MD-U54

Single and Multi-Strip DOA Cassettes and Dipstick Screen Panels (Urine)

For Forensic Use only

INTENDED USE

The DOA Cassettes / Panels are rapid chromatographic immunoassays for the qualitative and simultaneous detection of one to fourteen of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

Parameter	Calibrator	Cut-off(ng/mL)
THC	11-nor- Δ^9-THC-9-carboxylic acid	15/50/100/200

This assay provided 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) or Liquid Chromatography/ Mass Spectrometry (LC/MS) are 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.

INTRODUCTION

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 DOA Cassettes / Panels are based on the principle of the highly specific immunochemical reactions of antigens and antibodies, which are used for the analysis of specific compounds in human urine. The DOA Screen Panels are rapid, visual, competitive panel immunoassay that can be used for the simultaneous, qualitative detection of 11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid.The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity and diet.

PRINCIPLE

The DOA Cassettes / Panels are one-step immunoassay in which chemically labeled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs which may be present in urine. The test device contains membrane strips which are pre-coated with drug-protein conjugates on the test band(s). Each strip, the drug antibody-colloidal gold conjugate pad is placed at one end of the membrane. In the absence of drug in the urine, the solution of the colored antibody-colloidal gold conjugate move along with the sample solution upward chromatographically by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugate then attach to the drug-protein conjugates to form visible lines as the antibody complex with the drug conjugate. Therefore, the formation of the visible precipitant in the test zone occurs when the test urine is negative for the drug. When the drug is present in the urine, the drug/metabolite antigen competes with drug-protein conjugate on the test band region for the limited antibody. When a sufficient concentration of the drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody (drug-protein conjugate)-colloidal gold conjugate to the drug-protein conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result.

A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test device should be discarded.

MATERIALS

Materials Provided

- Multi-Drug Rapid Test device/strips
- Product insert
- Pipette

Materials Required but Not provided

- Specimen collection container
- Timer
- Positive and negative urine controls

PRECAUTIONS

- For forensic use only.
- The pouch containing the test device should be sealed. Discard the test device if package is ripped or torn.
- 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 AND STABILITY

The pouched DOA Screen Panels/Cassettes should be stored at normal humidity and room temperature or refrigerated (2-30ºC) until the expiration date stated on the pouch. The product is humidity-sensitive and should be used immediately after being opened. Any test in an improperly sealed pouch should be discarded.

SPECIMEN COLLECTION AND STORAGE

- Urine Collection: The DOA Cassettes / Panels are formulated for use with urine specimens. Fresh urine does not require any special handling or pretreatment. The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.
- Urine Storage: It is recommended the collected fresh urine to be tested immediately. Fresh urine maybe stored at room temperature (25ºC) for up to 4 hours or to be refrigerated (2-8ºC) for up to 48 hours prior to performing the test. For prolonged storage, specimens may be frozen and stored below -20ºC. 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.

PROCEDURE

Bring test device, patient's sample, and controls should be brought to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.

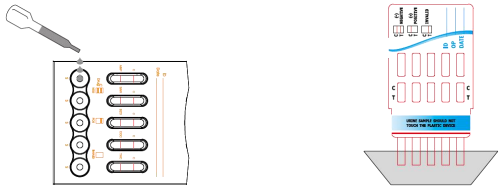
1. Remove the test device from the sealed pouch and use it as soon as possible.

For Single or Multi-Strip cassette test:

2. Place the device on a clean and level surface.
3. Draw the urine sample up the pipette and dispense 3 drops (approximately 120 µl) into each sample well. Avoid adding drops that contain air since air bubbles in the well may cause uneven flow or prevent the flow of the sample onto the test strip.

For Single or Multi-Strip dipstick card test:

4. Dip the sample pad area of the dipstick strip or dipstick card in the urine specimen submerging only up to the "MAX" mark of the dipstick strip or the edge of the dipstick card.



Reading Result:

5. The result(s) should be read at 5 minutes. However, negative results may be read and reported as early as 3 minutes but positive results must be reported at 5 minutes only.
6. Do not interpret the result(s) after 10 minutes after the addition of sample.

INTERPRETATION OF RESULTS

POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources and are recommended to be used daily. Use the same assay procedure as with a urine specimen. Controls should be challenging to the assay cutoff concentration. If control values do not fall within established limits, assay results are invalid. Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.
- The Drug Screen Panels provides built-in process control with a different antigen/antibody reaction at the control region (C) in each strip. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear, the test device should be discarded. The presence of this control band in the control region serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

LIMITATIONS OF THE TEST

1. The assay is designed for use with human urine only.
2. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
3. There is a possibility that technical or procedural error as well other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce either positive results, or that do not interfere with test performance.
4. 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.

PERFORMANCE CHARACTERISTI

Accuracy

Accuracy of the Drugs of Abuse Screen Devices or Panels was established by running urine sample against GC/MS specification.

Specimen	THC15	THC50	THC 100	THC200
Positive	96.8%	96.8%	98.9%	96.1%
Negative	98.3%	98.3%	98.9%	100%
Total	97.5%	97.5%	98.9%	98.1%

Analytical Sensitivity

The sensitivity of DOA Screen Panels was determined by tested GC/MS confirmed controls to the concentration at negative, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff and 3 times of cutoff. The results are summarized below:

Drug Conc.	n	THC15		THC 50		THC 100		THC200	
(Cut-off Range)		-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0
Cutoff	50	11	39	17	33	19	31	17	33
125% Cutoff	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50
3X Cutoff	50	0	50	0	50	0	50	0	50

Specificity

The specificity for The DOA Cassettes / Panels has been tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in drug-free normal human urine. The DOA Cassettes / Panels performance at cutoff point are not affected when pH range of urine specimens is at 3.0 to 8.5 and specific gravity range of urine specimens is at near 1.005 to 1.03. The following compounds were found to produce positive results when tested at levels greater than the concentrations (in ng/mL) listed below:

THC 15 related compounds	**Concentration(ng/mL)**
11-nor-Δ9-THC-9-COOH	15
11-nor-Δ8-THC-9-COOH	15
Δ9-tetrahydrocannabinol	7,500
Δ8-tetrahydrocannabinol	7,500
Cannabinol	10,000
THC 50 related compounds	
11-nor-Δ9-THC-9-COOH	50
11-nor-Δ8-THC-9-COOH	50
11-hydroxy-Δ9-Tetrahydrocannabinol	50
Δ8-Tetrahydrocannabinol	15,000
Δ9-Tetrahydrocannabinol	15,000
Cannabinol	20,000
Cannabidiol	>100,000
THC 100 related compounds	
11-nor-Δ9-THC-9-COOH	100
11-nor-Δ8-THC-9-COOH	100
Δ 8-Tetrahydrocannabinol	20,000
Δ 9-Tetrahydrocannabinol	20,000
Cannabinol	20,000

THC 200 related compounds	
11-nor-Δ9-THC-9-COOH	200
11-nor-Δ8-THC-9-COOH	200
Δ9-tetrahydrocannabinol	30,000
Δ8-tetrahydrocannabinol	30,000
Cannabinol	20,000

Non Cross-Reacting Compounds
The following compounds were found not to cross-react when tested at concentrations at 100 μg/mL.

Acetaminophen	Benzocaine	Ibuprofen
(-)-Ephedrine	Bilirubin	Imipramine
(+)-Naproxen	b-Phenylethylamine	Lidocaine
(+/-)-Ephedrine	Caffeine	L-Phenylephrine
(+/-)-Isoproterenol	Chlorpheniramine	N-Methyl-Ephedrine
4-Dimethylaminoantipyrine	Creatine	Oxalic Acid
Acetone	Dextrorphan tartrate	Penicillin-G
Albumin	Dopamine	Pheniramine
Amitriptyline	Erythromycin	Phenothiazine
Ampicillin	Ethanol	Procaine
Aspartame	Furosemide	Quinidine
Aspirin	Guaiacol Glyceryl Ether	Ranitidine
Atropine	Hemoglobin	Vitamin C

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse