

### INTENDED USE

The *Multi-Drug of Abuse Urine Test* is a rapid qualitative immunoassay. The device provides preliminary results for the detection of potential abuse of one or more drugs (see list below\*). This is not a screening device to monitor prescription medication use and it is not for internal use. The device is intended for laboratory\*\* and home use.

Abbreviation	Test	Cutoff
AMP	Amphetamine	1000 ng/ml
BAR*	Barbiturates	200 ng/ml
BZD*	Benzodiazepine	300 ng/ml
COC	Cocaine	300 ng/ml
MET or mAMP	Methamphetamine	1000 ng/ml
MDMA or XTC	MDMA or Ecstasy	500 ng/ml
MOR/OPI	Morphine/Opiates	2000 ng/ml
MOR/OPI300	Morphine/Opiates	300 ng/ml
MTD	Methadone	300 ng/ml
OXY100	Oxycodone	100 ng/ml
OXY300	Oxycodone	300 ng/ml
PCP	Phencyclidine	25 ng/ml
TCA*	Tricyclics	1000 ng/ml
THC	Marijuana/Hashish	50 ng/ml

The Substance Abuse and Mental Health Services Administration (SAMHSA) has not recommended a screening cut off for Oxycodone positive specimens. \*Cutoff levels for many tests are those recommended by SAMHSA. However, there are no uniformly recognized drug-cutoff levels for barbiturates, benzodiazepines or tricyclic antidepressants in urine. When present in a device, the BAR, BZD and TCA tests will yield preliminary positive results when BAR, BZD or TCA respectively are ingested at or above therapeutic doses.

\*\* Laboratory users include medical professionals and lay persons who have received instructions for drugs of abuse testing from a physician or medical review officer and generally perform at least 5 tests per week.

The multi-drug of abuse test device provides a preliminary test result. The device shows only if a drug was or was not present at or above the cutoff level. Positive results must be confirmed by a more specific analytical method. Follow the instructions in the "Confirmation Testing" section if you get a positive result.

### CONFIRMATION TESTING

Performing a test with the multi-drug device may be only the first step of a two-step process for determining the presence of drugs of abuse. If you get a "preliminary positive" result, you should send the sample to a certified laboratory for confirmation testing with a more accurate and reliable method.

Materials needed to send samples for confirmation testing are not included in this kit. To obtain Confirmation Kits, call customer service (toll-free) at 800-340-4029 on weekdays from 8AM to 5PM EST.

For further information see the Section "Sending Samples for Confirmation"

### SUMMARY

Information regarding the drugs that may be tested by a given device is presented below:

#### Amphetamine (AMP)

Amphetamines are central nervous system stimulating drugs. Overdose or extended usage may lead to substance abuse. Amphetamine abuse may cause severe or permanent damage to the human nerve system. Amphetamines appear in the urine within three hours of administration. It may be present for about 24-48 hours.

#### Barbiturates (BAR)

Barbiturates are central nervous system depressants. Overdose or extended usage may lead to severe or permanent damage to the human nervous system. Barbiturates are classified as ultra-short, short-intermediate, and long-acting. The most commonly abused barbiturates are short- and intermediate-acting agents. The ultra short-acting compounds lasts 15 minutes to 6 hours. The intermediate acting compounds lasts 3 to 24 hours. A higher percentage of long-acting barbiturates are excreted in the urine unchanged. Shorter-acting compounds are extensively metabolized and excreted in the urine. A small percentage is unchanged drugs.

#### Benzodiazepines (BZD)

Benzodiazepines are sedative, hypnotic and anti-anxiety drugs. Most benzodiazepines are extensively metabolized in the liver. The metabolites excrete in the urine. Benzodiazepines have a low potential for physical or psychological dependence. Overdose and extended usage may lead to coma and possibly death. Benzodiazepines may remain effective for 4-8 hours. They are excreted in the urine primarily as parent compounds or an inactive metabolite, oxazepam glucuronide. They are detectable for one to two days. Oxazepam, a common metabolite of many benzodiazepines, is also a marketed drug.

#### Cocaine (COC)

Cocaine is a nervous system stimulating drug. It has pharmacological properties such as local anesthetic. It has addictive effects. It may lead to substance abuse. Cocaine may appear in urine for only few hours after use. Benzoylecgonine is a metabolite of cocaine. Benzoylecgonine may be detectable in urine over 2 days after taking cocaine. Its detection in human urine has been widely used to evaluate cocaine usage.

#### Methamphetamine (MET or mAMP)

Methamphetamine overdose causes restlessness, confusion, anxiety, and coma. Chronic abusers may develop paranoid psychosis. D-Methamphetamine is used in the treatment of obesity. Its duration is 2-4 hours. In normal conditions up to 43% of methamphetamine is eliminated unchanged in the 24-hour urine and about 4-7% as amphetamine. In acid urine, up to 76% is parent drug and 7% is amphetamine in 24 hours. In alkaline urine there is 2% parent drug and less than 0.1% amphetamine in 24 hours.

