

AmediCheck™ Instant Test Cup

Complete Test Instruction and Handbook

Be sure to read all instructions in this handbook before use

Indications For Use:

The AmediCheck™ Instant Test Cup is an *in vitro* diagnostic test for the rapid detection of the following drugs in human urine.

Drug (Analyte)	Cutoff	Device Code
THC (Marijuana)	50 ng/mL	THC
Cocaine	300 ng/mL	COC
Amphetamine	1000 ng/mL	AMP
Methamphetamine	1000 ng/mL	MET
Opiates	2000 ng/mL	OPI
Opiates300	300 ng/mL	OPI300
PCP	25 ng/mL	PCP
Barbiturates	300 ng/mL	BAR
Benzodiazepines	300 ng/mL	BZO
Methadone	300 ng/mL	MTD
Oxycodone	100 ng/mL	OXY
MDMA	500 ng/mL	MDMA
Tricyclic Antidepressants	1000 ng/mL	TCA

This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Tests for prescription drugs will yield preliminary positive results when prescription drugs are ingested, even at or above therapeutic doses. There are no uniformly recognized drug cutoffs for barbiturates, benzodiazepine, tricyclic antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is 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 obtained.

Storage

The AmediCheck™ Instant Test Cup should be stored at 2-30°C (36-86°F) in the original sealed pouch. Do not Freeze. Do not store and or expose reagent kits at temperature great than 30°C.

Caution:

Drug Testing involves a 2 step process:

- 1) A preliminary screen result.
- 2) A confirmation test performed in a lab.

The AmediCheck™ Instant Test Cup provides only the initial preliminary screening result. It will be necessary to confirm a presumptive positive result in a lab to conclude a test is positive. We hope that this kit and the information it provides will stimulate honest and candid discussions about the use of drugs.

Step by Step Instructions

Contents of the AmediCheck™ Instant Test Cup:

The AmediCheck™ Instant Test Cup is a self-contained easy to use urine drug test containing:

- 1) Complete Test Instructions and Handbook (answers to common questions).
- 2) AmediCheck™ Instant Test Cup (with affixed temperature strip) in foil pouch.
- 3) Drug Test Form with a unique specimen ID number.
- 4) Leakage pad.
- 5) Pouch with self-adhesive sealer.
- 6) Pre-addressed shipping box/pouch for confirmation testing.

Materials Needed but Not Provided:

- 1) Timing Device (timer, clock, watch, etc.)

Distributed By: Blue Grass Drug Screen, Inc.
 1-866-323-7236
 www.usscreeningsource.com

Performing the AmediCheck™ Instant Test Cup Procedure

The AmediCheck™ Instant Test Cup is designed to use with urine specimens. Fresh urine does not require any special handling. Test cup and urine samples, should be fresh or at room temperature prior to testing. Do not open foil pouch until ready to perform the assay.

Collection Procedure:

- Step 1: Remove all kit contents from box.
- Step 2: Read the Complete Test Instructions and Handbook.
- Step 3: Remove the AmediCheck™ Instant Test Cup from the sealed foil pouch. Give Test Cup (with affixed Temperature Strip) to donor.
- Step 4: Be careful to remove anything from the bathroom that could be added to the specimen. Things that may interfere with the test include: soap, bleach, vinegar, salt, or tap/toilet water. If this is a test on your child, you may want to be in the bathroom with your child to prevent any tampering with the sample.
- Step 5: Allow donor to provide 30 mL of urine (about 1/3 full).
- Step 6: Read specimen temperature using the strip affixed on the side of container within 4 to 5 minutes. A green color dot on the strip indicates the specimen temperature. The temperature of newly collected human urine specimen should read between 90-100° F. If no reading is present, temperature is out of range and sample should be discarded. A new sample should be collected with a new kit.

Reading the Results:

Negative results may be read as soon as 2 pink lines appear. For positive results, read result within 4 to 5 minutes after providing urine sample. Do not read result after 5 minutes. If the test is left standing more than 5 minutes, the intensity of the colored lines may change.

Negative – Presence of 2 rose pink lines (any intensity). One line is present in the control region and another line is present in the test region for each drug. A FAINT line indicates a negative result.

Presumptive Positive (send to Lab) – Presence of a 1 line in the control region and NO LINE is present in the test region. **Read at 5 minutes.** This is a preliminary result. More than one test may be a presumptive positive.

Invalid – No control line is present. The control line should always be present whether or not the test result is positive or negative. If the control line is not present after the test, the result is invalid.

Do not use the invalid test result. Use another device to retest. If problem persists, contact customer service.

