

line region of the specific drug strip. 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 line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

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

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Cocaine, Methamphetamine, Methyleneoxyamphetamine, Morphine, THC, Phencyclidine, Benzodiazepine, Methadone, Barbiturate or Tricyclic antidepressants.

S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Oxidants/PCC	0.36%	99.64%
Specific Gravity	0.25%	99.75%
pH	0.06%	99.94%

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For forensic use only. Do not use after the expiration date.
- The test cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

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

Specimen Storage

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

MATERIALS

Materials Provided

- AmeriCup™ Drug Screen Cups** has a Fahrenheit temperature strip affixed to aid in the determination of specimen validity. Please use this temperature strip in conjunction with your Drug Free Policy (if applicable).
- Chain of Custody Forms with Security Seals included
- Package insert
- Adulteration color brochure

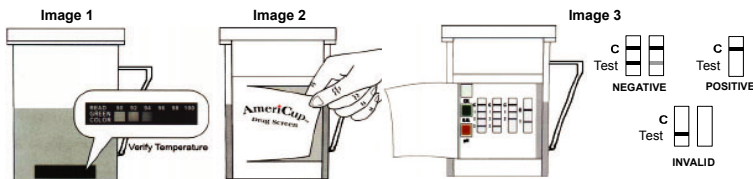
Materials Required But Not Provided

- Timer
- External controls

DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and insert it into the cup.
- Use the test as soon as possible.
- Donor provides specimen and secures the cap tightly.
- Start timer.
- Check the temperature label (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 32-38°C (90-100°F). **[See image (1)].**
- Peel off the label on the multi-drug test cup to view results. **[See image (2).]**
- Read the adulteration strip between 3 and 5 minutes. Compare the colors on the adulteration strip to the enclosed color chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen.
- The results should be read at 5 minutes. Results remain stable for up to sixty minutes. See the illustration below. **[See image (3).]**



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

***NOTE:** The shade of red in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

SVT/ADULTERANT INTERPRETATION

(Please refer to the color chart)

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

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The **AmeriCup™ Drug Screen Cup** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.^{3,4,7}
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A Positive result does not indicate level or intoxication, administration route or concentration in urine.
- A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.

S.V.T. ADULTERATION LIMITATIONS

- The adulteration tests included with this product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.
- Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
- Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the **AmeriCup™ Drug Screen Cup** and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BZO	Oxazepam, Nordiazepam, a-OH-Alprazolam, Desalkylflurazepam
COC	Benzoyllecgonine
THC	11-nor- ⁹ -tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine

MDMA	D,L Methyleneoxyamphetamine
OPI	Morphine, Codeine
PCP	Phencyclidine
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

%Agreement with Commercial Kit

	AMP	BAR	BZO	COC	THC	MTD
Positive Agreement	97%	>99%	90%	95%	98%	99%
Negative Agreement	100%	>99%	97%	>99%	100%	>99%
Total Results	98%	99%	94%	98%	99%	>99%

	mAMP	MDMA	MOP	OPI	PCP	TCA*
Positive Agreement	98%	100%	100%	>99%	98%	95%
Negative Agreement	100%	99%	100%	>99%	100%	>99%
Total Results	99%	99%	100%	>99%	99%	99%

%Agreement with GC/MS

	AMP	BAR	BZO	COC	THC	MTD
Positive Agreement	97%	>99%	96%	96%	97%	99%
Negative Agreement	95%	>99%	96%	>90%	88%	>94%
Total Results	96%	99%	96%	93%	91%	>96%

	mAMP	MDMA	MOP	OPI	PCP	TCA*
Positive Agreement	99%	96%	100%	>99%	100%	>99%
Negative Agreement	94%	98%	94%	>90%	97%	89%
Total Results	96%	97%	97%	>95%	98%	91%

Forty (40) clinical samples for each drug were run using each of the **AmeriCup™ Drug Screen Cup** by an untrained operator at a Professional Point of Care site. Based on GC/MS data, the operator obtained statistically similar Positive Agreement, Negative Agreement and Overall Agreement rates as trained laboratory personnel.