#### MDMA or Ecstasy (MDMA or XTC)

MDMA has street names such as Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits, and Shamrocks. MDMA is a stimulant with hallucinogenic tendencies. MDMA is a Class A drug, in the same category as heroin and 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 is administered either by oral ingestion or intravenous injection. The effects of the MDMA begin 30 minutes after taking. They peak in an hour and last for 2-3 hours. 65% of MDMA is excreted unchanged in urine and it is detectable in the urine for up to 3 days after use.

#### Morphine/Opiates (MOR/OPI)

Morphine is a popular marketed drug. It is used to treat moderate to severe pain. Morphine is also a common metabolite of opiates and heroin. The duration of morphine effect is 3-6 hours. 2-12% of morphine is excreted unchanged in urine. Heroin is rapidly metabolized to morphine in the body. Urinary excretion of heroin is similar to that of morphine. Codeine is also extensively metabolized. 10-15% of the

codeine is demethylated to form morphine and norcodeine. Unchanged morphine may remain detectable in urine for up to one week. Morphine has been used as a marker of opiates abuse.

#### Methadone (MTD)

Methadone possesses many of the pharmacological properties of morphine. However, it produces marked sedative effects with repeated administration. Methadone has been used as opiates substitute in drug treatment clinics. The effective duration of methadone is 12-24 hours. 5-50% of methadone excreted in urine unchanged in 24 hours. Methadone in urine may remain higher than 1,000 ng/ml 24 hours after overdose. Methadone in human urine has been used as a marker of methadone abuse.

#### Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structure similar to codeine. It is prescribed for the relief of moderate to severe pain. Like all opiate agonists, oxycodone provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension and respiratory arrest.

Oxycodone is metabolized by demethylation into oxymorphone and noroxycodone. After a single 5 mg oral dose, 13-19% of oxycodone is excreted unchanged in a 24-hour urine collection. The time window for detection of oxycodone in urine is expected to be similar to that of other opioids such as morphine.

#### Phencyclidine (PCP)

Phencyclidine is a popular drug of abuse. It is also a legitimate veterinary tranquilizer. PCP is self-administered by smoking, nasal insufflation, intravenous injection or oral ingestion. Its duration is 2-4 hours. 30-50% of an intravenous dose excreted unchanged in urine in 72 hours. 2% of a dose excreted in feces. On average 77% of an intravenous dose excreted in urine and feces in 10 days. PCP in human urine has been used as a marker of PCP abuse.

#### Tricyclics (TCA)

Tricyclic Antidepressants (TCA) are a group of antidepressant drugs that contain three fused rings in their chemical structure. TCA can be taken orally or intramuscularly (IM). The progressive symptomatology of TCA includes agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of TCA varies from few hours to few days. The commonly used tricyclic antidepressants are excreted with a very low percentage of unchanged drugs in the urine, less than 1%. Therefore, detecting TCA or metabolites of TCA in human urine has been used for screening the abuse of TCA.

#### Marijuana (THC)

Tetrahydrocannabinol is known as THC, Δ-9-THC, Δ-1-THC. It is the most active of the principal constituents and major metabolite of cannabinoids. Cannabinoids are a group of compounds including marijuana and hashish. Cannabinoids have been used as central nervous system depressants. Overdose and extended usage may lead to substance abuse. Cannabinoids abuse may cause severe or permanent damage to the human nerve system. The detection of THC in human urine has been widely used to assess cannabinoids abuse.

### PRINCIPLE OF THE TEST

The Multi-Drug of Abuse urine test device consists of one to twelve individual test strip(s) for the drugs (See list in the Intended Use section). The assay is a one-step qualitative immunoassay. If the drug is absent from the sample, a burgundy color band (T line) will appear. When the drug is present in the sample at or above the cutoff level, the color band will not form. The control line (C line) serves as an internal quality control of the system. The C line should always appear regardless of the presence of the drug.

### REAGENTS AND MATERIALS SUPPLIED

- 25 test devices. Each device is individually sealed in a foil pouch with a desiccant.
- 1 Instructions for Use

### MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection container
- Timer
- External positive and negative controls

### PRECAUTIONS

- Follow instructions exactly to obtain accurate results.
- Keep test device in the sealed pouch until use.
- Do not use expired devices.
- Dispose of all specimens and used assay materials according to local, state and federal regulations.
- Do not reuse the device.
- Do not use the test if you are color-blind.

### STORAGE AND STABILITY

- Store the kit at room temperature 15-30°C (59-86°F).
- Do not open the sealed pouch until use.
- Do not freeze device.
- Do not use after the expiration date printed on the pouch.



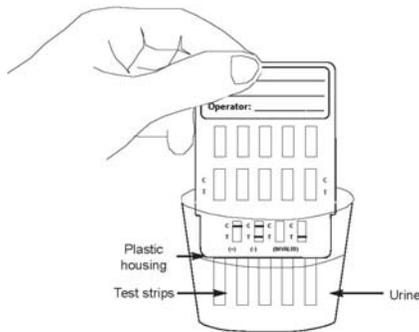
### SAMPLE COLLECTION AND HANDLING

- Collect each urine specimen in a clean and dry container. Do not combine specimens.
- Transfer a portion of the sample (minimum 35ml) to a second clean container for confirmation testing, if needed. (see Section on Confirmation Testing)
- Use specimens within eight hours of collection.
- Do not use urine specimens exhibiting visible precipitates.