Interpretation of Results



- | | | | |
|--|---|---|--|
| Negative:
Two Colored Lines in the Control and Test Region | Negative:
Line in Control Region, and Faint line in Test Region | Positive:
One Colored in the Control Region | Invalid:
No Colored in Control with or without line in Test Region |
|--|---|---|--|

Limitations of the Test

This is only the first step of a 2 step process (see below for confirmation procedure). See below to “Send a Sample to the Lab for Confirmation”.

- Step 1 – Preliminary screening to identify negatives
- Step 2 – Confirmation in a lab for all non-negatives (presumptive positives)

If you get a presumptive positive test result, when you use this product, we recommend that you send the urine to a Certified Laboratory, which can test the urine again with a more accurate and reliable test. The second test is called gas chromatography/mass spectrometry or GC/MS. We recommend that you consult with a counselor, doctor, or another qualified professional to help you understand the test results and to address problems such as drug abuse. Positive results for some drugs may be caused by prescription drug use.

Only Urine can be used.

The ID number is required to obtain confirmation results.

Some over the counter drugs or other prescription drugs may cause a false positive result on this preliminary screening test. Confirmation at the laboratory is necessary to eliminate these interfering substances.

Some prescription drugs (for example, narcotics) may cause a positive result.

Adulterated specimens (where something that is added to the urine) may cause an inaccurate result.

This test has no chain of custody and cannot be used for legal (forensic) purposes. We recommend counseling by a qualified substance abuse counselor to aid in understanding the test results.

To Send a Sample to the Lab for Confirmation

- 1) If result of preliminary test is non-negative (presumptive positive), tightly reseal collection cup with up to 30 mL of urine. Be sure to screw on cap securely in order to prevent leaking of specimen.
- 2) **Be sure an ID number is affixed to specimen bottle and also to the back of handbook in order to obtain results. This is your confidential ID number which is necessary to obtain results.**
- 3) Place specimen inside of tamper proof plastic pouch along with the absorbent pad and seal the pouch with the adhesive tape.
- 4) Place specimen into Pre-addressed shipping box to your Laboratory

THIS MAILER IS NOT PRE-PAID. You must affix postage. Drop preaddressed shipping box **with POSTAGE** into any mailbox.

Obtaining Confirmation Results:

Step 1: Retain Complete Test Instructions and Handbook with ID number affixed to back.

Step 2: Allow 7-10 working days for processing if sent via US Postal Service.

Step 3: Obtain confirmation results by calling our toll free number (866-468-3287).

Retain the specimen ID number which you affixed to the designated area on the back page of the Complete Test Instructions and Handbook.

Handbook - Frequently Asked Questions

Which drugs are tested?

The urine will be tested for:

- Marijuana (THC)
- Cocaine "Crack"
- PCP "Angel Dust"
- Opiates (Codeine, Morphine, Hydrocodone, Hydromorphone, Oxycodone, and Methadone)
- Amphetamines (Amphetamine, Methamphetamine, and Ecstasy (MDMA))
- Benzodiazepines (Anti-anxiety drugs)
- Barbiturates
- Tricyclic Antidepressants (Prescription drug with low abuse potential)

Why test at home?

- Gets parents and loved ones talking about drug use.
- Deterrent – The AmediCheck™ Instant Test Cup in the house will help with peer pressure and the temptation to experiment with drugs.
- Confidential – An anonymous unique ID number is used.
- Easy to use – Complete easy to use and simple instructions are provided.
- If a Presumptive Positive – Use Preaddressed shipping box and affix postage. Drop in any mailbox, call our toll free number (866-468-3287) for results.
- Affordable- No medical or other collection charges.
- Interpretation of Results- Our Customer Service Group answers your questions

What does a negative test result mean?

A negative result does not guarantee the absence of drugs. It means that the drugs tested were either not present or may be below our ability to detect the drugs. If you suspect that drug abuse is present, we recommend an evaluation by a counselor. A repeat urine test with AmediCheck™ Instant Test Cup may also be indicated.

What if this preliminary test is positive?

The test must be sent to the lab for confirmation. This initial test provides only a preliminary screen. See steps above to confirm a result.

How long are drugs detected on a urine drug test?