*Note: TCA was based on HPLC data.

Precision

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
500	5	5	0	4	1	5	0
750	5	5	0	1	4	1	4
1,250	5	0	5	0	5	0	5
1,500	5	0	5	0	5	0	5

BARBITURATES (BAR)

Secobarbital conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
150	5	4	1	5	0	5	0
225	5	1	4	4	1	5	0
375	5	0	5	0	5	2	3
450	5	0	5	0	5	1	4

BENZODIAZEPINES (BZO)

Oxazepam	n per	Site A	Site B	Site C
----------	-------	--------	--------	--------

conc. (ng/mL)	site	-	+	-	+	-	+
0	5	5	0	5	0	5	0
150	5	4	1	3	2	4	1
225	5	2	3	4	1	2	3
375	5	0	5	0	5	3	2
450	5	0	5	0	5	1	4

COCAINE (COC)

Benzoylcegonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
150	5	5	0	4	1	5	0
225	5	5	0	1	4	5	0
375	5	1	4	0	5	2	3
450	5	0	5	0	5	1	4

MARIJUANA (THC)

11-nor- 9 -THC-9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
25	5	5	0	3	2	5	0
37.5	5	5	0	2	3	5	0
62.5	5	1	4	1	4	1	4
75	5	0	5	0	5	0	5

METHADONE (MTD)

Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
150	5	5	0	5	0	5	0
225	5	2	3	5	0	4	1
375	5	1	4	2	3	2	3
450	5	0	5	0	5	0	5

METHAMPHETAMINE (mAMP)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
500	5	5	0	4	1	5	0
750	5	5	0	4	1	1	4
1,250	5	0	5	0	5	3	2
1,500	5	0	5	0	5	0	5

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
250	5	4	1	5	0	5	0
375	5	4	1	3	2	4	1
625	5	0	5	0	5	1	4
750	5	0	5	0	5	0	5

OPIATE (OPI 2000)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
1,000	5	5	0	4	1	5	0
1,500	5	5	0	4	1	4	1
2,500	5	0	5	1	4	2	3
3,000	5	0	5	0	5	0	5

OPIATES (OPI 300)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+

0	5	5	0	5	0	5	0
150	5	4	1	5	0	5	0
225	5	2	3	5	0	5	0
375	5	0	5	0	5	3	2
450	5	0	5	0	5	1	4

PHENCYCLIDINE (PCP)

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
12.5	5	4	1	5	0	5	0
18.75	5	2	3	5	0	3	2
31.25	5	1	4	0	5	1	4
37.5	5	1	4	0	5	0	5

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortriptyline conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
500	5	5	0	4	1	4	1
750	5	5	0	1	4	3	2
1,250	5	0	5	1	4	0	5
1,500	5	0	5	0	5	0	5

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug Concentration Cut-off Range	n	AMP		BAR		BZO		COC	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	27	3	26	4	30	0
Cut-off	30	18	12	22	8	12	18	4	26
+25% Cut-off	30	1	29	7	23	3	27	0	30
+50% Cut-off	30	0	30	2	28	0	30	0	30

Drug Concentration Cut-off Range	n	THC		MTD		mAMP		MDMA	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	29	1	30	0	30	0
-25% Cut-off	30	12	18	24	6	30	0	26	4
Cut-off	30	1	29	21	9	18	12	17	13
+25% Cut-off	30	1	29	2	28	1	29	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	OPI		PCP		TCA	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	30	0	19	11	22	8
Cut-off	30	13	17	16	14	12	18
+25% Cut-off	30	4	26	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by AmeriCup[®] Drug Screen Cup at 5 minutes.

