used specimens and devices in an approved biohazard container.

STORAGE AND STABILITY

The test device can be stored under refrigeration and at room temperature (2 - 30° C) and will be stable until the expiration date. **Do not** open foil pouch until ready to test.

SAMPLE COLLECTION AND PREPARATION

10 ml of urine must be collected in a clean, dry, plastic or glass container, that does not contain preservative. Some plastics may adsorb drugs. If not tested immediately, urine specimens may be stored refrigerated at 2-8°C for up to 7 days and then frozen(-20° C or colder) prior to assaying. Refrigerated or frozen samples must be warmed to room temperature and gently mixed before testing. Urine samples exhibiting visible precipitates or turbidity should be centrifuged or allowed to settle so a clear aliquot may be sampled for this assay. Collection of samples may require mandatory procedures and custody and control records. Poppy seed ingestion has been associated with positive test results in some samples.

ASSAY PROCEDURES

1. Bring all materials and specimens to room temperature.
2. Remove test strip from the sealed foil pouch.
3. Dip the test strip into the urine sample with the arrows pointing toward the specimen.
4. The urine level should reach the maximum line marked on the strip, but must not exceed the maximum line.
5. Hold the strip in the urine until a reddish color appears at the lower edge of the test membrane (approximately 10 seconds).
6. Withdraw the strip and place it face up on a clean, dry surface.
7. Read the result between 3 - 8 minutes after adding the sample.

READING THE TEST RESULTS

Read test results between 3 - 8 minutes.

Do not interpret results after 8 minutes.

NEGATIVE Two (2) pink/purple bands form. In addition to the control band, a pink/purple band also appears in the test region.

Note: This immunoassay is a screening test. A negative result indicates the drug level is below the detection sensitivity. It is important to understand that concentrations of the drug below cut off may cause a faint "ghost line" to form in the test region. This "ghost line" should be considered a negative result.

POSITIVE One (1) pink/purple band appears in the control region. No band is found in the test region. This is an indication that the drug level is above the detection sensitivity level.

INVALID If there is no pink/purple band in the control area of the strip, the test result is invalid. Retest the sample using a new device.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are positive. Positive results should be confirmed by an alternate method such as GC/MS.

QUALITY CONTROL

1. Each test device has a control band to indicate that the sample volume and migration is adequate, and that the colloidal gold is dissolving as expected. An invalid result must be repeated using a new test device.
2. Positive and negative, drug free urine controls can be used to validate reagent performance and establish test reliability. Commercial drug urine controls are available, but not provided with this test. NIDA recommended guidelines for drugs of abuse screening indicate controls should contain the drug at a level at least 20% above the NIDA cutoff value. If control values do not fall within the established limits, assay results are invalid.

EXPECTED RESULTS

The Advanced Quality THC Test identifies cannabinoid and its metabolites in human urine at a concentration of 50 ng/mL. The concentration of the drug cannot be determined using this test. The test is intended to screen urine to separate a negative result from a presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparative evaluation of 100 clinical specimens was performed using the Advanced Quality One Step Cannabinoid Test and a commercially available EIA screen/semi quantitative test (Table 1). The drug concentration of samples covered the entire assay range and included 20 samples around the cutoff concentration of 50ng/mL. The accuracy was 99%. Results of the Advanced Quality Cannabinoid Test were confirmed with GC/MS (Table 2) and the accuracy was 99%. The EIA results were also compared to GC/MS (Table 3) and the accuracy was greater than 99%.