DRUG

RETENTION TIME

Amphetamine Methamphetamine Ecstasy (MDMA)	2 - 3 days
Cocaine (Crack)	2 - 3 days
Marijuana (THC) (times are only approximations)	
Infrequent smoker	Days - 1 week
Moderate smoker	Days - Weeks
Chronic smoker	Several Weeks
Opiates (Codeine, Morphine, Hydrocodone, Hydromorphone, Oxycodone, Heroin)	2 - 3 days
Phencyclidine (PCP, Angel Dust) (Chronic use may be up to 30 days)	1 - 7 days
Benzodiazepines (Such as Diazepam, Oxazepam, Chlordiazepoxide, Alprazolam, Chlorazepate and others)	Up to 2 weeks
Barbiturates Short Acting (such as pentobarbital) Intermediate Acting (such as butalbital) Long Acting (such as phenobarbital)	1 day 2 - 3 days Several Weeks
Methadone	1 week
Tricyclic Antidepressants (TCAs) (Amitriptyline, Nortriptyline, Imipramine, Desipramine)	2 weeks

Times presented are only a general guideline.

What are the effects of drugs on the body?

Drugs of abuse affect the brain and either:

- slow down actions and reactions (depress)
- speed up actions and reactions (stimulate)

Drugs such as marijuana (active ingredient THC), opiates (such as codeine, morphine, heroin and alcohol are depressants while amphetamines and cocaine are stimulants.

Marijuana

What some signs of marijuana use?

- rapid loud talking and bursts of laughter
- sleepiness in later stages
- forgetfulness
- reduced concentration and coordination
- inflammation in whites of eyes
- pupils likely to be dilated
- hunger
- odor similar to burnt rope on clothing or breath
- tendency to drive cars slowly, below speed limit
- distorted sense of time passage
- use or possession of paraphernalia (rolling papers, pipes, dried plant material, roach clips)

Marijuana affects skills needed for safe driving. Thinking and reflexes are slowed, making it hard to respond to sudden events. A driver's ability to "track" through curves, brake quickly, maintain proper speed and distance between vehicles, is affected. Research shows that these skills are impaired for at least four to six hours after smoking a single marijuana cigarette.

How many people smoke marijuana? At what age do children generally start?

A recent government survey tells us:

Over 70 million Americans over the age of 12 have tried marijuana at least once. About 10 million had used the drug in the month before the survey. More than 5 million Americans smoke marijuana at least once a week. Among teens aged 12 to 17, the average age of first trying marijuana was 13.5 years old. A yearly survey of students in grades 8 through 12 shows that by 10th grade, nearly 16 percent are "current" users (that is, used within the past month). Among 12th-graders, nearly 40 percent have tried marijuana at least once, and 19 percent were current users. The use of marijuana and other drugs usually peaks in the late teens and early twenties, then goes down in later years.

How can I tell if my child has been using marijuana?

There are some signs you might be able to see. He or she might seem dizzy and have trouble walking, seem silly and giggly for no reason, have very red, bloodshot eyes; and have a hard time remembering things that just happened. When the early effects fade, over a few hours, the user can become very sleepy.

Parents should be aware of changes in their child's behavior. Parents should look for withdrawal, depression, fatigue, carelessness with grooming, hostility, and deteriorating relationships with family members and friends. Changes in school performance, increased absenteeism, lost interest in sports or other favorite activities. Changes in eating or sleeping habits could be related to drug use. However, these signs may also indicate problems other than use of drugs.

In addition, parents should be aware of signs of drugs and drug paraphernalia, including pipes and rolling papers, odor on clothes and in the bedroom, use of incense and other deodorizers, use of eye drops, and clothing, posters, jewelry, etc., promoting drug use.

Can a donor test positive through second hand smoke because he was in the same room with someone smoking marijuana?

It has been shown that it is possible to have detectable levels of THC from passive inhalation however not likely with the 50 ng/mL cutoff. It is *possible* under *extreme conditions* (like being in a tiny room with no ventilation for an extended period of time with many people smoking). It is not going to happen with exposure to smoke at a party or a concert.

How long is marijuana detectable on a urine test?

Marijuana is a fat soluble drug. If a person is a first time user, it will probably all be out of the system in about 5 days. For chronic users (several times a week for a long period of time) marijuana is stored in the fat and slowly released over time. In this case, marijuana can be detected for weeks after they have stopped using marijuana.

Cocaine "Crack"

What is the difference between "Crack" and Cocaine?

Cocaine is an anesthetic which stimulates the brain. It is snorted (inhaled through the nose), injected, or smoked by inhaling its vapors. It is sometimes called coke, toot, and nose candy. In its free-base form it is sometimes called rock, crack, or base. The effects of the drug begin within minutes after entering the system and start with a brief intense feeling of well-being, which peaks within 15 to 20 minutes and is followed by depression.

What are the signs of cocaine or "crack" use?

