



122 Smith Road
Kinderhook, NY 12106
1.800.227.1243 ■ +1.518.758.8158
www.abmc.com

Product Instructions

INTENDED USE

Rapid Drug Screen® (RDS®) InCup® is an in vitro diagnostic point of collection drugs of abuse testing device for professional use that incorporates collection and testing for the detection of drugs of abuse in human urine specimens. RDS InCup uses one-step, lateral flow immunoassays for the simultaneous detection of up to fifteen (15) drugs of abuse (each analyte occupies a separate channel in the device). All configurations of the product are covered by these product instructions.

RDS InCup is intended for use in the qualitative detection of the following drugs of abuse or nicotine, or for specimen validity testing in human urine at the following levels:

Compound	Test Abbreviation	Level (ng/mL)
Amphetamines (d-amphetamine sulfate)	AMP	1000*
Barbiturates (secobarbital)	BAR	300
Benzodiazepines (oxazepam)	BZO	300
Buprenorphine	BUP	12.5
Cocaine (benzoylecgonine)	COC	150 300*
MDMA ((+/-) 3,4-methylenedioxy-methamphetamine) (Ecstasy)	MDMA	1000
Metadone	MTD	300
Methamphetamines ((+)methamphetamine HCl)	METH	1000
Nicotine (Cotinine)	NIC	200
Opiates (morphine-3-b-D-glucuronide)	OPI	300 2000*
Oxycodone	OXY	100
Phencyclidine (phencyclidine HCl)	PCP	25*
Propoxyphene/ Norpropoxyphene	PPX	300
THC/ Cannabinoids (11-nor-Δ9-THC-9-carboxylic-acid)	THC	50*
Tricyclic Antidepressants (nortriptyline)	TCA	1000
Specimen Validity Tests: pH, Specific Gravity, Oxidants	SVT	3 Panel
Specimen Validity Test: pH, Specific Gravity, Creatinine, Glutaraldehyde, Nitrite, Oxidants	SVT	6 Panel

* Screening cut-off concentrations recommended by Substance Abuse Mental Health Services Administration (SAMHSA).

RDS InCup provides only a preliminary analytical test result.

SUMMARY AND EXPLANATION

RDS InCup incorporates competitive immunoassays utilizing highly specific reactions between antibodies and antigens for the simultaneous detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, cannabinoids (THC), cocaine, MDMA (Ecstasy), methadone, methamphetamines, opiates, oxycodone, phencyclidine, propoxyphene, and tricyclic antidepressants in human urine. Nicotine is also a rapid immunoassay for the qualitative detection of cotinine in human urine. The SVT strip aids in determining if the donor tampered with the specimen either by dilution or adulteration. Dilution can occur if water is added to a specimen or the donor has consumed copious quantities of liquid, referred to as "flushing". Adulteration can occur when a substance is added to the specimen. The specific gravity and creatinine will help determine if a specimen is dilute and the pH, Glutaraldehyde, Nitrite and oxidant tests will help determine if a specimen has been adulterated.

PRINCIPLES OF THE TEST

Each RDS InCup contains test strips for drugs of abuse or specimen validity that are one-step immunoassays. The specifically labeled drug (drug conjugate) competes for antibody binding sites with drugs or metabolites that may be present in the urine specimen. The test strip consists of a membrane strip with an immobilized drug conjugate. A colloidal gold-labeled antibody complex is dried at one end of the membrane. A control line, comprised of a different antibody/antigen reaction, is present on the membrane strip. The control line is not influenced by the presence or absence of a drug analyte in the urine specimen, and therefore, it should be present in all reactions.

In the absence of any drug in the urine specimen, the colloidal gold-labeled antibody complex moves with the urine by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the 'test' area. The formation of two (2) visible lines (control and test lines) occurs when the test is negative or below the cut-off for the drug.

When a drug analyte is present in the urine specimen, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the antibody binding sites on the colloidal gold-labeled antibody complex. If a sufficient amount of drug analyte is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. The formation of one (1) visible line (control line, no test line) is indicative of a preliminary positive result.

REAGENTS AND MATERIALS SUPPLIED

Each case of RDS InCup contains:

- Twenty five (25) RDS InCup devices packaged in a foil pouch with one (1) desiccant and one (1) device cover. The RDS InCup is a 120 mL urine collection cup with an identification label and temperature strip attached and with up to twelve (12) drugs of abuse or SVT strips in separate channels within the RDS InCup. Each drug test strip is made of a membrane with two (2) attached absorbent pads and a pad containing the immobilized colloidal gold-labeled antibody complex. The upper pad acts as a reservoir for the specimen after it migrates through the membrane. The test line contains a protein-drug conjugate for the individual analyte, dried on the membrane. A second line (control), containing an appropriate anti-IgG antibody, is placed above the test line on each membrane. The SVT strip has three (3) or six (6) pads affixed that are impregnated with reagents that test pH, specific gravity and oxidants or pH, Specific Gravity, Creatinine, Glutaraldehyde, Nitrite and Oxidants respectively.
- Tamper evident seals (for confirmation of specimen sent to laboratory)
- Product instructions
- SVT color chart (if SVT is part of the RDS InCup configuration)

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use.

For professional use.

Follow proper handling and disposal procedures.

While the Centers for Disease Control (CDC) has stated that "Universal precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine, and vomitus unless they contain visible blood," the use of gloves is recommended for handling of all samples and is good hygienic practice. The RDS InCup test device may be disposed of in a regular trash receptacle without any special handling.

Do not use if foil pouch seal is not intact (seal broken, tears, holes, etc.).

Do not use if beyond the expiration date printed on the pouch. The expiration date is formatted as YYYY/MM, e.g. 2010/01 means the kits should not be used after the end of January, 2010.

STORAGE

The RDS InCup device should be stored at room temperature (59° to 86°F or 15° to 30°C) or refrigerated (36° to 46°F or 2° to 8°C). If refrigerated, allow test device to warm up to room temperature before conducting any testing.

SPECIMEN COLLECTION AND HANDLING

Use fresh urine specimens. Urine specimens do not require any special handling or pretreatment. It is best to test urine specimens immediately after collection. If necessary, urine specimens may be refrigerated at 2° to 8°C for two (2) days or frozen at -20°C or colder for longer periods.

Instruct the donor to provide enough urine in the cup to be above the minimum line on the RDS InCup label.

A temperature strip is attached to the RDS InCup. For fresh urine specimens a reading between 90 - 100°F (32-38°C) is considered a viable sample. The temperature should be read within four (4) minutes and is indicated by a green dot. If the temperature strip remains black, the specimen is questionable.

Handle and dispose of urine specimens according to established protocols. Avoid contact with skin. Avoid cross-contamination of urine specimens by using a new container for each urine specimen.

