U-Cup 5 panel Drug Test Cup

Package Insert for testing of any combination of the following drugs:
BZO/COC/THC/MDMA/MOP
Available with Specimen Validity Tests (S.V.T.) for:
Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine

One step, rapid screening tests for the qualitative detection of drug(s) and drug metabolite(s) in human urine.

For Forensic Use Only.

INTENDED USE

Drug Tests Cup is a lateral flow chromatographic immunoassay designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test Name	Calibrator	Cut-off
Benzodiazepines/BZO	Oxazepam	200 ng/mL
Cocaine/COC	Benzoylecgonine	300 ng/mL
Marijuana/THC	Delta-9-THC-COOH	50 ng/mL
Methylenedioxymethamphetamine/MDMA	MDMA	500 ng/mL
Opiates 300/ Morphine/MOP/OPI 300	Morphine	300 ng/mL

Drug Tests Cup provides only a preliminary analytical test result. The test is not intended to be used in monitoring the drug levels. A more specific alternate method must be used in order to confirm the test result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST

Drug Tests Cup is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening specific drugs and their metabolites without the need of instrumentation. The method employs a unique mixture of antibodies to selectively detect the elevated levels of specific drugs and their metabolites in urine. **Drug Tests Cup** optionally includes an adulteration strip for testing Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine.

BENZODIAZEPINES / BZO

Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their presence by analgesia, drowsiness, confusion, diminished reflexes, lowering of body temperature, respiratory depression, blockade of adrenocortical response, and a decrease in peripheral resistance without an impact on the cardiac index. The major pathways of elimination are the kidneys (urine) and the liver where it is conjugated to glucuronic acid. Large doses of Benzodiazepines could develop tolerances and physiological dependency and lead to its abuse. Only trace amounts (less than 1%) of Benzodiazepines are excreted unaltered in the urine, most of Benzodiazepines in urine is conjugated drug. Oxazepam, a common metabolite of many benzodiazepines, remains detectable in urine for up to one week, which makes Oxazepam a useful marker of Benzodiazepines abuse.

COCAINE / COC

Cocaine is an alkaloid present in Coca leaves (Erythyroxine coca). Its pharmacological properties, such as stimulating and euphoric effects, have been known for centuries. Cocaine produces alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. In large dose, Cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Cocaine is excreted in the urine primarily as Benzoylecgonine, which can generally be detected for 24 – 48 hours after cocaine exposure.

MARIJUANA / THC

THC (Δ^9 – tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). THC is central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short-term memory, produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increases heart rate. Large doses of marijuana could develop tolerances and physiological dependency and lead its abuse. The main metabolite excreted in the urine is 11-nor- Δ^9 – tetrahydrocannabinol-9-carboxylic acid (Δ^9–THC-COOH), which is found in the urine within hours of exposure and remains detectable for 3-10 days after smoking.

METHYLENEDIOXYMETHAMPHETAMINE / MDMA

MDMA belongs to a family of man-made drugs. Its relatives include MDA (methylenedioxyamphetamine), and MDEA (methylenedioxyethylamphetamine). They all share the amphetamine-like effects. MDMA is a stimulant with hallucinogenic tendencies described as an empathogen as it releases mood-altering chemicals, such as cartooning and L-dopa, and may generate feelings of love and friendliness. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia and insomnia. MDMA is administered either by oral ingestion or intravenous injection. The effects of MDMA begin 30 minutes after intake, peak in an hour and last for 2 – 3 hours.

OPIATES 300 / MOP / OPI 300

Opiates refer to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opiates exert their effects on the central nervous system and organs containing smooth muscle. Opiates manifest their presence by analgesia, drowsiness, euphoria, lowering of body temperature, respiratory depression, blockade of adrenocortical response. The major pathways of elimination are kidneys (urine) and the liver where it is conjugated to glucuronic acid. Opiates and their metabolites can be detected in urine as result of heroin, morphine, codeine or poppy seed intake.

S.V.T. SUMMARY

The strips contain chemically treated reagent pads. 3 to 5 minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help to assess the integrity of the urine sample.

WHAT IS ADULTERATION?

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH, specific gravity and creatinine and to detect the presence of oxidants/PCC, nitrites or glutaraldehyde in urine.