- dilated pupils
- dry mouth and nose
- frequent lip licking
- excessive restless activity
- difficulty sitting still
- lack of interest in food or sleep
- irritable, argumentative, nervous
- talkative (conversation often lacks continuity)
- subjects change rapidly
- runny nose
- chronic cold or sinus/nasal problems
- nosebleeds and use or possession of paraphernalia (glass vials, glass pipe, white crystalline powder, razor blades, syringes, needle marks)
- experience severe shifts in mood
- Extremely sensitive to loud noises. This sensitivity can create paranoia which leads to an inability to concentrate on tasks.

What are some of the health risks of using "crack" or cocaine?

Cocaine over stimulates the circulatory, respiratory, and brain. Cocaine interferes with the natural chemical in the brain that stimulates and regulates the firing of nerve cells. Muscle spasms in various parts of the body can occur. Over stimulation of the nervous system can cause convulsions which can lead to respiratory collapse and death. Long term crack (rock-like bits of cocaine that can be smoked) users have also suffered permanent damage to the cortex, the part of the brain that is used to think.

Opiates (Narcotics)

What are opiate narcotics?

The opiate class of narcotics includes morphine, codeine, and heroin. Synthetic opiates are hydrocodone, hydromorphone, oxycodone, meperidine and others. These drugs are used medically to relieve pain, but also have a high potential for abuse. Opiates tend to relax the user. A user will feel an immediate rush when the opiates are injected or smoked (heroin), but may soon experience other unpleasant side effects including restlessness, nausea, and vomiting.

What are the signs of opiates use?

- mental dullness
- lethargy and drowsiness

- cold or moist skin
- scratches frequently
- slurred speech
- constricted pupils that fail to respond to light
- if injected, needle tracks or scars
- paraphernalia (syringes, spoons, medical droppers, bent spoons, metal bottle caps, small glassine bags or foil packets)

What are some of the health risks of using opiates (narcotics)?

These drugs, including codeine, morphine, and common painkillers are all legally manufactured from opium, which is a by-product of the poppy plant. Heroin, an illegally manufactured product, as well as those legal narcotics, all find their way into the drug marketplace. When taken outside a doctor's care, the user risks mental and physical dependence with lethargy, apathy, slurring of speech, and loss of judgment and self-control. All of these may result in convulsions, coma, nausea, diarrhea, vomiting, and malnutrition as the use of the drug replaces a balanced diet.

Amphetamine and Methamphetamine and Ecstasy

What are amphetamines?

Amphetamines are central nervous system stimulants which may be taken orally, smoked or injected. Included in this group are amphetamine, methamphetamine, and ecstasy (MDMA). Amphetamines tend to increase alertness and physical activity. Amphetamines are used to counteract drowsiness, whether caused by lack of sleep, sleeping pills, other "downers", or alcohol.

What are some of the signs of amphetamine use?

- dilated pupils
- dry mouth and nose
- frequent lip licking
- excessive restless activity
- difficulty sitting still
- lack of interest in food or sleep
- risk taking behavior
- irritable, argumentative, nervous
- talkative (conversation often lacks continuity)
- subjects change rapidly
- alertness, wakefulness, mood elevation
- loss of appetite, exhaustion
- sense of power and a false sense of security
- increased body temperature with Ecstasy

What are the health risks of using amphetamines?

Amphetamines are stimulants which tend to throw off the body's rest and repair system. Hyperactivity and mental anxiety are common. Repeated high dosage results in lethargy, exhaustion, mental confusion, and paranoia. Use can lead to hallucinations. Abuse can lead to physical problems such as blood pressure problems, heart attacks and strokes.

PCP "Angel Dust"

What is "angel dust" or PCP?

Phencyclidine (PCP), also commonly known as "angel dust", is an outlawed animal tranquilizer which may be smoked, snorted, injected, or taken orally. PCP is known for its long term potential to create psychotic behavior, violent acts, and psychosis. For many users, PCP changes how they see their own bodies and almost everything around them.

What are some of the signs of PCP use?

- unpredictable behavior with mood swings from passiveness to violence for no apparent reason, possibly including self-destructive behavior
- symptoms of intoxication
- disorientation with agitation and violence if exposed to excessive sensory stimulation
- fear, terror, rigid muscles, strange gait
- deadened sensory perception, possibly unaware of severe injuries
- pupils may appear dilated
- mask-like facial appearance
- seeing sounds, smelling colors
- comatose if large amount consumed
- inability to concentrate
- users are a potential safety risk

What are the health risks of using PCP?