### TEST PROCEDURE

**IMPORTANT: YOU MUST EQUILIBRATE REFRIGERATED SPECIMENS TO ROOM TEMPERATURE BEFORE TESTING.**

1. Bring the test device in sealed pouch to room temperature.
2. Immediately before use, open the pouch.
3. Remove test device from the pouch.
4. Label device with specimen identification.
5. Remove the cap from the device.
6. Dip the test strip(s) into the urine specimen.



**Note: You must dip the test strip(s) into the specimen completely ensuring that the plastic housing remains above the specimen surface. See picture to the left.**



7. Start the timer.
8. Remove the device from the specimen after 10 seconds.
9. Replace the cap back onto the device.
10. Set the device on a clean and level surface
11. Read results at 4-7 minutes.

### INTERPRETATION OF RESULTS

Each test strip is labeled with abbreviations for a test. For example, "COC" is for cocaine test. A complete list for each test can be found in the intended use section on Page 1.

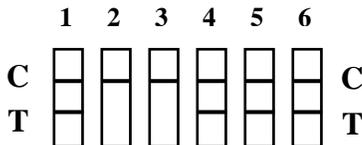
#### IMPORTANT:

- Read each test independently.
- Do not compare color intensity of one test to another.
- Do not compare color intensity of the T line to the C line.
- Do not interpret the results after 7 minutes.

#### Preliminary Positive:

If the C line appears and there is no T line, the test is positive result for that drug. More than one test may be Preliminary Positive.

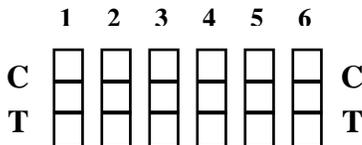
*Note: Positive results should be confirmed with a more specific method. GC/MS or HPLC is a preferred confirmatory method.*



**Preliminary Positive for test 2 and test 3**

#### Negative:

If both C line and T line appear on a test, the test is negative for that drug. If both C line and T line appear for all tests, the urine specimen is negative for all the drugs tested.

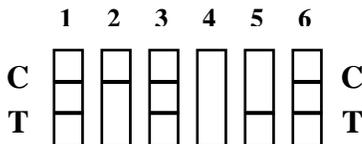


**Negative for all 6 drugs tested**

*Note: Even a very faint T line is negative.*

#### Invalid:

If no C line develops within 4 minutes on any test strip, the test is invalid. In this case, do not report test results. Repeat the assay with a new test device. If the result is still invalid, stop using the test devices. Contact the manufacturer.



**Invalid for test 4 and test 5**

A positive test result does not always mean a person took illegal drugs. Preliminary positive tests, for example, may arise from cross-reactions with other substances. In addition, drugs such as amphetamine or its derivatives are present in a number of prescription and over-the-counter medicines.

A negative result does not always mean a person did not take illegal drugs. For example, you will likely get a negative result if a cocaine test is performed but the person has only smoked marijuana. There are also a number of reasons why you can get a "false negative" test result.

A false negative test result means the test result is negative when a person actually has taken the drug that the test is designed to detect. This might happen if:

1. The drug was not in the sample at the time of collection. Since it takes a while after taking a drug for it to appear in urine, and it only stays in a person's urine for a limited amount of time, a negative result will occur if the sample was taken too early or too late.
2. The person, knowing that they were going to be tested, added something to the urine to prevent the test from performing properly. There are products sold that are advertised for the purpose.
3. The person may have taken a drug, but it is present at such a low concentration (below cutoff) that the drug cannot be detected by the test.
4. The tests are not working properly. For example, the device may have been damaged during

shipment or kept at the wrong temperature, either before or after you received it. Storing a product at temperatures that are too high or too low can damage the chemicals in the test(s).

If you get a negative test result but still suspect the person is taking drugs, you may test again at another time or test for the presence of different drugs.

### SENDING SAMPLES FOR CONFIRMATION

If you get a preliminary positive result, send the sample to a certified lab for confirmation as soon as possible.

If you have obtained a Confirmation Kit from this company Instant Technologies (800-340-4029) (toll-free) or its supplier, the kit includes a sample vial, Confirmation Test Label, security sealing tape, absorbent pad, specimen bag and pre-addressed mailing label. The following steps are followed for its use:

1. After filling 2/3 of the vial with the sample, put the cap on and tighten securely. Then, wrap the security tape around the vial and cap.
2. Fill out the Confirmation Test Label for the lab:
  - a. Identify the drug that tested positive on the label. For example, if the screening test indicated the THC was positive, mark an "X" next to the name THC.
  - b. Fill in the blank for "Sample Collection Date" \_\_\_\_\_.
3. Keep the top portion of the label with the Identification Number for your records – you will need it to obtain results.
4. Place the Confirmation Test Label onto the side of the vial.
5. Place the sample vial into the specimen bag containing an absorbent pad. Seal the bag as instructed.
6. Place the sealed bag into the shipping box. Then close and seal the box.
7. Attach the Mailing Label to the shipping box. Send the box with sample to the lab via overnight delivery.
8. Normally you can get test results in 3 to 10 business days. Call 800-433-3823 and identify yourself with your Identification Number to receive results. Results are kept for 30 days, so you must call within 30 days of sending the sample.

