

ADC[®] CLIA WAIVED Marijuana (THC) and COCAINE Test

For *In Vitro* Diagnostic Use
This test is waived under CLIA

Intended Use

The ADC CLIA Waived Test for THC / Cocaine is an *in vitro* screen for the rapid detection of 11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid (THC) and cocaine and its metabolite, benzoylecgonine in human urine above the following concentrations.

THC	11-nor- Δ^9 -THC-9-COOH	50 ng/ml
COC	Benzoylecgonine	300 ng/ml

The test is used to obtain a visual qualitative result and is intended for professional use.

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. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Summary and Explanation

Marijuana(THC) 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 nausea 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 ingested, the drug is metabolized by the liver. The primary urinary metabolite of marijuana is 11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid (THC), and its glucuronide. The presence of detected cannabinoids, including the primary carboxyl metabolite in the urine indicates the use of marijuana (cannabis).

Cocaine

Derived from leaves of coca plant, cocaine is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in the urine primarily as benzoylecgonine in a short period of time. Benzoylecgonine has a biological half-life of 5 to 8 hours, which is much longer than that of cocaine (0.5 to 1.5 hour), and can be generally detected for 24 to 60 hours after cocaine use or exposure.

Urine based screening tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method for screening urine for drugs of abuse.

The ADC CLIA Waived THC/COCAINE Test is based on the principle of highly specific immunochemical reactions of antigens and antibodies, which are used for the analysis of specific compounds in human urine. The ADC CLIA Waived THC/COCAINE Test is a rapid, visual, competitive panel immunoassay that can be used for the simultaneous, qualitative detection of 11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid and benzoylecgonine in urine.

Test Principle

The ADC CLIA Waived THC/COCAINE Test is a one-step immunoassay in which a chemically labeled drug (drug conjugate) competes for limited antibody binding sites with drugs, which may be present in urine. The test device contains a membrane strip that is pre-coated with drug conjugates i.e., THC and COC metabolite, benzoylecgonine, on the test bands. A colored anti-drug monoclonal antibody-colloidal gold conjugate pad is placed at the sample end of the membrane. In the absence of both drugs in the urine, the colored antibody colloidal gold conjugate moves by capillary action, along with the sample urine, across the membrane to the immobilized drug conjugate zones on the test membrane. There it binds to the drug conjugate to form visible lines as the antibody complexes with the drug

conjugates. Therefore, the formation of the visible precipitant in the test zone occurs when the test urine is negative for the drug. When drug is present in the urine, the drug/metabolite antigen competes with drug conjugates in the test band zones for the limited antibody sites in the anti-drug monoclonal antibody-colloidal gold conjugate. The limited antibody binding sites will be filled when a sufficient concentration of drug is present. Preventing the binding of the colored antibody-colloidal gold conjugate to the drug conjugate zone in the test band region. Therefore, absence of the color band on the test zone indicates a positive result.

A control band in the control zone (C) verifies that sufficient volume is added and proper flow of sample is obtained. If the control line does not appear the test card should be discarded.

Reagents and Materials Supplied

Each ADC CLIA Waived THC/COC Test Kit contains:

1. Directions for Use
2. Test Devices: Each device contains a membrane coated with two test lines; the benzoylecgonine bovine protein conjugate and THC bovine protein conjugate and a goat anti-rabbit antibody control line. It also contains a pad coated with THC/benzoylecgonine monoclonal antibody gold complex and rabbit antibody gold complex.
3. Specimen Pipette is enclosed with each device:

Materials Required But Not Provided

1. Timer.
2. Negative and positive controls are commercially available and recommended for use with this test.

Warnings and Precautions

1. FOR IN-VITRO DIAGNOSTIC USE ONLY
2. For professional use only
3. Urine specimens may be potentially infectious. Proper handling and disposal methods should be established. Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.

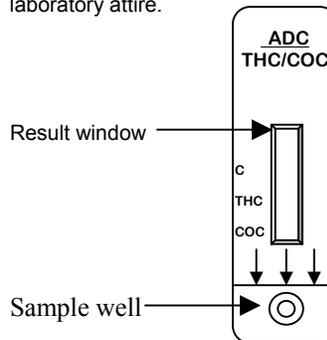
Storage

The reagents contained in the ADC CLIA Waived THC/COC Test should be stored at room temperature or refrigerated (2-30°C).

Specimen Collection and Handling

The ADC CLIA Waived THC/COC Test is formulated for use with urine specimens. Fresh urine does not require any special handling or pretreatment. Urine samples should be collected so that testing may be performed as soon as possible after the specimen collection, preferably during the same day. The specimen may be refrigerated at 2-8°C for 2 days or frozen at -20° C for a longer period of time. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.



Assay Procedure

1. **IMPORTANT:** If specimen, control, or test device has been stored at refrigerated temperature, allow it to warm to room temperature before testing. Do not open pouch until you are ready to add sample.