TABLE 1 – COMPARISON SUMMARY

Commercial EIA	AQ(+)	AQ(-)	Row Totals
(+)	59	1	60
(-)	0	40	40
Col. Totals	59	41	100

TABLE 2 – COMPARISON SUMMARY

GC/MS	AQ(+)	AQ(-)	Row Totals
(+)	59	1	60
(-)	0	40	40
Col. Totals	59	41	100

TABLE 3 – COMPARISON SUMMARY

GC/MS	Commercial EIA(+)	Commercial EIA(-)	Row Total
(+)	60	0	60
(-)	0	40	40
Col. Totals	60	40	100

Precision

Three lots of Advanced Quality Cannabinoid were assayed using control urine containing 0ng/mL, 24ng/mL, 48ng/mL and 75ng/mL 11 nor- Δ^9 -THC-9-COOH, for 20 days. Three individuals read the results independently. A correct positive result was obtained by all individuals, 100% of the time with the 50 and 75 ng/mL concentrations. A correct negative result was found by all individuals, 100% of the time with the 0 ng/mL concentration. The 25ng/mL results varied somewhat depending on the experience of the observer. The inexperienced observer reported this level as positive 100% of the time, while the two experienced readers reported negative results 100% of the time.

Sensitivity

The compounds detected by this assay have been identified and the levels which produce a positive result are listed in Table 4. Some users, depending on experience in reading this test, may find presumptive positive results up to -50% of the cutoff, i.e. 25ng/mL. GC/MS testing must be performed to confirm positive results.

TABLE 4 - COMPOUNDS DETECTED BY ADVANCED QUALITY ONE STEP CANNABINOID TEST

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	1800 ng/mL
Δ^9 -THC	2000 ng/mL
Cannabinol	5000 ng/mL
11-hydroxy- Δ^9 -THC	800ng/mL

Specificity and Interfering Substances

The following substances did not interfere with the Advanced Quality Cannabinoid Test:

Glucose	2000 mg/dL	Uric Acid	10 mg/dL
Human Albumin	2000 mg/dL	Urea	4000 mg/dL
Hemoglobin	10 mg/dL	Bilirubin	2m g/dL

TABLE 5 - COMPOUNDS THAT GIVE NEGATIVE RESULTS AT CONCENTRATIONS UP TO 100 μ g/mL

Acetaminophen	Diazepam	Methylphenidate
4-Acetamidophenol	Digitoxin	Morphine glucuronide
Acetylsalicylic Acid	Digoxin	Morphine sulfate
Amikacin	Ecgonine Hydrochloride	Naloxone
Ampicillin	Ecgonine Methyl Ester	Neomycin
d,l-Amphetamine	Ephedrine	Niacinamide
Amitriptyline	Epinephrine	Oxazepam Perphenazine
Arterenol	Gentisic Glucose Acid	Penicillin G
Aspartame	Guaiaacol	Phencyclidine
Atropine Sulfate	Glyceryl Ether	Phenobarbital
Benzoic acid	Histamine	Phenylethylamine- α
Benzoyllecgonine	Hydrochlorothiazide	Phenylpropranolamine
Caffeine	Hydrocodone	Promethazine
Camphor	Hydromorphone	Pseudoephedrine
Chloroquine	Homatropine	Rantidine
Chlorpheniramine	Imipramine	Salicylic acid
Chlorpromazine HCl	Isoproterenol	Secobarbital
Cocaine Hydrochloride	Ketamine	Tetracycline
Cocaine	Lidocaine	Tetrahydrozoline
Cimetidine	d-Methamphetamine	Theophylline
Cortisone	Meperidine	Thioridazine
Deoxyephedrine	Methadone	Trifluoperazine
Dextromethorphan	Methaqualone	Tryptophan

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of Cannabinoid and its metabolites in human urine only.
2. Although The Advanced Quality One Step Cannabinoid Test is very accurate in detecting the level of THC in urine, there is a possibility of false results due to the presence of interfering substances in the urine.
3. The test is a qualitative screening assay and is not suggested for determining the quantitative level of Cannabinoid in urine.
4. Adulterant, such as bleach or other strong oxidizing agents, when added to urine specimens, may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.
5. There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g. technical or procedural errors.
6. A positive result indicates the presence of cannabinoid and its metabolites in urine. This does not indicate the level of intoxication nor is it intended to monitor drug levels.
7. Results should be confirmed using an alternate method. GC/MS is the preferred confirmatory method.

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