PROCEDURE

- Verify the foil pouch is intact. Verify the product is within the expiration date as indicated on the pouch.
- Remove the RDS InCup and cover from the foil pouch just prior to collection.
- Provide the donor with the InCup device and device cover.
- Instruct the donor to provide an adequate sample volume. Urine level must be above the minimum line as indicated on the RDS InCup label.
- Upon receipt of the specimen and within four (4) minutes, read the temperature strip to ensure it is between 90 - 100° F (32-38°C). If the optional internal security seal is included, verify the seal is attached and intact (not torn) by observing the label through the RDS InCup, do not open the cup.
- The tests in the RDS InCup will begin running once urine is introduced into the cup. Keep the RDS InCup in an upright position or place on a flat surface.
- The SVT strip should be read within two to five (2-5) minutes, and not after five (5) minutes. Compare the color development on the pads to the color chart included.
- Allow the test to proceed undisturbed until all reddish-purple control lines appear and the test background clears. The control line is the uppermost line in each channel in the test area. Once all control lines are visible the tests are ready to be interpreted, typically this occurs in three to five (3-5) minutes. The nicotine test strip may yield a result with in one to two (1-2) minutes.
- Read results as explained under Interpretation of Results.

INTERPRETATION OF RESULTS: DRUG TESTS

The test results may be interpreted as soon as the control lines have formed and the background on the test strips have cleared. This will occur in approximately three to five (3-5) minutes. The nicotine test strip may yield a result with in one to two (1-2) minutes. All test results, except for nicotine, are stable for up to sixty (60) minutes in a human urine specimen. Do not interpret the results for nicotine after ten (10) minutes.

Test Valid

The device control line is the uppermost line appearing on each test strip. Before reading the test result lines, verify that the control lines have formed, indicating that the test is valid. If one of the control lines does not appear, the test is *invalid* and the test results must not be used. The test should be repeated using a new device. The intensity of the control lines may vary. **Any line, without regard to intensity, color or size, is a line.**

Test Invalid

If no control line appears after approximately ten (10) minutes, consider the test *invalid*. Repeat the test using another RDS InCup.

Negative

A **NEGATIVE** result for any single drug is the presence of two (2) reddish-purple lines, the upper control line and the lower test line below the control line on the drug strip. The intensity of the test lines may vary. **Any line, without regard to intensity, color or size is a line.**

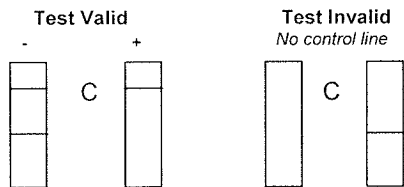
Preliminary Positive

A **PRELIMINARY POSITIVE** result for any single drug is the presence of only one reddish-purple line (the control line) and no test line on the strip for the particular drug.

CONTROL LINE/ TEST LINE INTERPRETATION

Control Line	Test Line for Each Drug	Interpretation
No control line present	No test line present	Invalid test
No control line present	Test line present	Invalid test
Control line present	Test line present	Negative
Control line present	No test line present	Preliminary Positive

Examples of Results



Note: It was determined in a study that there is no contamination of a urine sample from any component of the RDS InCup, the reagent strips or the reagents in the strip that causes any interference with the test results during re-analysis by GC/MS of the sample after seven (7) days storage at room temperature. Both negative and preliminary positive samples were tested in this study at one (1), three (3) and seven (7) days post initial analysis. Negative results were obtained on all negative samples and preliminary positive results were obtained on all positive samples, showing no interference after one (1), three (3) and seven (7) days. Therefore, a sample that is transported to a laboratory for confirmation will not be affected due to storage of the sample in the RDS InCup during transport and need not be transferred to another container.

INTERPRETATION OF RESULTS: SPECIMEN VALIDITY TESTS

Read the SVT results in two to five (2-5) minutes. Do not read after five (5) minutes. Compare color development on each pad to the corresponding test on the color chart included.

pH: Tests for the presence of acidic and alkaline adulterants. Normal urine pH ranges from 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 are indicative of adulteration.

Specific Gravity: Tests for specimen dilution. Normal levels range from 1.003—1.030.

Creatinine: Tests for specimen dilution. Normal levels range from 20 – 350 mg/dL.

Glutaraldehyde: Tests for adulteration. Glutaraldehyde is not normally found in urine. A purple or blue color will form on the glutaraldehyde pad when glutaraldehyde is present in the specimen.

Nitrite: Tests for adulteration. Nitrite is not a normal component of urine however it may indicate a urinary tract infection or bacterial infections. Nitrite levels > 20mg/dL may cause a false positive glutaraldehyde result.

Oxidants: Tests for the presence of oxidants such as bleach, nitrites, peroxide, and chromates. A blue or green color will form on the oxidant pad when oxidants are present in the specimen.

Note: the SVT should not be interpreted by persons that are color blind.

QUALITY CONTROL

A procedural control (the control line [C]) is built into each test strip, indicating that the reagents on the device are present and functioning properly. It is also good laboratory practice to use positive and negative controls to ensure proper test performance. Control samples are commercially available. Positive and negative controls should be used: 1) prior to using a new lot/shipment of test devices, 2) if the product has been stored outside the recommended storage conditions, or 3) as determined by your organization's protocol.

LIMITATIONS OF PROCEDURE

The RDS InCup is designed for use with human urine only.

RDS InCup provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method⁽¹⁾. HPLC may be used as the confirmatory method for tricyclic antidepressants. Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained⁽²⁾.

Other substances and/or factors not listed may interfere with the test and cause erroneous results, such as adulterants, procedural errors or cross reactivity with other drugs or agents. Refer to the Performance Characteristics section for more information.

The SVT strip provides a screen to determine dilution and common adulterants. High levels of antioxidants in the specimen, such as ascorbic acid, may result in a false negative oxidant result. Elevated levels of protein in the specimen may cause the specific gravity values to be elevated. If any of the SVT results are abnormal, adulteration is suspected and a fresh urine specimen should be obtained and the testing repeated.

PERFORMANCE CHARACTERISTICS

SPECIFICITY

Interference and cross reactivity studies were performed by testing the drug analytes in the RDS InCup device with various other drugs. Below is the list of drugs that will give a preliminary positive result at or above the concentration stated. All of the following drugs were added to normal, drug-free urine. Note: The drugs listed are preliminary positive for only the drug test specified.