- **Oxidants/PCC (Pyridinium chlorochromate)** tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium chlorochromate (sold under the brand name UrineLuck) is a commonly used adulterant.[6] Normal human urine should not contain oxidants of PCC.
- **Specific gravity** tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.
- **pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
- **Nitrite** tests for commonly used commercial adulterants such as Klear and Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.[9] Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.
- **Glutaraldehyde** tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative results by disrupting the enzyme used in some immunoassay tests.[7] Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.
- **Creatinine** is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.[8] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to "flush" the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low Creatinine and specific gravity levels may indicate dilute urine. The absence of Creatinine (<5 mg/dl) is indicative of a specimen not consistent with human urine.

PRINCIPLE OF TEST

Drug Tests Cup is a competitive binding immunoassay in which drugs and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of urine specimen is applied to the sample pad of the test device, the urine specimen migrates through the test device by capillary action. If the drug or drug metabolite concentration in the specimen is below the cut-off level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line of the nitrocellulose membrane to form a T line, which indicates a negative result. If the concentration of drug in the urine specimen is above the cut-off level, it will bind with antibodies conjugated with colloidal gold particles, so that no T line will be developed in the test region, which indicates a positive result.

REAGENTS

Drug Tests Cup contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the T zone, goat polyclonal antibody against gold-protein conjugate at the C zone, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibodies specific against to Benzodiazepines, Cocaine, Marijuana, Mehtylenedioxymethamphetamine, Opiates 300.

S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Oxidants / PCC	0.36%	99.64%
Specific Gravity	0.25%	99.75%
pH	0.06%	99.94%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
Creatinine	0.04%	99.96%

MATERIALS PROVIDED

- Drug Tests Cup
- Product insert
- Security Seal
- Procedure Card

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer
- External positive and negative controls

PRECAUTIONS

1. For Forensic Use Only.
2. Do not use after the expiration date.
3. The drug tests should remain in the sealed pouch until use.
4. All specimens should be considered potentially hazardous and handle in the same way as an infectious material.
5. All used drug tests should be discarded according to federal, state and local regulation.

STORAGE AND STABILITY

Store **Drug Tests Cup** in the sealed pouch at 2℃ to 30℃. The drug tests is stable through the expiration date printed on the sealed pouch. The drug tests must remain in the sealed pouch until use. If store at 2℃ to 8℃, allow the drug tests to reach room temperature (15℃ to 30℃) before performing the test. Dot not freeze, do not use beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE

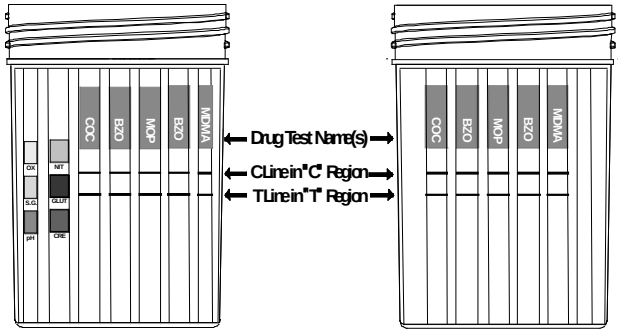
Fresh urine specimens should be collected directly into a clean and dry container. Urine collected at any time of the day may be used for testing. Urine specimen exhibiting visible precipitates should be centrifuged, filtered or allowed the precipitates to settle to obtain a clear specimen for testing.

For best results, test a fresh specimen immediately following collection. Storage of specimens should not exceed 2 hours at room temperature or 4 hours refrigerated (2-8°C) prior to using.

TEST PROCEDURE

Allow the cup, urine specimen, and/or controls to reach room temperature (15-30°C) before testing.

1. Remove the cup from the sealed pouch and use it as soon as possible.
2. Collect specimen in the cup and secure the cap tightly.
3. If the temperature strip is included with Drug Test Cup, please read urine temperature between 2-4 minutes after voiding to verify the temperature ranges between 90–100℉ (33-38℃).
4. Place the cup on a flat surface.
5. Date and initial the security seal, and place the security seal on the cap.
6. Peel off the label on the cup to view the results.
7. If adulteration test is included on the test cup, read the adulteration test results between 2 to 5 minutes. See the color chart for interpretation. If the specimen indicates adulteration, we recommend not to interpret the drug test results and either retest the urine or collect another specimen.
8. **Read the test results at 5 minutes.** See the illustration below. For detailed operation instructions, please refer to the Procedure Card.