PCP or "angel dust" was originally made as a human, then animal, tranquilizer. It causes violent and self-destructive behavior. "Dust" affects brain functions. It takes the user out of reality and into a dangerous mind set. Users often place themselves in situations that may cause serious injury. They may become irrational and think they are indestructible. Use may also result in blurred vision, diminished sensations, incoordination, and muscle

spasms, hallucinations, which may lead to other aggressive or bizarre behavior. High use may lead to convulsions, coma, fever, respiratory depression and death.

Barbiturates

What are barbiturates?

Barbiturates are prescription sedative hypnotic drugs used to treat anxiety, stomach (gastrointestinal) discomfort, pain, and sleep disorders, and longer acting barbiturates such as phenobarbital used to treat epilepsy. Some are short acting such as pentobarbital (Nembutal[®]), secobarbital (Seconal[®]); intermediate acting such as amobarbital (Amytal[®]), butalbital (Fiorinal[®], Fioricet[®], Esgic[®] and others); and long acting Phenobarbital (Donnatal[®] and many others).

What are the signs of barbiturate use?

- central nervous system depressant
- mild intoxication (similar to alcohol)
- slurred speech
- lack of coordination
- lethargy
- headaches
- sensations of numbness or tingling
- dizziness
- confusion
- drowsiness

What are some of the health risks of using barbiturates?

As with other sedative hypnotics, barbiturates can produce physical dependence and withdrawal. Barbiturates were first introduced in the early 1900's and in the 1970's barbiturate overdose was a leading cause of death. Due to the abuse and overdose potential, barbiturates can be very dangerous if taken in greater than prescribed dosages. These drugs are very dangerous when used in combination with other central nervous system depressant drugs such as alcohol. Overdose can result in depression of the central nervous system and cardiovascular system and respiratory depression which can lead to death. Other dangerous effects of overdose are: shock with cool and clammy skin, decreased blood pressure, decreased oxygen carrying capacity of the blood, and coma.

Benzodiazepines

What are benzodiazepines?

Benzodiazepines are one of the most commonly prescribed drugs in the United States. They are sedative hypnotic drugs which relieve anxiety with less harmful side effects than the barbiturates. The benzodiazepine class of drugs include: Diazepam (Valium[®]), Oxazepam (Serax[®]), Chlordiazepoxide (Librium[®]), Chlorazepate (Tranxene[®]), Temazepam (Restoril[®]), Alprazolam (Xanax[®]), Triazolam (Halcion[®]), Lorazepam (Ativan[®]) and Prazepam (Centrax[®]).

What are the signs of benzodiazepine use?

- lethargy
- sedation
- motor incoordination
- intellectual impairment
- sleepiness
- impaired speech
- decreased anxiety
- muscle relaxation
- light headedness
- confusion
- disorganization of thought

What are some of the health risks of using benzodiazepines?

They are relatively safe even at high doses which is why they are replacing the barbiturates as sedative hypnotics. Sedation and respiratory depression at high doses are enhanced with alcohol and other central nervous system depressants. These drugs have an abuse potential.

Tricyclic Antidepressants (TCAs)

These anti-depressant drugs are prescription drugs with low abuse potential and are not considered addictive. Tricyclic antidepressants were developed in the 1950s and are still widely used. Examples are Amitriptyline, Nortriptyline, Imipramine and Desipramine. They are used in numerous applications mainly indicated for the treatment of clinical depression and some other disorders but their use has decreased in recent years because of newer drugs with fewer side effects. TCAs have been shown to be effective in treating attention-deficit hyperactivity disorder (ADHD) and also for bed wetting. Some signs and symptoms are:

- dry mouth
- blurred vision
- decreased intestinal motility which may lead to constipation
- urinary retention or difficulty with urination
- drowsiness
- anxiety

- restlessness
- confusion, dizziness and memory difficulties
- weakness, nausea and vomiting
- increased heart rate and irregular heart rhythms

TCAs may enhance the response to alcohol and the effects of barbiturates and other CNS depressants. Tricyclic antidepressants overdose is a significant cause of fatal drug overdose.

Where can I get some help?

The following organizations provide a variety of information services and, in some cases, published materials. Most of these groups are either non-profit organizations or federal government agencies.