DRUG TEST	CONCENTRATION (ng/mL)
Amphetamines	
d-Amphetamine	1000
d, l-amphetamine	1000
l-Amphetamine	20,000
Phentermine (a, a-Dimethylphenethylamine)	1250
(+/-) - Methyleneoxyamphetamine (MDA)	750
Barbiturates	
Allobarbitol (5,5-Diallylbarbituric Acid)	300
Amobarbital (Amytal; 5-Ethyl-5-Isocamylbarbituric Acid)	1000
Aprobarbital	150
Barbital (Barbitone; 5,5-Diethylbarbituric Acid; Veronal)	1250
Butabarbital	750
Butalbital	300
Butethal	500
5, 5 Diphenylhydantoin (Phenytoin)	2500
Pentobarbital (Nembutal)	300
Phenobarbital	1500
Secobarbital (Quinalbarbitone)	150
Talbutal	75
Benzodiazepines	
Alph-hydroxyalprazolam	10,000
Alprazolam	75
Bromazepam	400
Chlordiazepoxide	150
Clobazam	100
Clonazepam	300
Clorazepate	100
Desalkylfurazepam	500
Desmethyldiazepam	100
N-desmethyllunirazepam	50
Diazepam	100
Estazolam	500
Flunitrazepam	150
2-Hydroxyethylfurazepam	5000
4-Hydroxynordiazepam	4000
(+/-)Lorazepam	2200
Lorazepam glucuronide	250
Lormetazepam	500
Nitrazepam	75
Norchlordiazepoxide	500
Nordiazepam	150
Oxazepam	300
Oxazepam glucuronide	250
Sulindac	7500
Temazepam	100
Temazepam glucuronide	75
Triazolam	1500
Buprenorphine	
Buprenorphine glucuronide	12.5
Codine	10
Codeine	10,000
Hydrocodone	25,000
Lysergic Acid Diethylamide (LSD)	50,000
Metoclopramide	50,000
Morphine	25,000
Nalmefene	75,000
Naltrexone	100
Norbuprenorphine	10,000
Norbuprenorphine glucuronide	1500
Cocaine 150 ng/mL	
Benzoylcegonine	150
Cocaeethylene	150
Cocaine (Ecgonine Methyl Ester Benzoate)	100
Metoclopramide	80,000
Procaine (Novocaine)	75,000
Cocaine 300 ng/mL	
Benzoylcegonine	300
Cocaeethylene	300
Cocaine (Ecgonine Methyl Ester Benzoate)	100
Metoclopramide	80,000
Procaine (Novocaine)	75,000

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MDMA (Ecstasy)	
(+/-) 3,4-methylenedioxy-methamphetamine (MDMA)	1000
+/- Methamphetamine	1000
+ Methamphetamine	500
(+/-) 3,4-Methylene-n-ethylmethamphetamine (MDEA)	20,000
Procaine	60,000
Ranitidine	50,000
Trimethobenzamide	20,000
Methadone	
Benzotriopine Methane sulfonate	30,000
Diphenhydramine	50,000
Disopyramide	60,000
Isopropamide	500
(+/-) Methadone	300
(-)- α -Methadol	300
(-)- β -Acetylmethadol (LAAM)	2500
Procyclidine	50,000
Suxibuzone	25,000
Methamphetamines	
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
+/- Methamphetamine	1000
+ Methamphetamine	500
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	1000
Nicotine	
Cotinine	200
Niacinamide	100,000
Nicotine	100,000
Nicotinic Acid	100,000
Opiates 300 ng/mL	
6-Acetylmorphine	500
Codeine	100
Eserine (Physostigmine)	15,000
Ethylmorphine	100
Heroin (Diacetylmorphine)	500
Hydromorphone	2000
Hydrocodone	1250
Morphine	300
Morphine-3-b-D-Glucuronide	75
Nalorphine	500
Norcodeine	35,000
Oxycodone	75,000
Thebaine (Paramorphine)	13,000
Opiates 2000 ng/mL	
6-Acetylmorphine	1000
Codeine	800
Ethylmorphine	400
Heroin (Diacetylmorphine)	10,000
Hydromorphone	2000
Hydrocodone	5000
Morphine	1600
Morphine-3-b-D-Glucuronide	2000
Oxycodone	50,000
Thebaine (Paramorphine)	26,000
Oxycodone	
6-Acetylcodeine	25,000
6-Acetylmorphine	75,000
Codeine	12,500
Dihydrocodeine	3125
Hydromorphone	2500
Hydrocodone	625
Morphine	6250
Noroxycodone	50,000
Oxycodone	100
Oxymorphone	100
Thebaine	25,000
Phencyclidine (PCP)	
Phencyclidine	25
4-Hydroxy phencyclidine	90
Phencyclidine Morpholine	625
<i>RDS InCup PCP also detects high concentrations of the cough suppressant, dextromethorphan. In young children, dextromethorphan overdoses may produce a preliminary positive result for PCP. However, adults ingesting therapeutic dosages of dextromethorphan should not produce a preliminary positive result.</i>	
Propoxyphene	
Propoxyphene	300
Norpropoxyphene	200
THC/ Cannabinoids (Tetrahydrocannabinol)	
Cannabinol	25,000
11-Hydroxy-D9-Tetrahydrocannabinol	5000
11-Nor-D8-Tetrahydrocannabinol-9 Carboxylic Acid	50
11-Nor-D9-Tetrahydrocannabinol-9 Carboxylic Acid	50
11-Nor-D9-Tetrahydrocannabinol-9 Carboxylic Acid Glucuronide	2500
D8-Tetrahydrocannabinol	20,000
D9-Tetrahydrocannabinol	20,000
Tricyclic Antidepressants	
Amtriptyline	1000
Clomipramine	75,000
Cyclobenzaprine	8000
Cyproheptadine	50,000
Desipramine	1000
Doxepin	5000
Imipramine	1000
Norclomipramine	2500
Nordoxepin	500
NorInipryline	1000
Promazine	12,500
Protriptyline	2000
Trimipramine	3000

EFFECTS OF pH AND SPECIFIC GRAVITY

A series of experiments were conducted to evaluate the effects of pH on the reactivity of the RDS InCup individual drug tests. Normal urine was adjusted to various pH levels by the addition of NaOH or HCl. Exogenous target drug or metabolite was then added to these pH-adjusted specimens to give a final concentration of the target cut-off level for that assay. A pH range of 3.0 to 12.0 was investigated. In all cases pH was found not to affect the ability of the RDS InCup to detect the targeted level of drug or metabolite for that assay.

Additional experiments determined that specific gravity did not affect the ability of RDS InCup individual drug tests to detect the targeted drug or metabolite at the target cut-off level for that assay. Normal urines, specific gravity of 1.020, were diluted to produce urines with lower specific gravity values. Exogenous drug or metabolite was then added to these specimens to give a final concentration of the target cut-off for that assay.

An aqueous solution (specific gravity of 1.000) of the drug or metabolite with a concentration of the target cut-off was also evaluated. In all cases, over the specific gravity range of 1.005 to 1.020 positive results were obtained by the RDS InCup individual drug tests.