If you are using a different lab for confirmation testing, use that laboratory's Mailing Label and/or packaging.

### QUALITY CONTROL

#### Internal Control features:

This test contains a built-in control feature, the C line. If C line appears, the test performs properly. The C line should always appear. If the C line does not develop within 4 minutes, review the entire procedure. Repeat the test with a new device.

#### External Quality Control:

External controls (positive and negative) should be run to determine if tests are working properly with each new lot received, each new shipment even if it is the same lot received previously, and each new operator (or operator who has not performed the test recently). External controls also should be run monthly, as a check on storage conditions, when problems (storage, operator, instrument or other) are suspected or identified, and if otherwise required by your laboratory's standard QC procedures.

For assistance in obtaining external control solutions, call technical service at (800-340-4029) (toll-free) on weekdays from 8AM to 5PM Eastern Time.

### LIMITATIONS

1. The device is for human urine testing only.
2. The device is a qualitative, screening test that can indicate the presence of drugs or drug metabolites in urine. Tests do not reflect the degree of intoxication.
3. Positive results are preliminary. They must be confirmed by more specific methods, preferably GC/MS and/or HPLC.
4. Urine samples are perishable. If you need confirmatory testing, send the sample to a certified laboratory as soon as possible.
5. Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results. When adulteration or dilution is suspected, collect a fresh sample, repeat the test with a new device.
6. Do not use dark urine or samples suspected of bacterial contamination. Contaminants may interfere with the test and cause false results.
7. Certain foods and medicines such as cough syrup, diet pills and nutritional supplements may cause positive results. Amphetamine, for example, is present in numerous medications. The multi-drug test device cannot distinguish between drugs of abuse and prescription or over-the-counter medications.
8. Substances and procedural errors not described in this instruction may also interfere with the tests, causing false results.

### EXPECTED VALUES

This test can detect one or more drug and/or drug metabolite in human urine. See list in the Intended Use section on page 1.

### PERFORMANCE CHARACTERISTICS

#### Accuracy

A comparison study was performed at two Physician's Office Laboratories (POL) and a Reference Laboratory. Samples were blind labeled and tested for each analyte (drug or drug metabolite). Each sample was tested at each site, with the multi-drug of abuse urine test device, and compared to GC/MS or HPLC/MS results. The test results are grouped into drug free, below 75% cutoff (Negative), above 125% cutoff (Positive), between 75% cutoff and cutoff, between cutoff and 125% cutoff according to the analyte concentrations from GC/MS for all analytes except TCA, which was tested with HPLC/MS. Overall, this device agrees with the results from the selected analytical method more than 90% for each analyte. The test results are tabulated below.

Method			GC/MS					Overall
Test Device			Drug-free	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	
Drug	Cutoff (ng/ml)							
AMP	1000	Positive	0	0	37	15	148	476
		Negative	176	76	23	1	0	
		Total	176	76	60	16	148	
		Agreement	100%	100%	38.3%	93.8%	100%	
BAR	200	Positive	0	0	0	27	140	400
		Negative	200	12	20	1	0	
		Total	200	12	20	28	140	
		Agreement	100%	100%	100%	96.4%	100%	
BZD	300	Positive	0	0	7	32	144	400
		Negative	168	24	25	0	0	
		Total	168	24	32	32	144	
		Agreement	100%	100%	78%	100%	100%	
COC	300	Positive	0	0	9	24	164	400
		Negative	188	4	11	0	0	
		Total	188	4	20	24	164	
		Agreement	100%	100%	55%	100%	100%	
MET or mAMP	1000	Positive	0	0	12	24	136	400
		Negative	200	16	12	0	0	
		Total	200	16	24	24	136	
		Agreement	100%	100%	50%	100%	100%	
MDMA or XTC	500	Positive	0	0	2	9	10	80
		Negative	40	10	9	0	0	
		Total	40	10	11	9	10	
		Agreement	100%	100%	82%	100%	100%	
MOR/OPI	2000	Positive	0	0	2	28	144	400
		Negative	132	64	30	0	0	
		Total	132	64	32	28	144	
		Agreement	100%	100%	93.8%	100%	100%	
MTD	300	Positive	/	0	10	36	144	400
		Negative	/	192	18	0	0	
		Total	/	192	28	36	144	
		Agreement	/	100%	64.3%	100%	100%	
PCP	25	Positive	/	0	8	32	160	400
		Negative	/	184	16	0	0	
		Total	/	184	24	32	160	
		Agreement	/	100%	66.7%	100%	100%	
THC	50	Positive	0	0	11	17	156	396
		Negative	160	36	13	3	0	
		Total	160	36	24	20	156	
		Agreement	100%	100%	54.2%	85%	100%	

Method			HPLC/MS					Overall
Multi-Drug of Abuse Urine Test			Drug-free	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	
Drug	Cutoff (ng/ml)							
TCA	1000	Positive	0	0	2	8	12	80
		Negative	40	10	8	0	0	
		Total	40	10	10	8	12	
		Agreement	100%	100%	80%	100%	100%	

A comparison field study was performed at 3 separate locations. The test results are tabulated below.