Adult Children of Alcoholics	213-534-1815
Al-Anon Family Group Headquarters	212-683-1771
Alateen	212-683-1771
Alcoholics Anonymous	212-870-3400
Alcohol Hotline	800-ALCOHOL
American Council on Alcoholism Helpline	800-527-5344
American Council for Drug Education	800-488-3784
Center on Addiction and Substance Abuse	212-841-5200
Center for Substance Abuse Prevention	800-967-5752
Center for Substance Abuse Treatment	800-662-HELP
Cocaine Anonymous	800-347-8998
Cocaine Hotline	800-COCAINE
Community Anti-Drug Coalitions of America	703-706-0560
Just Say No Foundation	800-258-2766
Marijuana Anonymous	800-766-6779
Mothers Against Drug Driving	214-744-6233
Naranon Family Groups	213-547-5800
Narcotics Anonymous	818-773-9999
National Clearinghouse for Alcohol and Drug Information	800-729-6686
National Council on Alcoholism and Drug Dependence	800-NCA-CALL
National Drug & Alcohol Treatment Routing Service	800-662-HELP
National Families in Action	404-934-6364
National Federation of Parents for Drug-Free Youth	800-554-KIDS
National Helpline	800-COCAINE
National Helpline Spanish	800-662-9832
National Institute on Drug Abuse	800-622-HELP
National Parents Resource Institute for Drug Education	800-241-7946
Office of National Drug Control Policy	800-666-3332
Partnership for a Drug-Free America	212-922-1560
Substance Abuse & Mental Health Services Admin.	301-443-8956

[]

Additional Information for Healthcare Professionals

QUALITY CONTROL

Test external negative and positive liquid controls with each new lot shipment of product, with each new operator, monthly as a check on continued storage conditions, or as otherwise required by your laboratory's internal quality system procedures.

External Positive and Negative Controls are available separately. Please contact manufacturer for a list of approved controls that have been validated with the test system.

If unexpected results are seen when running the controls, review the test procedures and repeat the test with another device. If the problem persists, discontinue the use of test device immediately and contact the manufacturer.

PERFORMANCE CHARACTERISTICS

Lay user study performance

A total of 100 lay users were enrolled for the study to demonstrate that they can follow instruction, perform test and obtain results equivalent to those determined by GC/MS. No other instruction or training was given. The study results shown that untrained people are able to use the product and read test results with high degree accuracy as compared to confirmed results. The data are summarized as follows:

Drug	C/O	Results	Drug Concentration					Total	
			Neg	50% C/O	75% C/O	125% C/O	150% C/O		300% C/O
THC	50	Negative	179	19	12	5	0	96%	
		Positive	0	0	5	15	18		
		Total	179	19	17	20	18		20
		Agreement	100%	100%	71%	75%	100%		100%
MTD	300	Negative	180	19	11	7	0	95%	
		Positive	0	0	7	12	17		
		Total	180	19	18	19	17		20
		Agreement	100%	100%	61%	63%	100%		100%
COC	300	Negative	180	20	12	5	0	96%	
		Positive	0	0	5	14	18		
		Total	180	20	17	19	18		19
		Agreement	100%	100%	71%	74%	100%		100%
BZO	300	Negative	178	19	14	8	0	95%	
		Positive	0	0	6	12	17		
		Total	178	19	20	20	17		19
		Agreement	100%	100%	70%	60%	100%		100%
OPI	2000	Negative	167	14	7	1	0	98%	
		Positive	0	0	3	8	15		
		Total	167	14	10	9	15		16
		Agreement	100%	100%	70%	89%	100%		100%
OPI	300	Negative	25	10	7	3	0	93%	
		Positive	0	0	3	12	15		
		Total	25	10	10	15	15		15
		Agreement	100%	100%	70%	80%	100%		100%
OXY	100	Negative	180	19	12	5	0	96%	
		Positive	0	0	6	12	20		
		Total	180	19	18	17	20		19
		Agreement	100%	100%	67%	71%	100%		100%
PCP	25	Negative	182	19	14	3	0	97%	
		Positive	0	0	4	16	18		
		Total	182	19	18	19	18		17
		Agreement	100%	100%	78%	84%	100%		100%
TCA	1000	Negative	179	19	12	7	0	95%	
		Positive	0	0	7	12	18		
		Total	179	19	19	19	18		19
		Agreement	100%	100%	63%	63%	100%		100%
MDMA	500	Negative	176	20	14	5	0	96%	
		Positive	0	0	6	14	19		
		Total	176	20	20	19	19		19
		Agreement	100%	100%	70%	74%	100%		100%
MET	1000	Negative	175	20	14	5	0	96%	
		Positive	0	0	5	15	20		
		Total	175	20	19	20	20		19
		Agreement	100%	100%	74%	75%	100%		100%
AMP	1000	Negative	176	20	13	4	0	97%	
		Positive	0	0	5	16	19		
		Total	176	20	18	20	19		20
		Agreement	100%	100%	72%	80%	100%		100%
BAR	300	Negative	177	20	12	5	0	96%	
		Positive	0	0	6	15	18		
		Total	177	20	18	20	18		20
		Agreement	100%	100%	67%	75%	100%		100%

The AmediCheck™ Instant Test Cup is CLIA waived. A certificate of waiver is needed for your laboratory in order to run this test. All applicable state and local laws must be met. Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing the test, including use with only the waived specimen type(s). Any modification to the test or manufacturer's instructions will result in the test being classified as high complexity and is no longer CLIA waived.