Specific gravity has little or no effect on the reactivity of RDS InCup drugs of abuse tests.

While abnormal pH and specific gravity do not affect the performance of the test, substances that may be added to the specimen to tamper with the results, may have an effect on the results and may be detected due to abnormal pH and/or specific gravity.

SENSITIVITY

Known concentrations of drug were added to normal, drug-free urine. Ten (10) determinations were made at each serial dilution of the single analyte. Sensitivity is defined as that concentration which produced preliminary positive responses in all ten (10) replicates.

DRUG	AVERAGE CONCENTRATION (ng/mL)	DRUG	AVERAGE CONCENTRATION (ng/mL)
Amphetamines	1000	Methamphetamines	1000
Barbiturates	300	Nicotine	200
Benzodiazepines	300	Opiates	300
Buprenorphine	12.5	Oxycodone	100
Cocaine	150	Phencyclidine	25
Cocaine	300	Propoxyphene	300
MDMA (Ecstasy)	1000	THC/Cannabinoids	50
Methadone	300	Tricyclic Antidepressants	1000

SUMMARY

No immunoassay that produces a single response in relation to the presence of multiple components in a mixture can reliably quantify the concentration of these components. (For example, the RDS InCup Barbiturates test detects several barbiturates. Attempts to establish semi-quantitative concentrations are not recommended. The sensitivity of this test to detect barbiturates is at an average concentration of 300 ng/mL.)

Drug	Concentration	Results (# pos/10)
Amphetamines	500	0/10
	1000	8/10
	1250	10/10
Barbiturates	150	0/10
	225	8/10
	300	10/10
	375	10/10
Benzodiazepines	150	0/10
	225	2/10
	300	10/10
	375	10/10
Buprenorphine	5	0/10
	10	2/10
	12.5	10/10
	15	10/10
Cocaine, 150 ng/mL	75	2/10
	113	8/10
	150	10/10
Cocaine, 300 ng/mL	187	10/10
	150	0/10
	225	9/10
	300	9/10
MDMA (Ecstasy)	375	10/10
	0	0/20
	500	1/20
	1000	20/20
Methadone	1250	20/20
	150	1/10
	225	7/10
	300	10/10
Methamphetamines	375	10/10
	500	0/10
	1000	10/10
	1250	10/10

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Drug	Concentration	Results
Nicotine	100	0/25
	150	0/25
	200	10/25
	250	21/35
	300	25/25
Opiates, 300 ng/mL	150	1/10
	225	9/10
	300	10/10
	375	10/10
Opiates, 2000 ng/mL	1000	0/10
	2000	10/10
	2500	10/10
Oxycodone	50	1/10
	75	8/10
	100	10/10
	125	10/10
Phencyclidine	12.5	0/10
	25	10/10
	37.5	10/10
Propoxyphene	0	0/10
	150	1/10
	225	5/10
	300	10/10
	375	10/10
THC/Cannabinoids	37	10/10
	50	9/10
	62.5	10/10
Tricyclic Antidepressants	500	0/10
	1000	9/10
	1250	10/10

ACCURACY

The RDS InCup reagents were compared to GC/MS at the claimed cut-off levels. RDS InCup was proven to correlate greater than 99% with GC/MS at a 95% confidence level.

Drug	Concentration (ng/mL)	InCup POS/ NEG	GC/MS POS/ NEG
Amphetamines	>650	32/ 0	40/0
	<650	0/58	
Barbiturates	>150	40/0	40/0
	<150	0/50	
Benzodiazepines	>160	39/0	40/0
	<160	0/51	
Buprenorphine**	> 5.2	49/0	49/0***
	< 5.2	0/51	0/51***
Cocaine, 150 ng/mL	>71	32/0	32/0
	<71	0/50	43/0
Cocaine, 300 ng/mL	>225	38/0	40/0
	<225	0/52	
MDMA (Ecstasy)	>958	60/0	60/0
	<958	0/40	
Methadone	>146	33/0	33/0
	<146	0/57	
Methamphetamines	>625	40/0	40/0
	<625	0/50	
Nicotine	>200	49/1	50/0
	<200	0/100	
Opiates, 300 ng/mL	>225	40/0	40/0
	<225	0/50	
Opiates, 2000 ng/mL	>440	43/0	43/0
	<440	0/57	
Oxycodone	>43	38/0	38/0
	<43	0/2	0/2
PCP	>19	40/0	40/0
	<19	0/50	
Propoxyphene	>233	30/0	30/0
	<233	0/60	
THC/ Cannabinoids	>33	38/0	40/0
	<33	0/52	
Tricyclic Antidepressants***	>1000	40/0	40/0**
	<1000	0/50	

**Confirmation was done with LC/MS

***Confirmation was done with HPLC

REPRODUCIBILITY

Reproducibility studies were carried out using commercially available standards. Each standard was diluted in normal, drug-free urine to give the appropriate concentration. Each specimen, at each concentration of analyte, was tested four (4) times daily, in duplicate, for five (5) consecutive days using two (2) different lots of RDS InCup. Note the following exceptions: 1. Amphetamines was tested with three (3) clinically metabolized amphetamine urine specimens at concentrations determined by GC/MS. 2. Benzodiazepines was tested with three (3) different lots. 3. Tricyclic Antidepressants was tested using positive control urines and negative control urines. Each was tested four (4) times daily, in duplicate, for five (5) days.

Drug	Concentration: ng/mL	#	Results	Precision
Amphetamines	0	40	40 neg	>99%
	1000	40	32 pos	>80%
	1250	40	40 pos	>99%
Barbiturates	0	40	40 neg	>99%
	150	40	40 neg	>99%
	225	40	36 pos	>90%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
Benzodiazepines	0	40	40 neg	>99%
	150	40	39 neg	>97%
	225	40	36 neg	>90%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
Buprenorphine	0	40	40 neg	>99%
	9.4	40	28 pos	>70%
	12.5	40	40 pos	>99%
	15	40	40 pos	>99%
Cocaine, 150 ng/mL	0	40	40 neg	>99%
	75	40	7 pos	>82%
	113	40	36 pos	>89%
	150	40	40 pos	>99%
	187	40	40 pos	>99%
Cocaine, 300 ng/mL	0	40	40 neg	>99%
	225	40	40 neg	>99%
	300	40	36 pos	>90%
	375	40	40 pos	>99%
	0	80	80 neg	>99%
MDMA (Ecstasy)	500	80	72 neg	>90%
	1000	80	80 pos	>99%
	1250	80	80 pos	>99%
	0	40	40 neg	>99%
Methadone	150	40	39 neg	>97%
	225	40	4 neg	>10%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
Methamphetamines	0	40	40 neg	>99%
	1000	40	40 pos	>99%
	1250	40	40 pos	>99%
Nicotine	100	30	30 neg	>99%
	400	30	30 pos	>99%
Opiates, 300 ng/mL	0	40	40 neg	>99%
	225	40	36 pos	>90%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
Opiates, 2000 ng/mL	0	40	40 neg	>99%
	1500	40	40 pos	>99%
	2000	40	40 pos	>99%
Oxycodone	0	80	80 neg	>99%
	25	80	78 neg	>97%
	50	80	72 neg	>90%
	75	80	15 neg	>18%
	100	80	80 pos	>99%
Phencyclidine	125	80	80 pos	>99%
	0	40	40 neg	>99%
	25	40	40 pos	>99%
	32	40	40 pos	>99%
	0	40	40 neg	>99%
Propoxyphene	150	40	35 neg	>88%
	225	40	16 neg	>40%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
	0	40	40 neg	>99%
THC/ Cannabinoids	50	40	40 pos	>99%
	75	40	40 pos	>99%
	0	40	40 neg	>99%
Tricyclic Antidepressants	500	40	40 neg	>99%
	750	40	8 neg	>20%
	1000	40	36 pos	>90%
	1250	40	40 pos	>99%

CROSSREACTIVITY

The following drugs are not detected by RDS InCup at concentrations less than 100,000 ng/mL unless otherwise specified:

Acetabulol	2-Butynoic Acid Ethyl Ester (<i>Ethyl-2-Butynoate</i>)	Diltiazem	4-Hydroxy-3-Methoxyphenylacetic Acid (<i>Homovanillic Acid</i>)
Acetaldehyde	Butylophenone	Diltiazem-cardzem	4-Hydroxy Phencyclidine (<i>except PCP</i>)
Acetaminophen (<i>4-Acetamidophenol, N-Acetyl-paminophenol</i>)	Caffeine (<i>1,3,7-Trimethylxanthine</i>)	Dimethydrinate	11-Hydroxy- Δ^9 -Tetrahydrocannabinol* (<i>except THC</i>)
Acetazolamide	(+/-) Camphor	Dimercaprol (2,3-Dimercaptopropanol)	5-Hydroxytryptamine (<i>Serotonin</i>)
Acetone	Cannabidiol	4-Dimethylaminoantipyrine (<i>Aminopyrine</i>)	3-Hydroxytryptamine
3-(α -acetylonybenzyl)-4-hydroxycoumarin (<i>Warfarin</i>)	Cannabinol (<i>except THC</i>)	1,1-Dimethylbiguanide (<i>Metformin</i>)	Hydroxyzine (<i>Atarax</i>)
Acetophenetidin	Canrennic Acid	Dimethyl Sulfoxide (<i>DMSO</i>)	L-Hyoscyamine
Acetopromazine	Captopril	1,3-Dimethyluric Acid	lbutrofen
N-Acetyl-L-cysteine	Carbamazepine	1,7-Dimethylxanthine	Irbesartan
6-Acetylmorphine (<i>except OPI & OXY</i>)	Carbamyl- β -methylcholine-chloride (<i>Bethanechochloride</i>)	Diphenhydramine (<i>except MTD</i>)	Imidazole-4-Acetic acid
N-Acetylprocainamide (<i>Acedinide</i>)	Carboplatin	5,5-Diphenylhydantoin (<i>Phenytoin</i>) (<i>except BAR</i>)	Imipramine (<i>except TCA</i>)
Acetylsalicylic Acid (<i>Aspirin, 2-Acetoxybenzoic Acid</i>)	(S)-(-)-Carbidopa	Dipyridamole	Indapamide
Albumin, standard	Cansoprodol	Dipyrene	Indole-3-Acetic acid
Albuterol	Carvedilol	Disopyramide (<i>except MTD</i>)	Indole-3-Butyric Acid
Allobarbitol (<i>5,5-Diallylbarbituric Acid</i>) (<i>except BAR</i>)	Cefactor	Divalproex	DL-Indole-3-Lactic Acid
Allopurinol (<i>4-Hydroxypyrazole (3,4-)</i> Pyrimidine)	Cefadroxil	Dobutamine	Indomethacin
Alpha-hydroxyriazolam*	Cefoxime	Doxbutamine	Interferon
Alprazolam (<i>except BZO</i>)	Cefotaxime	Doxycycline	Ipratropium Bromide
Alprenolol	Cefoxitin	Doxylamine	Iproniazid
Amantadine (<i>Adamantan-1-amine</i>)	Ceftriaxone	Droperidol	Isonicotinic Acid (<i>Pyridine-4-Carboxylic Acid</i>)
Aminoclonide	Cefuroxime	Ergonine	Isonicotinic Acid Hydrate
(+)-Amethopterin (<i>4-Amino-10-methylfolic acid, Methotrexate, Methylaminopterin</i>)	Cephalexin	Ergonine Methyl Ester	Isopropamide (<i>except MTD</i>)
Amikacin	Cephaloridine	Efavirenz	(+) Isoproterenol
Amiloride	Cephradine (<i>Cefradine</i>)	Emetine	(-) Isoproterenol
p-Aminobenzoic Acid	Cetirizine	Enalapril	(+/-) Isoproterenol
7-Aminoclonazepam	α -Chloralose	(-)- ψ Ephedrine	Isosuxiprine
7-Aminoflunitrazepam	Chloramphenicol (<i>Chloromycetin</i>)	(+)- ψ -Ephedrine	Kanamycin
DL-Aminoglutethimide	Chlorocyclizine	(+)-Ephedrine	Ketamine
7-Aminonitrazepam	Chloridiazepoxide (<i>except BZO</i>)	(+/-)Ephedrine	Ketoprofen
Amiodarone	2-(β -Chlorophenoxy)-2-Methylpropionic Acid Ethyl Ester (<i>Clofibrate</i>)	(-)-Epinephrine	Kynurenic Acid
Amitriptyline (<i>except TCA</i>)	Chloroquine	(+/-)Epinephrine	Labelalol
Ammonium Chloride	Chlorothiazide	Erythromycin	Lamotrigine
Amobarbital (<i>amylal, 5-Ethyl-5- Isoamyl barbituric Acid</i>) (<i>except BAR</i>)	Chlorotrianisene	Escitalopram	Lanoprazole
Amoxeltine	(+)Chlorpheniramine	Eserine (<i>Physostigmine</i>) (<i>except OPI</i>)	Lansoprazole
Amoxicillin	(+/-)Chlorpheniramine	Estazolam (<i>except BZO</i>)	Levorphanol
Amphotericin B	Chlorpromazine	β -Estradiol	Levothyroxine
D-Amphetamine (<i>except AMP</i>)	Chlorpropamide	Estradiol	Lidocaine
DL-Amphetamine (<i>except AMP</i>)	Chlorprothixene	Estrone	Linoleic Acid-Conjugated (CLA), Gamma Alpha
L-Amphetamine (<i>except AMP</i>)	Chlorthalidone	Estrone- β -D-Glucuronide	Eicosapentaenoic, docahexaenoic acid, omega 3/6/9
Ampicillin	Chlorzoxazone (<i>5-Chloro-2-Hydroxybenzoxazole</i>)	Estrone-3-Sulfate	Lithium Carbonate
D-Amygdalin	Cholesterol	Ethacrynic Acid	Loperamide
Aniline	Cimetidine	Ethambutol	Loratadine
Antipyrine (<i>Phenazone</i>)	Cinchonidine	Ethamivan (<i>N,N-Diethylvanillamide</i>)	(+/-) Lorazepam (<i>except BZO</i>)
Apomorphine	Cinoxacin	Ethanol, Standard	Lormetazepam (<i>except BZO</i>)
Aprobarbital (<i>except BAR</i>)	Ciprofloxacin	Ethosuximide (<i>2-Ethyl-2-Methylsuccinimide</i>)	Lysergic Acid Diethylamide (LSD) (<i>except BUP</i>)
Aripiprazole	Citalopram*	2-Ethyl -2-Phenylmalonamide	Mebendazole
(-) Arterenal [(<i>-</i>)Norepinephrine]	Citalopram Hydrobromide*	Ethylene Glycol	Meclozine
L-Ascorbic Acid	Clarithromycin	Ethylenediaminetetraacetic Acid (<i>EDTA</i>)	Meclofenamic Acid
ASP-PHE-Methyl-Ester (<i>Aspartame</i>)	Clemastine	2-Ethylidene-1,5-Dimethyl-3,3-diphenylpyrrolidine	Medazepam
D-Aspartic Acid	Clenbuterol	Ethylmorphine* (<i>except OPI & OXY</i>)	Metenamic Acid
DL-Aspartic Acid	Clindamycin	17- α -Ethinylestradiol	Melanin
L-Aspartic Acid	Clindamycin Phosphate	Etodolac	Meloxicam
