iClean®

6-Panel Urine Drug Screening Kit for MOP/MET/KET/MDMA/THC/COC Instruction of Use

REF CY-UDS-0601

For Employment and Insurance Use Only

iClean® 6-Panel Urine Drug Screening Kit for MOP/MET/KET/MDMA/THC/COC offers qualitative detection of the following drugs of abuse and their principal metabolites in human urine at specified cut-off levels: Morphine (MOP), Methamphetamine (MET), Ketamine (KET), Methylenedioxymethamphetamine (MDMA), Tetrahydrocannabinol (THC) and Cocaine (COC).

Intended Use

The 6-Panel Urine Drug Screening Kit is rapid urine screening test. The test is a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their metabolites in human urine at the following cut off concentrations:

Test	Calibrator	Cut off (ng/mL)
Morphine (MOP)	Morphine	150
Methamphetamine (MET)	D-Methamphetamine	500
Ketamine (KET)	Ketamine	500
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamp hetamine HCl (MDMA)	500
Tetrahydrocannabinol (THC)	11-nor-9 -THC-9 COOH	20
Cocaine (COC)	Benzoylecgonine	150

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

The assay provides a qualitative, preliminary test result. A more specific analytical method must be used in order to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Summary

The 6-Panel Urine Drug Screening Kit for MOP/MET/KET/MDMA/THC/COC is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

Morphine (MOP): Morphine is a popular marketed drug (Serax) for treatment of moderate to severe pain. It is also a common metabolite of opiates [morphine, codeine (methyl-morphine), and heroin (semi-synthetic derivatives of morphine)]. The opiates are administered either by smoking, intravenous injection, intramuscular injection or oral ingestion. Adverse or toxic effects of opiates usage include papillary constriction, constipation, urinary retention, nausea, vomiting, hypothermia,drowsiness, dizziness, apathy, confusion, respiratory depression, hypotension, cold and clammy skin, coma,and pulmonary edema. Death may occur following an over dosage.

The duration of effect of morphine is 3-6 hours. Morphine is metabolized extensively, with only 2-12% excreted as unchanged morphine in the urine.Heroin is rapidly metabolized to morphine in the body; the pattern of urinary excretion of heroin is similar to that of morphine.Codeine is also extensively metabolized, 10-15% of the dose is demethylated to form morphine and norcodeine. It has been reported that the unchanged morphine may remain detectable in urine for up to one week, which make morphine a marker of opiates abuse.

Ketamine (KET): Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss of coordination, sense of invulnerability, muscle rigidity, aggressive/violent behavior, slurred or blocked speech, exaggerated sense of strength, and a blank stare. There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained.The effects of Ketamine generally last 4-6 hours following use. Ketamine is excreted in the urine as unchanged drug (2.3%) and metabolites (96.8%).

Methamphetamine(MET): Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of Methamphetamine generally last 2-4 hours and the drug have a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use.

Methylenedioxymethamphetamine(MDMA): MDMA is an abbreviation of the chemical methylenedioxymethamphetamine. It is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. It also has street names such as Ecstasy,X, XTC,E, Love Doves, Clarity,Adam,Disco Biscuits, and Shamrocks. MDMA is a stimulant with hallucinogenictendencies. although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. It is described as an empathogen since it releases mood-alteringchemicals, such as cartooning and L-dopa, in the brain and may generate feelingsof love and friendliness. MDMA is a Class A drug, in the same category as heroinand cocaine. The adverse effects of MDMA use include elevated blood pressure,hyperthermia, anxiety, paranoia, and insomnia. Overdoses of MDMA can be fatal,often resulting in heart failure or heat stroke.

MDMA belongs to a"family"of man-made drugs;its"relatives"are MDA(methylenedioxyamphetamine), the parent drug of MDMA,and MDEA(methylenedioxyethylamphetamine),also know as EVE, the sister of MDMA. They all have the amphetamine-like effects. MDMA is administered either by oralingestion or intravenous injection. MDMA tablets come in different sizes and colors, and often have logos such as doves on them. Its clinical dose is 50-100mg;the threshold toxic dose is 500mg. The effects of the MDMA begin 30 minutesafter taking. They peak in an hour and last for 2-3 hours. Sixty five percent (65%)of MDMA is excreted unchanged in urine and it is detectible in the urine for up to 3 days after use.

Tetrahydrocannabinol (THC): Tetrahydrocannabinol is a hallucinogenic agent derived from the floweringportion of the hemp plant. The active ingredients in cannabinoids, THC and Cannabinol can be metabolized and excreted as 11-nor-△9-tetrahydrocannabinol-9-carboxylic acid with a half-life of 24 hours. It canbe detected for 1 to 5 days after use. When smoked or orally administered, THC produces euphoric effects. Higher doses used by abusers produce centralnervous system effects, altered mood and sensory perceptions, loss ofcoordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. A tolerance to the cardiacand psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea.Overdose and extended usage of cannabinoids may lead to substanceabuse,which may cause severe and/or permanent damage to the human nervesystem.

Cocaine (COC): Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine. Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.

Principle

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region. A drug-positive urine specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Precautions

1. Discard after first use. The test cannot be used more than once.
2. Do not use the test kit beyond expiration date.
3. Do not use the test if the pouch is punctured or not sealed.
4. Keep out of the reach of children.
5. Do not read results after 5 minutes.
6. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
7. The used test Panel should be discarded according to federal, state and local regulations.

Materials

Materials Provided

- Test devices
- Disposable droppers
- Package insert
- Procedure card
- Sample collection container

Material Required but Not Provided

- Timer

Storage and Stability

1.Store at 4°C-30°C (39°F-86°F) in the sealed pouch up to the expiration date.
2.Keep away from direct sunlight, moisture and heat.
3.DO NOT FREEZE.
4.Preferably open the pouch only shortly before collection and testing.

Specimen Collection and Preparation

Urine Assay

The urine sample must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine samples exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

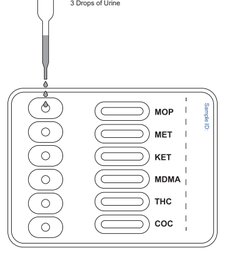
Sample Storage

Urine samples may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, samples may be frozen and stored below -20°C. Frozen samples should be thawed and mixed well before testing.

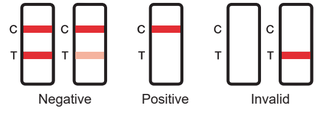
Test Procedure

Allow the kit and urine specimen to reach room temperature (18ºC-30ºC/65°F-86°F) before testing.

1. Remove the test device from the sealed pouch. Use it as soon as possible.
2. Place the test device on a clean and level surface. Add 100uL of urine (3 full drops using the included pipette) to each of the sample wells of the test device. Start the timer. Avoid trapping air bubbles in the sample well.
3. Wait for the colored lines to appear. The results should be read at 5 minutes. Do not read after 5 minutes.



Interpretation of Results



Negative (-)

A colored band is visible in the Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Positive (+)

A colored band is visible in the Control Region (C). No colored band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific Test Region (T).

Invalid

If a colored band is not visible in the Control Region (C), the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor with the lot number.

Note: There is no meaning attributed to line color intensity or width.

Quality Control

Though there is an internal procedural control line in the test device of Control Region (C), the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

Limitations of Procedure

1.The test provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

Performance Characteristic

1. Analytical Sensitivity

Standard drugs were spiked into negative PBS pool to the concentration of 0% Cut-off, -50% Cut-off，-25% Cut-off,Cut-off,+25% Cut-off and +50% Cut-off.The results were summarized below.

Drug Conc. (Cut-off range)	N	MOP		MET		KET		MDMA		THC		COC	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	25	5	27	3	23	7	23	7	25	5
Cut-off	30	10	20	13	17	2	28	10	20	14	16	15	15
25% Cut-off	30	3	27	5	25	1	29	4	26	3	27	6	24
50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

2. Analytical Specificity

Compound	ng/mL
Morphine (MOP)	
Morphine	150
Codeine	150
Ethyl Morphine	150
Hydrocodone	5000
Hydromorphone	5000
Morphinie-3-b-d-glucuronide	1000
Thebaine	30000
Methamphetamine (MET)	
D(+)-Methamphetamine	500
D-Amphetamine	50000
Chloroquine	50000
(+/-)-Ephedrine	50000
(-)-Methamphetamine	25000
(+/-)3,4-methylenedioxumethamphetamine(MDMA)	2,000
b-Phenylethylamine	50000
Trimethobenzamide	10000
Ketamine (KET)	
Ketamine	500
Methadone	50000
Pethidine	12500
Methylamphetamine	12500
Methoxyphenamine	12500
Promethazine	25000
Phencyclidine	25000
Methylenedioxymethamphetamine (MDMA)	
3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
3,4-Methylenedioxyamphetamine HCl	3000
3,4-Methylenedioxyethylamphetamine	300
l-Methamphetamine	25000
Marijuana (THC)	
11-nor-D9-THC-9-COOH	20
11-nor-D8-THC-9-COOH	30
11-hydroxy-D9-Tetrahydrocannabinol	2500
D8- Tetrahydrocannabinol	7500
D9- Tetrahydrocannabinol	10000
Cannabinol	10000
Cannabidiol	100000
Cocaine (COC)	
Benzoylecgonine	150
Cocaine HCl	500
Cocaethylene	12500
Ecgonine	32000

3. Cross-Reactivity

Considering the complexity of clinical urine specimens and the possibility that various urine specimens contain potentially interfering substances, we simulated above situations by adding the potentially interfering substances to a certain concentration as specimen. The following components show no cross-reactivity when tested with iClean® 6-Panel Urine Drug Screening Kit at a concentration of 100 ug/mL.

11-nor-D8-THC-9 COOH	Caffeine	Deoxycorticosterone	l-Ascorbic acid	Pentobarbital
3-acetate	Cannabidiol	Desalkylflurazepam	Loperamide	Perphenazine
3-Hydroxytyramine	Chloral hydrate	Chloral hydrate	Lorazepam	Phenelzine
4-Hydroxyphencyclidine	Chloramphenicol	Diacetylmorphine (Heroin)	Meperidine	Phenobarbital
5,5-Diphenylhydantoin	Chlordiazepoxide	Diazepam	Meprobamate	p-Hydroxyamphetamine
6-Monoacetylmorphine	Chlorothiazide	Diclofenac	Methylphenidate	Prednisone
Acetophenetidin	Chlorpheniramine	Diflunisal	Midazolam	Procyclidine

Acetylsalicylic acid	Chlorpromazine	Digoxin	N-Acetylprocainamide	Promazine
a-hydroxyalprazolam	Cholesterol	Diphenhydramine	Nalidixic acid	Quinidine
Allobarbital	Cis-tramadol	Disopyramide	Naloxone	Quinine
Alphenol	Clobazam	d-Norpropoxyphene	Naltrexone	RS-Lorazepamglucuronide
Alprazolam	Clonazepam	Doxylamine	Naproxen	Salicylic acid
Aminopyrine	Clonidine	d-Pseudoephedrine	n-Desmethyl-cis-tramadol	Secobarbital
Amobarbital	Clorazepatedipotass	Ecgonine	Niacinamide	Serotonin
Amoxicillin	Cocaethylene	Ecgonine methyl ester	Nicotine	ß-Phenylethylamine
Ampicillin	Cocaine	Erythromycin	Nifedipine	Sulfamethazine
Apomorphine	Cortisone	Estazolam	Nitrazepam	Sulindac
Aprobarbital	Cotinine	Estrone-3-sulfate	Norbuprenorphine	Talbutal
Aspartame	Creatinine	Ethyl-p-aminobenzoate	Norbuprenorphine 3-D-Glucuronide	Temazepam
Atropine	Cyclopentobarbital	Fenoprofen	Norchlordiazepoxide	Tetracycline
Barbital	d,l-Brompheniramine	Flunitrazepam	Nordiazepam	Tetrahydrocortisone
Benzilic acid	d,l-Chlorpheniramine	Furosemide	Norethindrone	Tetrahydrozoline
Benzodiazepines	d,l-Isoproterenol	Gentisic acid	Nor-LAAM	Thiamine
Benzoic acid	d,l-Octopamine	Hemoglobin	Noscapine	Thioridazine
Benzoylecgonine	d,l-O-Desmethylvenlafaxine	Hydralazine	o-Desmethyl-cis-tramadol	Tolbutamide
b-Estradiol	d,l-Propanolol	Hydrochlorothiazide	o-Hydroxyhippuric acid	Triamterene
Bilirubin	d,l-Tryptophan	Hydrocortisone	Oxalic acid	Triazolam
Bromazepam	d,l-Tyrosine	Isoxsuprine	Oxazepam	Trifluoperazine
Buprenorphine	d/l-Amphetamine	JWH-018	Oxolinic acid	Trimethoprim
Buprenorphine 3-D-Glucuronide	D8 -THC	JWH-073	Oxymetazoline	Tryptamine
Butabarbital	D9 -THC	Ketoprofen	Papaverine	Uric acid
Butalbital	d-Amphetamine	Labetalol	Penicillin-G	Verapamil
Butethal	Delorazepam	l-Amphetamine	Pentazocine	Zomepirac

From the results above, it is clear that iClean® 6-Panel Urine Drug Screening Kit resists well against interference from these substances.

Bibliography

[1] Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
[2] Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.
[3] Winger, Gail, A Handbook of Drug and Alcohol Abuse, Third Edition, Oxford Press, 1992, page 146.
[4] Robert DeCresce. Drug Testing in the workplace, 1989 page 114.
[5] Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991; 216.
[6] B. Cody, J.T., Specimen Adulteration in drug urinalysis. Forensic Sci. Rev., 1990, 2:63.
[7] Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City, CA 2002.
[8] Hardman JG, Limbird LE. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.

Index of Symbols

30°C 4°C	Temperature limit		Consult instructions for use
	Do not re-use	LOT	Batch code
Σ	Contains sufficient for <n> tests		Keep away from sunlight
	Use-by date		Manufacturer
REF	Catalogue number		Do not use if package is damaged and consult instructions for use
IVD	In vitro Diagnostic medical device		

Manufacturer

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