Method			HPLC/MS					Overall
Multi-Drug of Abuse Urine Test			Drug-free	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	
Drug	Cutoff (ng/ml)							
MOR300	300	Positive	0	0	3	46	44	384
		Negative	212	29	49	1	0	
		Total	212	29	52	47	44	
		Agreement	100%	100%	94.2%	97.9%	100%	
OXY	100	Positive	0	0	2	42	163	384
		Negative	101	27	45	4	0	
		Total	101	27	47	46	163	
		Agreement	100%	100%	95.7%	91.3%	100%	
OXY300	300	Positive	0	0	2	39	45	384
		Negative	71	180	43	4	0	
		Total	71	180	45	43	45	
		Agreement	100%	100%	95.6%	90.7%	100%	

### Reproducibility

Reproducibility of each test was determined by replicate assays of three different production lots with four levels of samples: drug-free, 75% cutoff, 125% cutoff and 300% cutoff. For AMP, COC, THC and MDMA tests, the devices were tested for three consecutive days, six replicates per day, for a total of eighteen tests for each control. For BAR, BZD, MET, MOR, MTD, PCP and TCA tests, the devices were tested for five consecutive days, five times per day, for a total of 25 assays for each control. The results indicate 100% precision for the replicate within each lot and no appreciable inter-lot variation across the three different lots of devices.

### Cross Reactivity

Drug free urines spiked with structurally related compounds were tested on test devices. Compounds producing positive response on the device are listed below.

Drug	Related Compounds	Concentration (ng/ml)	Related Compounds	Concentration (ng/ml)
AMP	d-Amphetamine	1000	d,l-Amphetamine	1000
	l-Amphetamine	20,000	3,4-methylenedioxyamphetamine (MDA)	3000
BAR	Amobarbital	250	Phenobarbital	200
	Barbital	250	Pentobarbital	250
	Butabarbital	300	Secobarbital	200
	Butalbital	200		
BZD	Alprazolam	300	Lormetazepam	300
	Bromazepam	500	Medazepam	300
	Clobazam	1500	Nitrazepam	250
	Chlonezepam	500	Nordiazepam	400
	Diazepam	200	Prazepam	250
	Desmethyldiazepam	300	Triazolam	300
	Flurazepam	300	Oxazepam	300
	Lorazepam	450		
COC	Cocaine	300	Isosuxprine	1500
	Benzoylcegonine	300		
MET or mAMP	d-Amphetamine	50,000	3,4-methylenedioxyamphetamine (MDA)	50,000
	l-Amphetamine	10,000		
MDMA or XTC	methylenedioxyamphetamine (MDA)	2000	Methylenedioxyethylamphetamine (MDEA)	1000
MOR/OPI	Codeine	2000		
	Ethyl Morphine	2000	Morphine- glucuronide	3000
	Hydromorphone	2500	Meperidine	30,000
MOR 300	Codeine	300	Meperidine	30,000
	Ethyl morphine	300	Morphine-6- glucuronide	500
	Hydromorphone	400	Oxycodone	1,000
MTD	(-)-a-Methadol	800	(-)-a-Acetylmethadol (LAAM)	1000
OXY	Ethyl morphine	100,000	Morphine	20,000
	Hydrocodone	100,000		
PCP	Methylphenidate	25,000	Tenocyclidine	2,000
	Pheniramine	25,000		
TCA	Nortriptyline	1,000	Clomipramine	5,000
	Amitriptyline	1,000	Doxepin	3,000
	Imipramine	800	Protriptyline	2,000
	Desipramine	800	Perphenazine	75,000
	Nordoxepine	1,000	Promazine	15,000
	Cyclobenzaprine	1,500	Trimipramine	2,000
THC	11-nor-D-8-THC-9-COOH	50	11-hydroxy-D-9-THC	100
	11-nor-D-9-THC-9-COOH	50	9-Tetrahydrocannabinol	10,000
	Cannabonol	10,000		

### Interference

Drug-free urines and urines spiked with a drug at the cutoff level were tested on the test device. Results are listed in the table below.