AMPHETAMINE	ng/mL
D-Amphetamine	1,000
D,L-Amphetamine sulfate	3,000
L-Amphetamine	50,000
(±)3,4-Methylenedioxyamphetamine	2,000
Phentermine	3,000
BARBITURATES	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butobarbital	75

Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES	
Oxazepam	300
Alprazolam	196
a-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Chlordiazepoxide HCl	781
Clobazam	98
Clonazepam	781
Clorazepate dipotassium	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±)Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
COCAINE	
Benzoylcegonine	300
Cocaine HCl	780
Cocaeethylene	12,500
Ecgonine HCl	32,000
MARIJUANA (THC)	
11-nor- ⁹ -THC-9 COOH	50
Cannabinol	20,000
11-nor- ⁹ -THC-9 COOH	30
⁹ -THC	15,000
⁹ -THC	15,000
METHADONE	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE	
D-Methamphetamine	1,000
-Hydroxymethamphetamine	30,000
L-Methamphetamine	8,000
(±)3,4-Methylenedioxyamphetamine	2,000
Mephentermine	50,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
D,L-3,4-Methylenedioxyamphetamine HCl (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyl-amphetamine (MDE)	300
OPIATE 300 (MOP)	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1500
6-Monoacetylmorphine	400
Morphine 3- -D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATES (2000)	

Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levophanol	75,000
6-Monoacetylmorphine	5,000
Morphine 3- -D-glucuronide	2,000
Norcodeine	12,500
Normorphone	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
PCP	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
TCA	
Notriptyline	1,000
Nordoxepin	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **AmeriCup™ Drug Screen Cup** was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the **AmeriCup™ Drug Screen Cup**. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxyamphetamine, Opiate, Phencyclidine or Tricyclic antidepressants. The following compounds show no cross-reactivity when tested with the **AmeriCup™ Drug Screen Cup** at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Acetophenetidin
N-Acetylprocainamide	Acetylsalicylic acid
Aminopyrine	Amoxicillin
Ampicillin	L-Ascorbic acid
Apomorphine	Aspartame
Atropine	Benzilic acid
Benzoic acid	Benzphetamine*
Bilirubin	D/L-Brompheniramine
Caffeine	Cannabidol
Chloralhydrate	Chloramphenicol
Chlorothiazide	D/L-Chloropheniramine
Chlorpromazine	Chloroquine
Cholesterol	Clonidine
Cortisone	L-Cotinine
Creatinine	Deoxycorticosterone
Dextromethorphan	Diclofenac
Diflunisal	Digoxin
Diphenhydramine	Ecgonine methyl ester
L -Ψ-Ephedrine	-Estradiol
Estrone-3-sulfate	Ethyl-p-aminobenzoate
[1R,2S] (-) Ephedrine	L(-)-Epinephrine
Erythromycin	Fenopropfen
Furosemide	Gentisic acid
Hemoglobin	Hydralazine
Hydrochlorothiazide	Hydrocortisone

O-Hydroxyhippuric acid
p-Hydroxytyramine
Iproniazid
Isoxsuprine
Ketoprofen
Loperamide
Meprobamate
Methylphenidate
Naloxone
Naproxen
Nifedipine
D-Norpropoxyphene
D/L-Octopamine
Oxolinic acid
Papaverine
Pentazocine hydrochloride
Phenelzine
L-Phenylephrine
Phenylpropanolamine
Prednisone
D-Propoxyphene
Quinacrine
Quindine
Salicylic acid
Sulfamethazine
Tetracycline
Tetrahydrocortisone 3 (-D-glucuronide)
Thiamine
D/L-Tyrosine
Triamterene
Trimethoprim
D/L-Tryptophan
Uric acid
Zomepirac

p-Hydroxyamphetamine
Ibuprofen
D/L-Isoproterenol
Ketamine
Labetalol
Meperidine
Methoxyphenamine
Nalidixic acid
Naltrexone
Niacinamide
Norethindrone
Noscapine
Oxalic acid
Oxymetazoline
Penicillin-G
Perphenazine
Trans-2-phenylcyclo-propylamine hydrochloride
-Phenylethylamine
Prednisolone
D/L-Propranolol
D-Pseudoephedrine
Quinine
Ranitidine
Serotonin
Sulindac
Tetrahydrocortisone 3-acetate
Tetrahydrozoline
Thioridazine
Tolbutamide
Trifluoperazine
Tryptamine
Tyramine
Verapamil

*Parent compound only; metabolizes into amphetamine and methamphetamine in the body.

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