Astemizole	Clobazam (<i>except BZO</i>)	Etoposide	Melphalan
Atenolol	Clobetasone Butyrate	Ezetimibe	(-)Menthol
Atomoxetine	Clomipramine (<i>except TCA</i>)	Famotidine	Meperidine
Atropine (<i>Tropinotropate</i>)	Clonazepam (<i>except BZO</i>)	Felodipine	Mephensin
Atrovastin	Clonidine	Fenfluramine	Mephentermine
Azathioprine	Clorazepate(except BZO)	Fenopropfen [(+/-)-2-(3-Phenoxyphenyl) Propionic Acid]	Meprobamate
Baclofen	Clorazepate Dipotassium	Ferrous Sulfate	6-Mercaptopurine
Barbital (<i>Barbitone, 5,5-Diethylbarbituric acid, Veronal</i>) (<i>except BAR</i>)	Cloxacillin	Fentanyl*	Mersalyl Acid
Barbituric Acid (<i>2,4,6- Trihydroxypyrimidine; Malonylurea</i>)	Clozapine	Ferrous Sulfate	Mescaline (<i>3,4,5-Trimethoxyphenethylamine</i>)
Beclomethasone	Coca ethylene (<i>except COC</i>)	Fexofenadine	DL-Metanephine
Beclomethasone Dipropionate	Cocaine (<i>Ecgonine Methyl Ester Benzoate</i>) (<i>except COC</i>)	Fluoxetine	Metaproterenol
Bendroflumethiazide	Codeine (<i>Desferrioxamine Mesylate</i>) (<i>except BUP, OPI & OXY</i>)	Flurbiprofen	Metaraminol [(<i>-</i>)- <i>m</i> -Hydroxyphenylpropanolamine]
Benzidine (<i>4,4 Diaminobiphenyl</i>)	Codeine	Flufenamic Acid	(+/-) Methadone (<i>except MTD</i>)
Benicar	Colchicine	Flunitrolide	(+) Methamphetamine (<i>Methylamphetamine, d-Desoxyephedrine</i>) (<i>except MDMA & MET</i>)
Benzyllic Acid β -diethylaminoethyl ester	Cortisone	Flurandrenolide	(+/-) Methamphetamine (<i>except MDMA & MET</i>)
Benzocaine (<i>Ethyl-p-Aminobenzoate</i>)	β -Cortol	Flurazepam (<i>except BZO</i>)	Methanol, Absolute
Benzoic Acid	Cotinine (<i>except NIC</i>)	Flurbiprofen	Methaqualone
Benzonatale	Creatinine	Formaldehyde	Methazolamide
Benzoyllecgonine (<i>except COC</i>)	Cromolyn (<i>Cromoglycic Acid</i>)	Furosemide	Methotrimeprazine
Benzphetamine (<i>α-dimethylphenethylamine</i>)	Cyclobenzaprine (<i>except TCA</i>)	Gabapentin	Methoxamine
Benzthiazide	Cyclophosphamide	Gemfibrozil	Methoxamine
Benztropine Methane sulfonate (<i>Benztropine Mesylate</i>)	Cyclosporin A	Gentamicin Sulfate	(S)-6-Methoxy- α -Methyl-2-Naphthalene Acetic Acid (<i>Naproxen</i>)
Benzyl alcohol	Cyproheptadine (<i>except TCA</i>)	Genistic Acid	Methoxyphenamine
Benzylamine	Dantrolene	Glucose	5-Methoxytryptamine
Benzylpiperazine	Deferoxamine Mesylate	(D)(+)-Glucose (<i>Dextrose</i>)	3-Methoxytyramine
Berberine	Deoxyepinephrine	Gibenclamide	2-Methyl-3-(3,4-dihydroxyphenyl)-DL-Alanine
Betamethasone	R-(-)-Deprenyl (<i>Selegiline</i>)	Griseofulvin	2-Methyl-3-(3,4-dihydroxyphenyl)-L-Alanine
Bilirubin	Desipramine (<i>except TCA</i>)	Guaiacol Glyceryl Ether	3,3'-Methylene-bis-(4-Hydroxycoumarin)
Bisacodyl	N-Desmethylclozapine (<i>Normethylclozapine</i>)	Guafenesin	(<i>Dicumarol</i>)
Bromazepam (<i>except BZO</i>)	Desmethylclonazepam (<i>except BZO</i>)	Halazepam	Methylene Blue
-Bromo- α -ergocryptine (<i>Bromocriptine mesylate</i>)	Desoximetasone	Haliclonide	(+/-) 3,4-Methylenedioxyamphetamine (<i>MDA</i>) (<i>except AMP</i>)
(+) Brompheniramine (<i>Dexbrompheniramine</i>)	Dexamethasone	Haloperidol	(+/-) 3,4-Methylenedioxy-methylamphetamine (<i>MDMA</i>) (<i>except MET & MDMA</i>)
(+/-) Brompheniramine	Dexbrompheniramine	Hemoglobin	(+/-) 3,4-methylenedioxy-n-ethylamphetamine (<i>MDEA</i>) (<i>except MET & MDMA</i>)
Bumetanide	Dextromethorphan	Heroin (<i>Diacetylmorphine</i>)* (<i>except OPI</i>)	1-Methylhistamine
Bupivacaine	4,4'-Diaminophenyl Sulfone (<i>Dapsone</i>)	Hexachlorocyclohexane	6 α -Methyl-17 α -Hydroxyprogesterone (<i>Medroxyprogesterone</i>)
Buprenorphine (<i>except BUP</i>)	Diazepam (<i>except BZO</i>)	Hexachlorophene	6 α -Methylprednisolone (<i>Medrol</i>)
Bupropion HCL	Diazoxide	Hexobarbital	Methylphenidate (<i>Ritalin</i>)
Buspiron	Dichloromethane (<i>Methylene Chloride</i>)	Hippuric Acid	Methyl Salicylate
Butabarbital (<i>except BAR</i>)	Dichlorophenamide	Histamine [2 (<i>4-Imidazolyl</i>) Ethylamine]	Methyl Viologen (<i>Gramoxone, Paraquat Dichloride</i>)
Butalbital (<i>except BAR</i>)	Diclofenac	DL-Homatropine	Melicrane
Butethal (<i>except BAR</i>)	Dicyclomine	Hydralazine (<i>1-Hydrazinophthalazine</i>)	Metoclopramide (<i>except BUP & COC</i>)
Butacaine	Diethylidithiocarbamic Acid	(1S, 9R)- β -Hydrastine	(+/-)Metoprolol
	N,N-Diethylnicotinamide (<i>Niacin Diethylamide; Nيكهتاميد</i>)	Hydrochlorothiazide	Metronidazole
	Diflorasone Diacetate	Hydrocodone (<i>except BUP, OPI & OXY</i>)	Mexiletine (<i>except AMP</i>)
	Diffurcortolone pivalate	Hydrocortisone	Mianserin
	Digoxin (<i>1,2 β-Hydroxydigoxin</i>)	Hydroflumethiazide	Midazolam (<i>except BZO</i>)
	DL-3,4 Dihydroxymandelic Acid	Hydroxocobalamin	Mirronone
	DL-3,4 Dihydroxyphenyl Glycol	O-Hydroxyhippuric Acid	
	3,4 Dihydroxyphenylacetic Acid	5-Hydroxyindole-3-Acetic Acid	
	(2,3-Dihydroxypropyl) Theophylline (<i>Dyphylline</i>)	5-Hydroxy-2-indole-2-Carboxylic Acid	

(Continued from previous page)

Minaprine
Minocycline
Mirtazapine (except BZO)
Morphine (except BUP, OPI & OXY)
Morphine-3-β-D-Glucuronide (except OPI)
Mupirocin
Nabumetone
Nadolol
Nafcillin
Nalburphine
Nalidixic Acid
Nalmefene (except BUP)
Nalorphine (except OPI)
Naloxone
Naltrexone (except BUP)
Naphazoline
α-Naphthalene Acetic Acid
β-Naphthalene Acetic Acid
α-Naphthol
Neomycin Sulfate
Niacinamide (except NIC)
Nialamide
Nicotic Acid (Niacin)
±- Nicotine (except NIC)
Nifedipine
Nitrazepam (except BZO)
Nitrofurantoin
Nomifensine
11-Nor-Δ8-Tetrahydrocannabinol-9-Carboxylic Acid* (except THC)
11-Nor-Δ9-Tetrahydrocannabinol-9-Carboxylic Acid*
except THC)
11-Nor-Δ9-THC-9-Carboxylic Acid
Glucuronide* (except THC)
Norclomipramine (except TCA)
Norcocaine
Norcodeine (except OPI)
Nordoxepin (except TCA)
Nordiazepam (except BZO)
Norethindrone
Norfloxacin
DL-Normetanephrine
Normorphine
d-Norpropoxyphene (except PPX)
Nortriptyline (except TCA)
Noscapine
Nyidrin
Olmesartan
Omeprazole
Orotic Acid (Uracil-6-Carboxylic Acid)
Orphenadrine
Oxalic Acid (Ethanedioic Acid)
Oxaprozin
Oxazepam (except BZO)
Oxolinic Acid
Oxybutynin Chloride
Oxycodone (except OPI & OXY)
Oxymetazoline
Oxyphenbutazone
Oxypropenol
Oxypurinol
Facilitaxel
Pancuronium Bromide
Pantoprazole
Papaverine
Pargyline
Paroxetine HCL
Phenazopyridine
Phencyclidine Morpholine (except PCP)
Penicillin G (Benzylpenicillin)
Pentachlorophenol
Pentobarbital (Nembutal) (except BAR)
Pentoxifylline (Trental)
Pentyleneetetrazole
Phencyclidine (except PCP)
Phendimetrazine
p-Phenylenediamine
Phenelzine
Phenformin
Pheniramine
Phenobarbital (except BAR)
Phenol
Phenolphthalein
Phenothiazine (Thiodiphenylamine)
Phenoxyethyl Penicillinic Acid (Penicillin V)
Phentermine (α, α-Dimethylphenethylamine) (except AMP)
Phentolamine
DL-Phenylalanine
L-Phenylalanine
Phenylbutazone
L-Phenylephrine
(±)-α-Phenylethylamine
(α-Methyl benzylamine)
β-Phenylethylamine
(R,+) α-Phenylethylamine
(±)- Phenylpropanolamine (PPA)
Phenylosamide
Phthalic Acid (1,2-Benzenedicarboxylic Acid)
Picrotoxin
Pilocarpine
Pimozide
Pinacidil
Pindolol
Pioglitazone
L-Pipecolic Acid

Pipemidic Acid
Piroxicam
Potassium Chloride
Potassium Iodide
Prazepam
Prazosin
Prednisolone (1-Dehydrocortisol)
Prednisone (Dihydrocortisone)
5-Pregnen-3β-OL-20-one
(EPI pregnanolone; Pregnenolone)
Prilocaine
Primaquine
Primidone (2-Desoxyphenobarbital)
Proadifen
Probenecid [p-(Dipropylsulfamoy) Benzoic Acid]
Procainamide
Procaine (Novocaine)(except COC, MDMA & MET)
Prochlorperazine
Procydiline (except MTD)
Promazine (except TCA)
Promethazine
Propionyl promazine
d-Propoxyphene (except PPX)
DL-Propranolol
2-Propylpentanoic Acid (Valproic Acid)
Protein
Pyridoxine
Protriptyline (except TCA)
d-Pseudoephedrine
Pyridine-2-AldoximeMethochloride (Pralidoxime Chloride)
Pyrilamine (Mepyramine)
Quinapril
Quinidine
Quinine
Quinolinic Acid (2,3-Pyridinedicarboxylic Acid)
Ramipril
Ranitidine (Zantac) (except MDMA & MET)
Rescinnamine
Reserpine
Ribavirin
Riboflavin
Ritodrine
Rosiglitazone
Rosuvastatin
Salbutamol (Albuterol)
Salicylamide (2-Hydroxybenzamide)
Salicylic Acid (2-Hydroxybenzoic Acid)
(-) Scopolamine (Hyoscine)
Secobarbital (Quinalbarbitone) (except BAR)
Sertraline
Simvastatin
Sodium Chloride
Sodium Formate
(+/-)Sotalol
Strychnine
Succinylcholine Chloride
Sulfamethazine
Sulfamethoxazole
Sulfanilamide (p-Aminobenzenesulfonamide)
Sulfathiazole
Sulfisoxazole
Sulindac (except BZO)
(+/-)Sulpiride
Suxibuzone (except MTD)
Talbutal (except BAR)
Tamoxifen
Tannic Acid
Temazepam (except BZO)
Tenoxicam
Terazonin
Terazosin
Terazosin HCl
Terbutaline
Terfenadine
Tetracycline
Tetraethyl Thiuram Disulfide (Disulfiram)
Δ8-Tetrahydrocannabinol (except THC)
Δ9-Tetrahydrocannabinol (except THC)
Tetrahydrozoline
Thebaine (Paramorphine) (except OPI & OXY)
Theobromine (3,7-Dimethylxanthine)
Theophylline (1,3-Dimethylxanthine)
Thiamine (Aneurine)
Thimerosal (Sodium Ethylmercurithiosalicylate)
Thioridazine
cis-Thiothixene
Thymol (5-Methyl-2-Isopropylphenol)
Timolol
Tobramycin
Tolazamide
Tolbutamide
Tolmetin
Toluene
cis-Tramadol
Trans-2-Phenylcyclopropylamine
(Tranlycypromine-mine)
Tramadol HCl
Trazodone
Triamcinolone (Fluoxiprednisolone)
Triamterene
Triazolam* (except BZO)
Trichlormethiazide
Trichloroacetic acid
2,2,2 Trichloroethanol
Trifluoperazine

Triflupromazine
DL-Trinexyphenidyl
Trimethobenzamide (except MDMA & MET)
Trimethoprim
3,5,5-Trimethyloxazolidine-2-4dione
(Trimethadione)
Trimipramine (except TCA)
Triprolidine
DL-Tropic Acid
Tropine
Tryptamine [3-(2-Aminoethyl) Indole]
DL-Tryptophan (3 β-Indolylalanine; (+/-)-α-Amino-3-Indolepropionic Acid)
d-Tubocurarine Chloride
Tyramine (4-Hydroxyphenethylamine)
DL-Tyrosine
Urea (Carbamide)
Uric Acid
Vancomycin
(+/-)Verapamil
Venlafaxine (except PCP)
Vincamine
Vitamins
Warfarin
Xylometazoline
Yohimbine
Zearalenone
Zolpidem
Zomepirac
Zopiclone
*tested at 10,000 ng/mL

Trouble Shooting Tips

Potential Failure	Potential Cause of Failure	Corrective/Preventive Action
One or more of the test strips fails to flow immediately	The test strips may not all begin to flow at the same time It is not uncommon for strips to flow at different rates	If one or more of the test strips fail to flow after 1 minute, agitate the cup on a flat surface for a few seconds All test strips should yield results within the 3 to 5 minute time period Do not turn the cup upside down during the testing period
One or more of the test strips fail to flow	Insufficient sample Sample is below the minimum fill line	Ensure sample is above the minimum fill line labeled on the cup
Test results are washed out or test lines appear smeared	Vigorously shaking the cup or turning the cup upside down will flood the test strips	Avoid excessive agitation or turning the cup upside down If agitation is necessary, lightly agitate the cup on a flat surface for a few seconds
Cup has leaked during shipment for confirmation	Lid was loosely placed on the cup prior to shipping	Ensure that the lid is placed on the cup and tightened appropriately prior to shipping
One or more of the Control Lines fail to appear after 5 minutes	Flooding of test strips by excessive agitation or turning the cup upside down	Test is considered invalid Repeat the test Avoid excessive agitation or turning the cup upside down If agitation is necessary, lightly agitate the cup on a flat surface for a few seconds
One or more of the Control Lines fail to appear after 5 minutes	Insufficient sample Sample below the minimum fill line	Test is considered invalid Repeat the test Ensure sample is above the minimum fill line labeled on the cup
Color blindness (For analyte result interpretation)	Result and control lines are colored	Color differentiation is not required to interpret the test results Once the control lines have formed the results are read by the appearance or lack of a line
Questionable results	Physical degradation of device, improper storage, opening package too soon prior to testing, attempting to read test results outside of result interpretation window	Follow product instructions for correct product storage, handling and result interpretation
Questionable results or excessive invalid results	Specimen adulteration	Upon receipt of the specimen and within four (4) minutes, read the temperature strip to ensure it is between 90 – 100° F (32-38°C) A specimen validity strip can be used to ensure that the specimen has not been diluted or adulterated
Questionable results/ non-confirmation of preliminary positive results	Incorrect or lack of specimen confirmation testing	For the most reliable confirmation results, confirm by GC/MS at limit of detection levels

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Rapid Drug Screen InCup was developed and is manufactured by American Bio Medica Corporation.
Customer Service/ Technical Support: Within the U.S.: 1.800.227.1243 / Outside the U.S.: +1.518.758.8158. Website: www.abmc.com

ABMC hereby warrants that its products covered under these Product Instructions will be free from defects in workmanship and materials at the time of sale. ABMC shall only be responsible for direct damages that may result from such defect in workmanship or materials. Test results should be confirmed by an accepted reference method such as GC/MS.



American Bio Medica Corporation
122 Smith Road
Kinderhook, NY 12106
Tel: +1.518.758.8158
Fax: +1.518.758.8171
E-mail: tech@abmc.com

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January, 2010.

STORAGE

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SPECIMEN COL

Use fresh urine s
pretreatment. It
necessary, urine
at -20°C or colder

Instruct the donor