Common substances listed in this table were found not to interfere with the test results at 100 µg/ml		
Acetaminophen	Oxalic Acid	Ethanol
Acetylsalicylic Acid	Caffeine	Lidocaine
Amikacin	(+)-Chlorpheniramine	Penicillin-G
Amitriptyline	Cocaine	Phenylpropanolamine
Ampicillin	Codeine	Ranitidine
Arterenol	Cortisone	Salicylic Acid
Aspirin	Methadone	Thioridazine
Atropine	Methanol	Trifluoperazine
Benzoic Acid		

Biological Analytes	Concentration	Biological Analytes	Concentration
Albumin	200 µg/ml	pH	5.0 – 9.0
Bilirubin	100 µg/ml	Specific Gravity	1.002 – 1.035 g/ml
Creatine	100 µg/ml	Uric Acid	100 µg/ml
Glucose	200 µg/ml	Vitamin C	100 µg/ml
Hemoglobin	100 µg/ml	(L-Ascorbic Acid)	

It is possible that substances or factors not listed above may interfere with the test. (e.g., technical or procedural errors)

### REFERENCES

- Clinical Laboratory Improvement Amendments of 1988, <http://www.cms.hhs.gov/CLIA/>
- FDA Guidance for Labeling Urine Drugs of Abuse Screening Testing, Kshit Mohan, 7/21.
- Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, 4th ED., Biomedical Publ., Davis, CA; p713-715, 1995.
- Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Register. (69): 11970 (1988).
- Wilson, John. Abused Drugs II, a Laboratory Pocket Guide., AACC Press. Washington, DC; 1994.
- Gilman AG, Rall TW, Nies AS, Taylor P eds., Goodman and Gilman's the Pharmacological Basis of Therapeutics, 8<sup>th</sup> ed., New York, Pergamon Press, 1990.
- Dorland's Illustrated Medical Dictionary, 26<sup>th</sup> Edition, W.B. Saunders Company, Philadelphia, PA, pp89, 1981. Urine Testing for Drugs of Abuse, National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
- Peroutka, S-J. ed. Ecstasy: The clinical, pharmacological and neurotoxicological effects of the drug MDMA. Kluwer Academic Publishers, 1990

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 San Diego, CA – USA  
 MADE IN USA

For technical assistance call  
**Direct/International:**  
 1-757-318-4810  
 Toll-free:  
 1-800-340-4029

### FREQUENTLY ASKED QUESTIONS

#### 1. What does the multi-drug of abuse urine test do?

The multi-drug of abuse urine test is a drug screen test. It provides preliminary results for the detection of one or more of the drugs at the cut-off level:

Abbreviation	Test
AMP	Amphetamine
BAR	Barbiturates
BZD	Benzodiazepine
COC	Cocaine
MET or mAMP	Methamphetamine
MDMA or XTC	MDMA or Ecstasy
MOR/OPI	Morphine/Opiates
MOR/OPI300	Morphine/Opiates
MTD	Methadone
OXY100, OXY300	Oxycodone
PCP	Phencyclidine
TCA	Tricyclics
THC	Marijuana/Hashish

#### 2. What is cut-off level?

The cut-off level is the specified concentration of a drug in a urine sample. Above that concentration the test is called positive, and below that concentration it is called negative.

#### 3. What are drugs of abuse?

Examples of drugs of abuse include marijuana, cocaine, opiates, heroin, amphetamines, Ecstasy or MDMA, and phencyclidine. Prescription drugs, such as morphine, codeine or other painkillers, also may be abused.

#### 4. Common Street Names for Drugs

Drug	Street Name
AMP – Amphetamines	Speed, Amp, Bennie, Chalk, Black Beauties, Uppers
BAR – Barbiturates	Barbs, Barbies, Sleepers, Block Busters
BZD – Benzodiazepine	Benzos, Candy, Downers, Sleeping Pills, Xanies, Tranks, Ludes, Roofies
COC – Cocaine	Big C, Coke, Snow, Flake, Candy, Crack, Blow, Rock
mAMP – Methamphetamines (MET)	Crystal, Meth, Ice, Glass, Christina, Uppers, Tina
MDMA – Ecstasy (XTC)	Ecstasy, E, Adam, XTC, X
MOR/OPI – Morphine/Opiates	Heroin, H, Hairy Hombre, Horse, Jones, Scag
MTD – Methadone	Meth, MTD, Juice, Green
OXY – Oxycodone	Oxy, Hillbilly Heroin, Oxycotton, OC, Killers
PCP – Phencyclidine	Angel Dust, Hog, Killer Weed
TCA – Tricyclic Antidepressant	Vivactil, Anafranil, Janimine, Tofranil
THC – Marijuana	Pot, Weed, Herb, Bud, MJ, Doobie, Reefer, Grass, Joint, Homegrown, Spliff, Mary Jane

#### 5. How long can the drugs be detected in urine?

The following are guidelines only. The times can vary significantly from these estimates depending on how long the person has been taking the drug, amount of drug they use, or the person's metabolism.

Drug	Detection Times	
	Minimum	Maximum
Amphetamines	2-7 hours	2-4 days
Barbiturates	4-6 hours	4-7 days
Benzodiazepine	4-6 hours	3-7 days
Cocaine	2-6 hours	2-3 days
Methamphetamines	2-7 hours	2-4 days
MDMA/ Ecstasy	2-4 hours	1-3 days
Morphine/Opiate	2-5 hours	2-4 days
Methadone	2-7 hours	2-4 days
Oxycodone	2-3 hours	2-4 days
Phencyclidine	4-6 hours	7-14 days
Tricyclic Antidepressants	4-6 hours	1-10 days
Marijuana	1-3 hours	Infrequent use: up to 10 days Chronic use: up to 6 weeks

#### 6. How accurate is the test?

The test is fairly sensitive to the presence of drugs in the urine. This means that if drugs are present, you will usually get a preliminary positive result. If you get a preliminary positive result, you should send the urine sample to the laboratory for a second, more accurate test.

It is very important to send the urine sample to the lab, because the drug of abuse urine screening may give positive results when no drugs are actually present. Certain foods, food supplements, beverages, diet pills, or over-the-counter medicines can cause a reaction with the tests. Laboratories use a very reliable test, with very few errors, to determine whether or not your sample contains drugs.

Many things can affect the accuracy of this test, including but not limited to:

- The way you did the test
- The way you stored the test or urine
- What the person ate or drank before taking the test
- Any prescription or over-the-counter drugs the person may have taken before the test

128 consumers participated in a field study. The results of the study are summarized below. All 16 incorrect results were at drug concentrations of 75%-150% of the cut offs. 7 negative samples were read as positive. 9 positive samples were read as negative.

Drug	Cutoff Conc. (ng/ml)	# Test	Result Interpretation	
			Correct	Incorrect
MOR300	300	384	380	4
OXY100	100	384	378	6
OXY300	300	384	378	6

118 consumers participated in a field study. The results of the study are summarized below. 30 of the 34 incorrect results are at drug concentrations at 50% ~ 150% of the cutoffs. 2 positive samples were read negative. 2 negative samples were read positive.

Drug	Cutoff Conc. (ng/ml)	# Test	Result Interpretation	
			Correct	Incorrect
AMP	1000	592	585	7
BAR	200	592	590	2
BZD	300	592	589	3
COC	300	592	590	2
MET or mAMP	1000	592	588	4
MDMA or XTC	500	532	531	1
MOR	2000	592	587	5
MTD	300	592	587	5
PCP	25	592	592	0
THC	50	592	588	4
TCA	1000	532	531	1

#### 7. If the test results are negative, can you be sure that the person did not take drugs?

No. There are several factors that can make the test results negative even though the person is using drugs. Because

- You may have tested for the wrong drugs.
- You may not have tested the urine when it contained drugs. It takes time for drugs to appear in the urine after a person takes them, and they do not stay in the urine indefinitely; you may have gotten the urine too soon or too late.
- The person knowingly added something to the urine to prevent it from reacting with the test chemicals.
- The chemicals in the test went bad because they were stored incorrectly or they passed their expiration date.

If you get a negative result, but still suspect drug abuse, you can test again at a later time. You should also consider testing other types of drugs. Talk to your doctor if you need more help deciding what steps to take next.

#### 8. What is false positive result?

A false positive result is a screening test read positive when the drug or drug metabolite is not present or its concentration is less than the cutoff level.

#### 9. What does Preliminary Positive mean?

The Multi-Drug Urine Test is a screening test. It is the first step in a two-step process. Screening tests are not as accurate as laboratory test. It is possible to get a positive result when the person did not take drugs. For example, some medicines and food may cause the screening tests to incorrectly read positive. Things such as diet pills, inhalers and cough syrup can cause a positive result. You consult with your doctor to better understand how medications may interfere with this test.

#### 10. Does a positive screen test mean that you have found drugs of abuse?

No. Wait until you get the laboratory's result. Remember that many factors may cause a false positive result in the home test. It is important to send any sample giving positive results to the laboratory for further evaluation.

#### 11. What if the lab test confirms a positive result?

The lab uses very accurate and reliable equipment to run the tests. If the lab reports a positive result, it means the drug was present in the urine sample. But do not assume the urine sample came from a drug abuser.

People can test positive THC (or marijuana) because they have been repeatedly around heavy marijuana smoke even they did not smoke marijuana themselves.

Consider all amphetamine results carefully, even those from the lab. Some over-the-counter medications contain amphetamines that cannot be distinguished from illegally abused amphetamines.

- If you received a positive result and you do not believe the test, consult your doctor. They have your medical history and they can provide you with detailed information.
- If a positive result was confirmed, consult your doctor to identify counselors who will help you. You can also contact one of the resources listed below for help.

#### 12. Additional Resources

National Institute on Drug Abuse  
Phone: 301-443-1124  
[www.drugabuse.gov](http://www.drugabuse.gov)

National Clearinghouse for Alcohol and Drug Information  
Phone: 800-729-6686 (toll-free)  
[www.ncadi.samhsa.gov](http://www.ncadi.samhsa.gov)

Center for Substance Abuse Prevention  
Substance Abuse and Mental Health Services Administration  
Phone: 301-443-9110  
[www.prevention.samhsa.gov](http://www.prevention.samhsa.gov)

National Council on Alcoholism and Drug Dependence  
Phone: 800-622-2255 (toll-free)  
[www.ncadd.org](http://www.ncadd.org)

Centers for Disease Control and Prevention  
Phone: 404-639-3534  
Phone: 800-311-3435 (toll-free)  
[www.cdc.gov](http://www.cdc.gov)

American Council for Drug Education  
Phone: 301-443-3860  
[www.acde.gov](http://www.acde.gov)

Safe and Drug-Free Schools Program  
U.S. Department of Education  
Phone: 800-872-5327 (toll-free)  
[www.ed.gov/offices/OESE/SDFS](http://www.ed.gov/offices/OESE/SDFS)

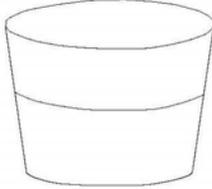
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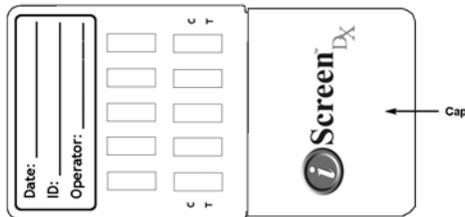
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### TEST PROCEDURE

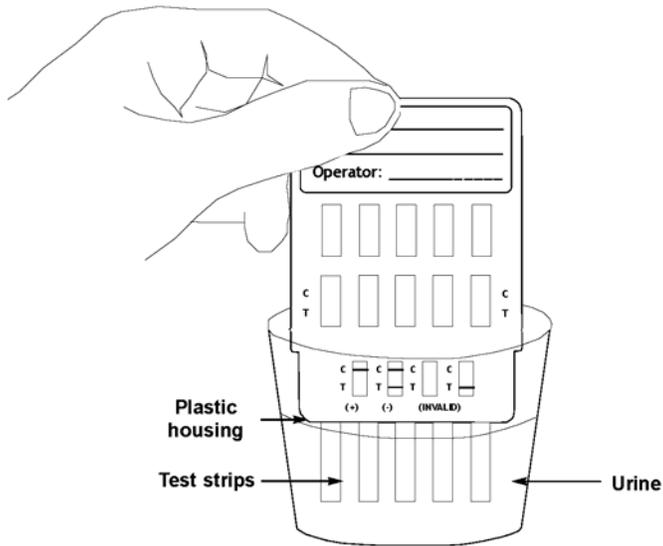
1. Obtain a fresh urine specimen in a clean and dry container. Use specimens within 8 hours of sample collection. Specimens may be kept longer at 2-8°C for up to 3 days and at -20°C or lower for long term storage. **Do not use any samples exhibiting visible precipitates or particles.**



2. Bring the test device in the sealed pouch (and the urine, if refrigerated) to room temperature before initiating the test.
3. Immediately before use, remove the test device from its pouch.
4. Remove the cap from the device.



5. Dip the test strip(s) end of the device into the urine specimen. Remove the device from the specimen after **10 seconds**. Replace the cap and place it on a clean and level surface.



6. Read the test result between four (4) to seven (7) minutes after adding the specimen.

### QUALITY CONTROL

The manufacturer recommends running controls monthly, with a new shipment, and with every new lot of test devices. For assistance in obtaining controls, contact the Instant Technologies at (800) 340-4029.

### INTERPRETATION OF RESULTS

**IMPORTANT:** Do not read test results after seven (7) minutes. The T Line should always be interpreted independently of the C Line.

#### Preliminary Positive:

If only the C line appears, the result is positive. Drug or drug metabolite was detected in the sample at or above the cutoff concentration.

**Samples with preliminary positive results should be confirmed with a more specific method before a positive conclusion is made.**

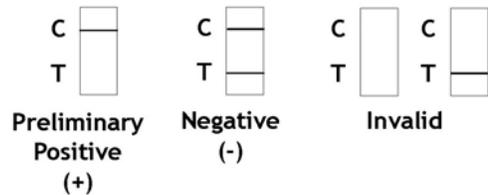
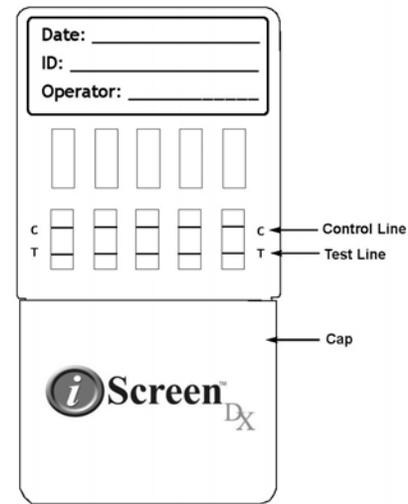
#### Negative:

If both the C line and T line appear, the result is negative. No drug was detected in the sample.

**Note: A very faint T line should be considered negative.**

#### Invalid:

If no C line develops within 4 minutes, repeat the assay with a new test device.



#### Note:

1. Substances in urine, including structurally related compounds, can interfere with test results (see Instructions for Use).
2. A positive result does not always mean that a person took illegal drugs. Many prescribed medications contain compounds that may be detected. Some OTC medications may also cause a cross-reaction. Consult the Instructions for Use for more details.

### CONFIRMATION OF POSITIVE RESULTS AND TECHNICAL ASSISTANCE

Preliminary positive results must be confirmed by sending the sample to an accredited laboratory for testing. See attached Instructions for Use. To obtain confirmation kits for this device contact customer service at (800) 340-4029 (8am – 5pm Weekdays EST). For additional information or assistance with confirmation testing contact Technical Support at (757) 318-4810 or (800) 340-4029.