- Remove the test device from the sealed pouch.
- Draw the urine sample up the pipette and dispense 2 to 3 drops (approximately 0.1 ml) into the sample well

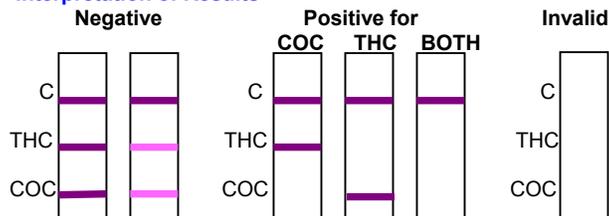
OR

Grasping the ADC end of the card, dip the card into the urine until the urine reaches the dip line. Do not wet the result window.

- Hold the card in the urine until the urine/conjugate mixture begins to show in the result window. Remove and place on a flat, clean surface.

Start timer and read result 8 minutes after the addition of sample. Do not read result after 10 minutes as the intensity of the test lines may change or new lines may appear.

Interpretation of Results



Note: All positive results must be confirmed. Weak/faint lines must be confirmed with a more specific method (such as GC/MS) prior to reporting a positive result.

Quality Control

Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources. Use the same assay procedure as with a urine specimen.

Limitations 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 procedural errors as well as other substances or factors not listed may interfere with the test and cause false results.

Performance Characteristics

Accuracy

Accuracy has been established by comparing the ADC CLIA Waived THC/COC results with results of 157 clinical samples analyzed by GC/MS and Emit II. Results are as follows:

Emit II GC/MS ng/ml	N Results	ADC THC POS	±	ADC THC NEG	ADC COC POS	±	ADC COC NEG
NEG	200	0	0	100	0	0	100
THC 24-49	10	2	5	3	NA	NA	NA
THC 54-77	8	6	2	0	NA	NA	NA
THC 80-832	38	37	1	0	NA	NA	NA
COC 151-312	5	NA	NA	NA	0	3	2
COC 362- 469	10	NA	NA	NA	8	2	0
COC495- 4920	42	NA	NA	NA	40	2	0
TOTALS	313	45	8	103	48	7	102

Overall correlations are 97% with GC/MS and 98% with Emit II.

Precision

Commercially available spiked urine controls were assayed using two lots, twice a day, for twelve days. Three individuals, including one non-technical, interpreted results. An additional 20 replicates were assayed at + 25% and -25% of the cut off for each drug.

Results are as follows:

THC			THC			COC		
ng/mL	ng/mL	N	POS	+/-	NEG	POS	+/-	NEG
0	0	144	0	0	144	0	0	144
24	146	144	0	56	88	0	49	95
36	234	20	0	20	0	0	20	0
64	362	20	0	20	0	0	20	0
77	468	144	82	62	0	75	69	0
144	899	144	144	0	0	144	0	0

Sensitivity

The following structurally related compounds produce positive THC results when tested at levels greater than the concentrations listed below.

Compound	ng/mL
11 -nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid	50
11 -nor- Δ^8 -tetrahydrocannabinol-9-carboxylic acid	50
11 -hydroxy- Δ^9 -tetrahydrocannabinol	2,500
Δ^9 -tetrahydrocannabinol	10,000
Δ^8 -tetrahydrocannabinol	7,500
Cannabinol	10,000
Cannabidiol	100,000

The following structurally related compounds produce positive COC results when tested at levels greater than the concentrations listed below.

Benzoylcegonine	300
Cocaine	300

Interfering Compounds

The following compounds did not cross-react when tested at concentrations up to 100 ug/ml in drug free urine.

Acetaminophen	Erythromycin
Acetylsalicylic acid	Guaiacolglycerol ether
Amitriptyline	Imipramine
Ampicillin	Isoproterenol
Aspartame	Lidocaine
Ascorbic acid	(1R,2S)-(-)-N-methyl-ephedrine
Atropine	(+) Naproxen
Benzocaine	Oxalic acid
Caffeine	Penicillian
Chloroquine	β -Phenylethylamine
(+) Chlorpheniramine	Phenothiazine
(\pm) Chlorpheniramine	L-Phenylephrine
Dexbrompheniramine	Pheniramine
Dextromethorphan	Procaine
4-Dimethylaminoantipyrine	Quinidine
Dopamine	Ranitidine
Ephedrine	Sulindac
(-) Epinephrine	Thioridiazine
(\pm) Epinephrine	Tyramine

Endogenous Substances

The following levels of endogenous substances did not interfere with the expected result in drug free urine and urine spiked with 50 ng/mL 11-nor- Δ^9 -THC-9-carboxylic acid and 300ng/mL of benzoylcegonine.

Glucose	2000mg/dL
Human albumin	2000mg/dL
Human hemoglobin	10mg/dL
Bilirubin	2mg/dL
Urea	4000mg/dL
Uric acid	10mg/dL
Acetone	0.01%
Creatinine	10mg/dL
Sodium Chloride	0.85%
Specific gravity	1.01- 1.03
pH	3, 7, 9

Bibliography

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San Diego, CA 92130 Tel: 1-888-882-7739