Note: This assay provides only preliminary analytical test results. A more specific alternative chemical method must be used in order to obtain confirmed analytical results. 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 results indicated positive.

PERFORMANCE CHARACTERISTICS

- Sensitivity:** The AmediCheck™ Instant Test Cup detects drugs of abuse and their major metabolites in urine at concentrations equal to or greater than the cut-off level for the specific drug.
- Accuracy:** AmediCheck™ Instant Test Cup strips were evaluated using urine specimens from clinical laboratories where the samples were analyzed by GC/MS. The results are listed below:

2.01 AMPHETAMINE

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	45	2
AmediCheck Negative	1	78

When compared with GC/MS, the agreement for positive samples was 97.8% and for negative samples was 97.5%. With respect to GC/MS, the agreement for all samples was 97.6%.

2.02 BARBITURATES

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	54	2
AmediCheck Negative	2	58

When compared with GC/MS, the agreement for positive samples was 96.4% and for negative samples was 96.7%. With respect to GC/MS, the agreement for all samples was 96.6%.

2.03 BENZODIAZEPINES

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	40	2
AmediCheck Negative	1	79

When compared with GC/MS, the agreement for positive samples was 97.6% and for negative samples was 97.5%. With respect to GC/MS, the agreement for all samples was 97.5%.

2.04 COCAINE

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	49	4
AmediCheck Negative	3	84

When compared with GC/MS, the agreement for positive samples was 94.2% and for negative samples was 95.5%. With respect to GC/MS, the agreement for all samples was 95%.

2.05 MARIJUANA

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	60	2
AmediCheck Negative	3	73

When compared with GC/MS, the agreement for positive samples was 95.2% and for negative samples was 97.3%. With respect to GC/MS, the agreement for all samples was 96.4%.

2.06 MDMA

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	48	2
AmediCheck Negative	3	64

When compared with GC/MS, the agreement for positive samples was 94.1% and for negative samples was 97%. With respect to GC/MS, the agreement for all samples was 95.7%.

2.07 METHAMPHETAMINE

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	48	2
AmediCheck Negative	3	77

When compared with GC/MS, the agreement for positive samples was 94.1% and for negative samples was 97.5%. With respect to GC/MS, the agreement for all samples was 96.2%.

2.08 METHADONE

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	52	3
AmediCheck Negative	2	64

When compared with GC/MS, the agreement for positive samples was 96.3% and for negative samples was 95.5%. With respect to GC/MS, the agreement for all samples was 95.9%.

2.09 OPIATES 300

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	68	2
AmediCheck Negative	2	69

When compared with GC/MS, the agreement for positive samples was 97.1% and for negative samples was 97.2%. With respect to GC/MS, the agreement for all samples was 97.2%.

2.10 OPIATES 2000

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	64	2
AmediCheck Negative	2	71

When compared with GC/MS, the agreement for positive samples was 97% and for negative samples was 97.3%. With respect to GC/MS, the agreement for all samples was 97.1%.

2.11 OXYCODONE

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	51	2
AmediCheck Negative	2	59

When compared with GC/MS, the agreement for positive samples was 96.2% and for negative samples was 96.7%. With respect to GC/MS, the agreement for all samples was 96.5%.

2.12 PHENCYCLIDINE

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	55	5
AmediCheck Negative	3	75

When compared with GC/MS, the agreement for positive samples was 94.8% and for negative samples was 93.8%. With respect to GC/MS, the agreement for all samples was 94.2%.

2.13 TRICYCLIC ANTIDEPRESSANTS

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
AmediCheck Positive	55	2
AmediCheck Negative	3	58

When compared with GC/MS, the agreement for positive samples was 94.8% and for negative samples was 96.7%. With respect to GC/MS, the agreement for all samples was 95.8%.

3. Specificity: The specificity of AmediCheck™ Instant Test Cup was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine.