INTERPRETATION OF RESULTS

Positive: One colored line appears in the Control zone (C). No line appears in the Test zone (T). The absence of a line in the test region (T line) indicates a positive result. The positive result indicates that the drug level is above the detectable level.

Note: The samples with positive results should be confirmed with more specific method.

Negative: One colored line appears in the Control zone, and another colored line appears in the Test zone. The negative result indicates the drug or its metabolite level is below the detectable level.

Invalid: No line appears in the Control zone. If no C line or no C line and T line develop within 5 to 10 minutes, the test is invalid. The test should be repeated with a new test device. Insufficient specimen volume or the incorrect procedural techniques are the most likely reasons for invalid result. Review the procedure and repeat the test using a new test strip or device. If the problem persists, discontinue using the current lot and contact your suppliers.

ADULTERATION INTERPRETATION

(Please refer to the color chart, if applicable)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

QUALITY CONTROL

1. Built-in Control: the test contains a built-in control feature, the C line. The presence of the C line indicates that the test is performed properly. If a C line does not form, the test is considered invalid. In this case, the testing should be repeated with a new drug test.
2. External Quality Control: Control materials are not supplied with this kit. However, it is recommended that positive and negative controls should be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.
3. Test each new lot and shipment by using external quality control materials (positive and negative), with each new untrained operator, monthly for storage, and as otherwise required by your lab internal quality system procedures.

S.V.T. ADULTERATIONS LIMITATIONS

1. The adulteration tests included with the product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an "all-inclusive" representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. pH tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
5. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
6. Glutaraldehyde: is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high protein diets) may interfere with the test results.
7. Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

LIMITATIONS

1. **Drug Tests Cup** provides only a qualitative, preliminary testing result. A more specific testing method must be used in order to obtain a confirmed testing result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants such as bleach or other oxidizing agents may produce erroneous results. If suspected, the test should be repeated with a fresh specimen and a new drug tests.
4. The urine specimens with bacterial contamination should not be used for testing, as these contaminations may interfere with the test and cause false results.
5. A positive result does not indicate the level of intoxication, the route of the drug administration or the concentration of the drug in the urine.
6. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of test.
7. Test does not distinguish between drugs of abuse and certain medications.
8. Certain foods or food supplements may cause a false positive result.

PERFORMANCE CHARACTERISTICS

Accuracy:

The comparison studies were conducted using **Drug Tests Cup** and commercially available rapid drugs of abuse tests. The studies were performed on approximately 128 clinical specimens per drug type previous collected from the clinical settings. Presumptive positive results were confirmed by GC/MS. The following results are summarized from these comparison studies:

% Agreement with Commercial Kit

	COC	THC	MDMA	MOP
Positive Agreement	100%	100%	97%	100%
Negative Agreement	100%	98%	97%	100%
Total Agreement	100%	99%	97%	100%

% Agreement with GC/MS

	COC	THC	MDMA	MOP
Positive Agreement	100%	100%	97%	100%
Negative Agreement	100%	98%	97%	100%
Total Agreement	100%	99%	97%	100%

Sensitivity:

Sensitivity of **Drug Tests Cup** was characterized by validating the test performance around the claimed cut-off concentration of each test. The cut-off of each test was determined by the lowest concentration of drug which produces at least 50% positive testing results in total numbers of determinations. The results were summarized as the following:

Drug concentration Cut-off Range	n	BZO		COC		THC		MDMA	
		-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0
-25% Cut-off	20	19	1	20	0	20	0	20	0
+25% Cut-off	20	1	19	0	20	0	20	0	20
+50% Cut-off	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	MOP	
		-	+
0% Cut-off	20	20	0
-50% Cut-off	20	20	0
-25% Cut-off	20	20	0
+25% Cut-off	20	0	20
+50% Cut-off	20	0	20

Based on above data, sensitivity of the assay to the 5 analytes is as follows:

Benzodiazepines:	200 ng/mL	MDMA:	500 ng/mL
Cocaine:	300 ng/ mL	Opiates 300:	300 ng/mL
Marijuana:	50 ng/mL		

Precision / Reproducibility:

Reproducibility was determined by replicating tests on five different concentrations of each drug in urine specimens: negative, 50% below cut-off, 25% below cut-off, 25% above cut-off and 50% above cut- off. Each drug test was tested four times daily for five consecutive days with a total 20 assays at each concentration. The data are summarized below:

Benzodiazepines Precision/Reproducibility Study:

Benzodiazepines Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
100	20	20/0	100%
150	20	19/1	95%
250	20	1/19	95%
300	20	0/20	100%

Cocaine Precision/Reproducibility Study:

Cocaine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	0/20	100%
450	20	0/20	100%

Marijuana Precision/Reproducibility Study:

Marijuana Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
25	20	20/0	100%
37.5	20	20/0	100%
62.5	20	0/20	100%
75	20	0/20	100%

MDMA Precision/Reproducibility Study:

MDMA Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
250	20	20/0	100%
375	20	20/0	100%
625	20	0/20	100%
750	20	0/20	100%

Opiates 300 Precision/Reproducibility Study:

Opiates 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	0/20	100%
450	20	0/20	100%

The data presented here demonstrates excellent precision/ reproducibility of **Drug Tests Cup** across multiple concentrations of human urine.

Analytical Specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine /a negative control. Analyzing various concentration of each compound by using **Drug Tests Cup**, the concentration of the drug that produced a response approximately equivalent to the cut-off concentration of the assay was determined. Results of those studies appear in the table(s) below:

Drug Compound	Response equivalent to cutoff in ng/mL
BENZODIAZEPINES (BZO)	
Oxazepam	200
Alprazolam	100
α-Hydroxyalprazolam	1000
Bromazepam	1000
Chlordiazepoxide	1000
Clobazam	30
Clonazepam	1500
Diazepam	1000
Flunitrazepam	125
Lorazepam	6000
Midazolam	50000
Nitrazepam	1000
Nordiazepam	125
Temazepam	100
Triazolam	12500
Estazolam	40
COCAINE (COC)	
CocaineHcl	10000
Benzoylecgonine	300
Ecgonine Hcl	100000
MARIJUANA (THC)	
11-nor-Δ8-THC-9-COOH	50
(-)-delta8-THC	>100000
(-)-delta9THC	>100000

Cannabinol	>100000
Cannabidiol	>100000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
(±)- MDMA	500
S(+)-Amphetamine	100000
R(-)-Methamphetamine	25000
(±)-MDEA	50
(±)-MDA	1000
OPIATE 300/MORPHINE (MOP/OPI 300)	
Morphine	300
Codeine	75
Hydrocodone	10000
Hydromorphone	3500
Morphine-3beta-D-glucuronide	300
6-Monoacetylmorphine	25
Oxycodone	>100000
Oxymorphone	>100000
Thebaine	80000

Interfering Compounds:

The following compounds in both drug-free urine and drug positive urines with Benzodiazepines, Cocaine, Marijuana, Mehtylenedioxymethamphetamine, Opiates 300, show no cross-reactivity when tested with **Drug Tests Cup** at a concentration of 100 µg/mL.

Common Substances:

Acetaminophen	Dextromethorphan	Lidocaine
Acetone	Dopamine	(+)-Naproxen
Albumin	(+/-)-Epinephrine	Niacinamide
Ampicillin	Erythromycin	Nicotine
Ascorbic Acid	Ethanol	Oxalic Acid
Aspartame	Furosemide	Penicillin-G
Aspirin	Glucose	Phenothiazine
Atropine	Guaiacol Glyceryl Ether	Quinidine
Benzocaine	Hemoglobin	Riboflavin
Bilirubin	Ibuprofen	Sodium Chloride
Caffeine	(+/-)-Isoproterenol	Sulindac
(+/-)-Chlorpheniramine	Ketamine	Theophylline
Creatine	Levorphanol	4-Dimethylaminoantipyrine

Biological Materials:

Albumin	Vitamin(L-Ascorbic Acid)
Bilirubin	Uric Acid
Creatine	Urine pH 4.5-9.0
Hemoglobin	Urine Specific Gravity 1.002-1.035 g/mL
Glucose	

(There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results.)

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Revised: Jan, 2019