(1) The following structurally related compounds produce positive results when tested at levels greater than the concentrations (ng/ml) listed below:

The following Amphetamine-related substances yield positive results for **Amphetamine**:

d-Amphetamine	1,000
l-Amphetamine	10,000
3,4 methylenedioxyamphetamine(MDA)	4,500
p-Methoxyamphetamine(PMA)	1,500
Methylenedioxyethylamphetamine(MDEA)	>100,000
Methylenedioxymethamphetamine(MDMA)	>100,000

The following Barbiturate-related substances yield positive results for **Barbiturates**:

Secobarbital	300
Alphenal	400
Amobarbital	2,000
Aprobarbital	300
Barbital	300
Butabarbital	300
Butalbital	3,000
Pentobarbital	400
Phenobarbital	300

The following Benzodiazepine-related substances yield positive results for **Benzodiazepines**:

Oxazepam	300
Alprazolam	400
Bromazepam	2,000
Chlordiazepoxide	8,000
Clobazam	400
Clonazepam	5,000
Diazepam	2,000
Estazolam	20,000
Flunitrazepam	1,000
Lorazepam	4,000
Lometazepam	5,000
Nitrazepam	200
Nordiazepam	500
Temazepam	200
Triazolam	8,000

The following Cocaine-related substances yield positive results for **Cocaine**:

Benzoylcegonine	300
Cocaine	50,000
Ecgonine	>100,000
Ecgonine Methyl Ester	>100,000

The following Marijuana-related substances yield positive results for **Marijuana**:

11-Nor- Δ -9-THC-9-COOH	50
Δ -9-THC	10,000
Cannabidiol	100,000
Δ -8-THC	7000
11-hydroxy- Δ -9-THC	2,000
Cannabinol	100,000

The following MDMA-related substances yield positive results for **MDMA**:

3,4 methylenedioxyamphetamine(MDMA)	500
d-Methamphetamine	250
d-amphetamine	10,000
l-Methamphetamine	500
Methylenedioxyethylamphetamine(MDEA)	500
3,4 methylenedioxyamphetamine(MDA)	>100,000
p-Methoxyamphetamine(PMA)	>100,000

The following Methamphetamine-related substances yield positive results for **Methamphetamine**:

d-Methamphetamine	1000
d-amphetamine	40,000
l-Methamphetamine	20,000
Methylenedioxyethylamphetamine(MDEA)	2,000
Methylenedioxyamphetamine(MDA)	2,000
3,4 methylenedioxyamphetamine(MDA)	>100,000
p-Methoxyamphetamine(PMA)	>100,000

The following Methadone-related substances yield positive results for **Methadone**:

Methadone	300
(\pm)-2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium(EDDP)	50,000
2-Ethyl-5-methyl-3,3-diphenylpyrroline (EMDP)	50,000

The following Opiates 300-related substances yield positive results for **Opiates 300**:

Morphine	300
6-Acetylmorphine	300
Codeine	300
Ethyl morphine	2,000
Hydromorphone	3,000
Hydrocodone	3,000

The following Opiates 2000-related substances yield positive results for **Opiates 2000**:

Morphine	2000
6-Acetylmorphine	2000
Codeine	2000
Ethyl morphine	25,000
Hydromorphone	30,000

The following Oxycodone-related substances yield positive results for **Oxycodone**:

Oxycodone	100
Oxymorphone	80000

The following PCP-related substances yield positive results for **Phencyclidine**:

Phencyclidine (PCP)	25
Thienylcyclohexylpiperidine (TCP)	3000

The following TCA-related substances yield positive results for **TCA**:

Nortriptyline	1,000
Amitriptyline	1,000
Desipramine	800
Imipramine	1,000
Nordoxepine	1,500
Cyclobenzaprine	3,000
Clomipramine	10,000
Doxepine	5,000
Protriptyline	3,000
Perphenazine	50,000
Promazine	30,000
Trimipramine	5,000

(2) The following compounds were found not to cross-react when tested at concentrations of 100 ug/ml:

Acetaminophen	Bilirubin	Erythromycin	Penicillin-G
Acetone	Caffeine	Ethanol	Pheniramine
Albumin	Chlorpheniramine	Furosemide	L-Phenylethylamine
Ampicillin	Creatine	Guaiacol Glyceryl Ether	Quindine
Aspartame	Dextromethorphan	Hemoglobin	Sulindac
Aspirin	4-Dimethylaminoantipyrine	Isoproterenol	Tyramine
Atropine	Dopamine	Lidocaine	Vitamin C
Benzocaine	(-)-Ephedrine	N-Methyl-Ephedrine	

: