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Product Instructions

INTENDED USE

Rapid TOX® is a one-step, lateral flow immunoassay for the simultaneous detection of up to ten (10) abused drug analytes in urine (each analyte is represented by a separate test line in the test window of the cassette).

The **Rapid TOX** test is CLIA waived, and is only waived for urine specimens. The **Rapid TOX** test may be used by sites holding a Certificate of Waiver. Certificate of Waiver sites must follow the complete manufacturer's instructions for performing the test.

Rapid TOX is intended for use in the qualitative detection of the following drugs of abuse in human urine at the following levels:

Compound	Test Abbreviation	Level (ng/mL)
Amphetamines (d-amphetamine sulfate)	AMP	1000 *
Barbiturates (butalbitol)	BAR	300
Benzodiazepines (oxazepam)	BZO	300
Buprenorphine	BUP	12.5
Cocaine (benzoylecgonine)	COC	150 300 *
MDMA ((+/-) 3,4-methylenedioxy-methamphetamine)	MDMA	1000
Methadone	MTD	300
Methamphetamines ((+)methamphetamine HCl)	MET	1000
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

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

Rapid TOX provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectrometry (GC/MS) is the recommended confirmatory method.

SUMMARY AND EXPLANATION

Rapid TOX incorporates competitive immunoassays utilizing highly specific reactions between antibodies and antigens for the detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, cannabinoids (THC), cocaine, MDMA (Ecstasy), methadone, methamphetamines, opiates, oxycodone, phencyclidine, propoxyphene and tricyclic antidepressants in urine.

PRINCIPLES OF THE TEST

Each **Rapid TOX** contains test strips for drugs of abuse 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 for the drug.**

REAGENTS AND MATERIALS SUPPLIED

Each case of **Rapid TOX** contains:

1. Fifty (50) **Rapid TOX** test devices. Each test device is packaged in a sealed foil pouch containing:
   a. One (1) test device with one (1) or two (2) channels containing a test strip that has immunoassays for up to five (5) different drugs. Each test strip is comprised 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 lines contain a carrier-drug conjugate for the individual analytes, dried on the membrane. The control line, containing goat anti-mouse IgG, is placed above the test lines on the membrane.
   b. One (1) pipette
   c. Desiccant
2. Product instructions

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 **Rapid TOX** test devices 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 or embossed 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 **Rapid TOX** 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 up to two (2) days.

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.

PROCEDURES

Dip Procedure

1. Instruct donor to provide adequate sample volume. **Rapid TOX** dip procedure can be done with as little as three (3) mL in a collection cup. If an adequate sample is not provided, see the Pipette Procedure.
2. Verify the foil pouch is intact. Verify the product is within the expiration date as indicated on the pouch. When an acceptable sample is obtained, the test device may be removed from the foil pouch.
3. Insert the bottom of test cassette into the urine sample up to the dip line for three to five (3-5) seconds. Do not allow urine to touch the cassette above the dip line.
4. Remove the test device from the sample and lay flat across the top of the cup or on a flat surface. The cassette can be left in the urine for the entire test period, provided the urine does not touch the cassette above the dip line.
5. Allow the test to proceed until a reddish-purple control line appears and the test background clears. The control line [C] is the uppermost line in the channel. Once the control line is visible the test is ready to interpret; typically this occurs in three to five (3-5) minutes.
6. Read results as explained under Interpretation of Results.

Pipette Procedure/ Low Volume

1. Verify the foil pouch is intact. Verify the product is within the expiration date as indicated on the pouch. When an acceptable sample is obtained, the test device may be removed from the foil pouch.
2. Lay test device flat. An absorbent pad may be placed under the test device.
3. Using a pipette, apply three (3) drops of urine (approximately 120µL) to the sample well at the bottom of each device.
4. Allow the test to proceed undisturbed until a reddish-purple control line appears and the test background clears. The control line [C] is the uppermost line in the test channel. Once the control line is visible, the test is ready to be interpreted; typically this occurs in three to five (3-5) minutes.
5. Read results as explained under Interpretation of Results.

INTERPRETATION OF RESULTS - DRUG TEST

The test results may be interpreted once the control line(s) have formed and the background on the test strip(s) has cleared. This will occur in approximately three to five (3-5) minutes. The test results are determined by the presence or absence of the test and control lines, therefore color blindness will not affect reading the results of the test. The test results are stable for up to six (6) hours.

Test Valid

The device control line will form in the control area labeled (C) on the cassette. The control line is the uppermost line appearing in each test channel. Before reading the test result lines, verify that the control line has formed in each test channel, indicating that the test is valid. If the control line does not appear in each test channel, the test is *invalid* and the test results must not be used. The test should be repeated using a new **Rapid TOX** device. The intensity of the control lines may vary. ***Any line, without regard to intensity 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 **Rapid TOX** device.

Negative

A **NEGATIVE** result for any single drug is the presence of a reddish-purple line adjacent to the drug name, or in the test area labeled (T) on the cassette. The intensity of the test lines may vary. ***Any line, without regard to intensity or size, is a line.***

Preliminary Positive

A **PRELIMINARY POSITIVE** result for any single drug is the absence of a line adjacent to the drug name or test area labeled (T) on the cassette.

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drug of abuse tests are more accurate than others.

For Preliminary Positive Tests: In general, the Substance Abuse and Mental Health Services Administration (SMASHA) reports the accuracy of drug tests as[a]:

60 out of 100 times a “preliminary positive” result from an opiates test is a “false preliminary positive” result. A “false preliminary positive” result means that the result of the first test was “preliminary positive” even though the person did not take an illegal drug.

50 out of 100 times a “preliminary positive” test result from an amphetamines or methamphetamines test is a “false preliminary positive” result.

50 out of 100 times a “preliminary positive” result from a PCP (phencyclidine) test is a “false preliminary positive” result.

10 out of 100 times a “preliminary positive” result from a marijuana test is a “false preliminary positive” result.

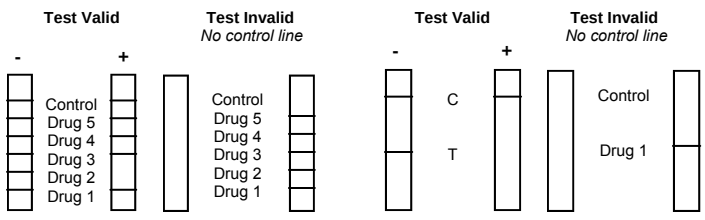
2 out of 100 times a “preliminary positive” result from a cocaine test is a “false preliminary positive” result.

[a] Data was generated from laboratory tests that have the following cutoff concentrations: cannabinoids (THC), 50 ng/mL; cocaine, 300 ng/mL; phencyclidine, 25 ng/mL; opiates, 2000 ng/mL; amphetamines, 1000 ng/mL. In general, the rates of false preliminary positive results will increase as the cutoff concentration of the test is lowered.

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



Example: Drug 2 results are preliminary positive

QUALITY CONTROL-WAIVED LABS

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, each new shipment, and every thirty days to check storage of test devices, 2) if the product has been stored outside the recommended storage conditions, or 3) in accordance with your laboratory defined policies.

QUALITY CONTROL-NON WAIVED LABS

In addition to the quality control procedure recommended for Waived Labs it is also suggested that non-Waived labs include running a positive and negative drug control for each drug assay being tested on each day of use. Control samples are commercially available.

If the test does not perform as expected with quality control solutions, or for additional quality control recommendations call ABMC at 1.800.227.1243 / Outside the U.S.: +1.518.758.8158.

LIMITATIONS OF PROCEDURE

The assay is designed for use with human urine only.

Rapid TOX 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. If adulteration is suspected, obtain a fresh urine specimen and repeat testing.

PERFORMANCE CHARACTERISTICS

SPECIFICITY

Interference and cross reactivity studies were performed by testing the drug analytes in the **Rapid TOX** 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 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-Dimethlphenethylamine)	1250
(+/-) - Methylenedioxyamphetamine (MDA)	750
Barbiturates	
Allobarbital (5,5-Diallybarbituric Acid)	300
Amobarbital (Amytal; 5-Ethyl-5-Isoamylbarbituric Acid)	1000
Aprobarbital	150
Barbital (Barbitone; 5,5-Diethlybarbituric 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-desmethylflunitrazepam	100
Diazepam	100
Estazolam	500
Flunitrazepam	150
2-Hydroxyethylflurazepam	5000
4-Hydroxynordiazepam	4000
(+/-)Lorazepam	2200
Lorazepam glucuronide	250
Lormetazepam	500
Nitrazepam	75
Norchlordiazepoxide	500
Nordiazepam	150
Oxazepam	300
Oxazepam glucuronide	750
Sulindac	7500
Temazepam	100
Temazepam glucuronide	75
Triazolam	1500

(Continued from previous page)

DRUG TEST	CONCENTRATION (ng/mL)
Buprenorphine	12.5
Buprenorphine glucuronide	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
Norbuphrenorphine glucuronide	1500
Cocaine150 ng/mL	
Benzoylecgonine	150
Cocaethylene	150
Cocaine (Ecgonine Methyl Ester Benzoate)	100
Metoclopramide	80,000
Procaine (Novocaine)	75,000
Cocaine 300 ng/mL	
Benzoylecgonine	300
Cocaethylene	300
Cocaine (Ecgonine Methyl Ester Benzoate)	100
Metoclopramide	80,000
Procaine (Novocaine)	75,000
MDMA	
(+/-) 3,4-methlylenedioxy-methamphetamine (MDMA)	1000
+/- Methamphetamine	1000
+ Methamphetamine	500
(+/-) 3,4-methylene-n-ethyl methamphetamine (MDEA)	20,000
Procaine	60,000
Ranitidine	50,000
Trimethobenzamide	20,000
Methadone	
Benzatropine Methane sulfonate	30,000
Diphenhydramine	50,000
Disopyramide	60,000
Isopropamide	500
(+/-) Methadone	300
(-)-á-Methadol	300
(-)-á-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
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	50,000
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	75,000
Thebaine (Paramorphine)	26,000
Oxycodone	
6-Acetyl codeine	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
Propoxyphene	
Propoxyphene	300
Norpropoxyphene	300
THC/ Cannabinoids (Tetrahydrocannabinol)	
Cannabinol	
Efavirenz**	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	
Amitriptyline	1000
Clomipramine	75,000
Cyclobenzaprine	8000
Cyproheptadine	50,000
Desipramine	1000
Doxepin	5000
Imipramine	1000
Norclomipramine	2500
Nordoxepin	500
Nortriptyline	1000
Promazine	12,500
Protriptyline	2000
Trimipramine	3000

***Rapid TOX** PCP also detect 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.*

** Efavirenz is the generic drug found in some HIV treatment medications. Research sources have indicated that it is highly possible false positive results for THC may be observed in patients taking medications which may include Efavirenz.

Effect of pH and Specific Gravity

A series of experiments were conducted to evaluate the effects of pH on the reactivity of the **Rapid TOX** 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 **Rapid TOX** drugs to detect the targeted level of drug or metabolite for that assay.

Additional experiments determined that specific gravity did not affect the ability of **Rapid TOX** individual drug tests to detect the targeted drug or metabolite at the target cut-off level for that assay. Normal urine, specific gravity of 1.020, were diluted to produce urine 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 preliminary positive results were obtained by the **Rapid TOX** individual drug tests. Specific gravity has little or no effect on the reactivity of **Rapid TOX** drugs of abuse tests.

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 positive responses in all ten (10) replicates.

DRUG	AVERAGE CONCENTRATION (ng/mL)	DRUG	AVERAGE CONCENTRATION (ng/mL)
Amphetamines	**1000**	**Methamphetamines**	**1000**
Barbiturates	**300**	**Opiates**	**300**
Benzodiazepines	**300**	**Opiates**	**2000**
Buprenorphine	**12.5**	**Oxycodone**	**100**
Cocaine	**150**	**Phencyclidine**	**25**
Cocaine	**300**	**Propoxyphene**	**300**
MDMA	**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. (e.g. the **Rapid TOX** 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 in ng/mL	Results # Pos./10
Amphetamines	500	0/10
	750	2/10
	1000	10/10
	1250	10/10
Barbiturates	150	0/10
	225	2/10
	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	0/10
	113	2/10
	150	10/10
	187	10/10
Cocaine 300 ng/mL	150	0/10
	225	3/10
	300	10/10
	375	10/10
MDMA	500	0/10
	750	2/10
	1000	10/10
	1250	10/10
Methadone	150	1/10
	225	3/10
	300	10/10
	375	10/10
Methamphetamines	500	0/10
	750	3/10
	1000	10/10
	1250	10/10
Opiates 300 ng/mL	150	0/10
	225	2/10
	300	10/10
	375	10/10
Opiates 2000 ng/mL	1000	0/10
	1250	3/10
	2000	10/10
	2500	10/10
Oxycodone	50	0/10
	75	3/10
	100	10/10
	125	10/10
Phencyclidine	13	0/10
	19	3/10
	25	10/10
	37	10/10
Propoxyphene	150	0/10
	225	3/10
	300	10/10
	375	10/10
THC/Cannabinoids	25	0/10
	38	3/10
	50	10/10
	75	10/10
Tricyclic Antidepressants	500	0/10
	750	2/10
	1000	10/10
	1250	10/10

ACCURACY

Clinical Samples of known GC/MS results were tested on the **Rapid TOX** at levels specified in the tables below.

Drug Name	Rapid TOX Result	Negative Less than 50% of the cutoff concentration	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (Greater than 50% above the cutoff concentration)	Percent Agreement
Amphetamines	Positive	0	7	21	19	100%
	Negative	13	21	0	0	83%
Barbiturates	Positive	0	3	11	34	100%
	Negative	16	12	0	0	90%
Benzodiazepines	Positive	0	7	13	27	100%
	Negative	15	21	0	0	84%
Buprenorphine**	Positive	0	6	11	30	100%
	Negative	13	20	0	0	85%
Cocaine 150 ng/mL	Positive	0	7	11	33	100%
	Negative	17	15	0	0	82%
Cocaine 300 ng/mL	Positive	0	4	15	30	100%
	Negative	15	17	0	0	89%
MDMA	Positive	0	9	8	33	100%
	Negative	6	29	0	0	80%
Methadone	Positive	0	7	10	30	100%
	Negative	22	14	0	0	84%
Methamphetamines	Positive	0	8	14	26	100%
	Negative	10	26	0	0	82%
Opiates 300 ng/mL	Positive	0	1	10	50	100%
	Negative	11	8	0	0	95%
Opiates 2000 ng/mL	Positive	0	11	12	28	100%
	Negative	29	19	0	0	81%
Oxycodone	Positive	0	1	9	37	100%
	Negative	10	13	0	0	93%
Phencyclidine	Positive	0	4	7	33	100%
	Negative	8	14	0	0	85%
Propoxyphene	Positive	0	13	18	22	100%
	Negative	4	30	0	0	72%
THC/Cannabinoids	Positive	0	4	17	27	100%
	Negative	15	17	0	0	89%
Tricyclic Antidepressants***	Positive	0	5	15	25	100%
	Negative	15	17	0	0	86%

**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 **Rapid TOX**. 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 were 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	500	40	40 neg	>99%
	750	40	34 neg	>85%
	1000	40	40 pos	>99%
	1250	40	40 pos	>99%
Barbiturates	150	40	40 neg	>99%
	225	40	36 neg	>90%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
Benzodiazepines	150	40	40 neg	>99%
	225	40	34 neg	>85%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
Buprenorphine	6.3	40	39 neg	>97%
	9.4	40	33 neg	>82%
	12.5	40	40 pos	>99%
	15.6	40	40 pos	>99%
Cocaine 150 ng/mL	75	40	40 neg	>99%
	113	40	33 neg	>82%
	150	40	40 pos	>99%
	187	40	40 pos	>99%
Cocaine 300 ng/mL	150	40	40 neg	>99%
	225	40	34 neg	>85%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
MDMA	500	80	80 neg	>99%
	750	80	65 neg	>81%
	1000	80	80 pos	>99%
	1250	80	80 pos	>99%
Methadone	150	40	39 neg	>97%
	225	40	36 neg	>90%
	300	40	40 pos	>99%
	375	40	40 neg	>99%
Methamphetamines	500	40	40 neg	>99%
	750	40	36 neg	>90%
	1000	40	40 pos	>99%
	1250	40	40 pos	>99%
Opiates 300 ng/mL	150	40	40 neg	>99%
	225	40	32 neg	>80%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
Opiates 2000 ng/mL	1000	40	40 neg	>99%
	1250	40	31 neg	>77%
	2000	40	40 pos	>99%
	2500	40	40 pos	>99%
Oxycodone	50	80	72 neg	>90%
	75	80	65 pos	>81%
	100	80	80 pos	>99%
	125	80	80 pos	>99%
Phencyclidine	13	40	40 neg	>99%
	19	40	35 neg	>87%
	25	40	40 pos	>99%
	37	40	40 pos	>99%
Propoxyphene	150	40	40 neg	>99%
	225	40	34 neg	>85%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
THC/Cannabinoids	25	40	40 neg	>99%
	38	40	32 neg	>80%
	50	40	40 pos	>99%
	75	40	40 pos	>99%
Tricyclic Antidepressants	500	40	40 neg	>99%
	750	40	34 neg	>85%
	1000	40	40 pos	>99%
	1250	40	40 pos	>99%

CROSS REACTIVITY

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

Acebutolol
Acetaldehyde
Acetaminophen *(4-Acetamidophenol; N-Acetyl-paminophenol)*
Acetazolamide
Acetone
3-(α-acetonylbenzyl)-4-hydroxycoumarin *(Warfarin)*
Acetophenetidin
Acetopromazine
N-Acetyl-L-cysteine
6-Acetylmorphine *(except OPI & OXY)*
N-Acetylprocainamide *(Acedainide)*
Acetylsalicylic Acid *(Aspirin; 2-Acetoxybenzoic Acid)*
Albumin, standard
Albuterol
Allobarbital *(5,5-Diallybarbituric Acid) (except BAR)*
Allopurinol *(4-Hydroxypyrazole (3,4-) Pyrimidine)*
Alpha-hydroxyriazolam*
Alprazolam *(except BZO)*
Alprenolol
Amantadine *(Adamantan-1-amine)*
Amcinonide
(+) Amethopterin *(4-Amino-10-methylfolic acid; Methotrexate; Methylaminopterin)*
Amikacin
Amiloride
p-Aminobenzoic Acid
7-Aminoclonazepam
7-Aminoflunitrazepam
DL-Aminoglutethimide
7-Aminonitrazepam
Amiodarone
Amitriptyline *(except TCA)*
Ammonium Chloride
Amobarbital *(amytal;5-Ethyl-5- Isoamyl barbituric Acid) (except BAR)*
Amoxetine
Amoxicillin
Amphotericin B
D-Amphetamine *(except AMP)*
DL-Amphetamine *(except AMP)*
L-Amphetamine *(except AMP)*
Ampicillin
D-Amygdalin
Aniline
Antipyrine *(Phenazone)*
Apomorphine
Aprobarbital *(except BAR)*
Aripiprazole
Ariprazole
(-) Arterenol *[(-)Norepinephrine]*
L-Ascorbic Acid
ASP-PHE-Methyl-Ester *(Aspartame)*
D-Aspartic Acid
DL-Aspartic Acid
L-Aspartic Acid
Astemizole
Atenolol
Atomoxetine
Atropine *(Tropinetropate)*
Atrovastin
Azathioprine
Baclofen
Barbital *(Barbitone;5,5-Diethylbarbituric acid; Veronal) (except BAR)*
Barbituric Acid *(2,4,6- Trihydroxypyrimidine; Malonylurea)*
Beclomethasone
Beclomethasone Dipropionate
Bendroflumethiazide
Benzidine *(4,4 Diaminobiphenyl)*
Benicar
Benzylic Acid β-diethylaminoethyl ester
Benzocaine *(Ethyl-p-Aminobenzoate)*
Benzoic Acid
Benzonatate
Benzoylecgonine *(except COC)*
Benzphetamine *(α-dimethylphenethylamine)*
Benzthiazide
Benztropine Methane sulfonate *(Benztropine Mesylate)*
Benzyl alcohol
Benzylamine
Benzylpiperazine
Berberine
Betamethasone
Bilirubin
Bisacodyl
Bromazepam *(except BZO)*
2-Bromo-α-ergocryptine *(Bromocriptine mesylate)*
(+) Brompheniramine *(Dexbrompheniramine)*
(+/-) Brompheniramine
Bumetanide
Bupivacaine
Buprenorphine *(except BUP)*
Bupropion HCL
Buspirone
Butabarbital *(except BAR)*
Butalbital *(except BAR)*
Butethal *(except BAR)*
Butacaine
2-ButynoicAcid Ethyl Ester *(Ethyl-2-Butynoate)*
Butyrophenone
Caffeine *(1,3,7-Trimethylxanthine)*
(+/-) Camphor
Cannabidiol
Cannabinol *(except THC)*
Canrenoic Acid
Captopril
Carbamazepine
Carbamyl-β-methylcholine-chloride *(Bethanechol Chloride)*
Carboplatin
(s)-(-)-Carbidopa
Carisoprodol
Carvedilol
Cefaclor
Cefadroxil
Cefotaxime
Cefoxitin
Ceftriaxone
Cefuroxime
Cephalexin
Cephaloridine
Cephradine *(Cefradine)*
Cetirizine
α-Chloralose
Chloramphenicol *(Chloromycetin)*
Chlorcyclizine
Chlordiazepoxide *(except BZO)*
2-(p-Chlorophenoxy)-2-Methylpropionic Acid Ethyl Ester *(Clofibrate)*
Chloroquine
Chlorothiazide
Chlorotrianisene
(+)Chlorpheniramine
(+/-)Chlorpheniramine
Chlorpromazine
Chlorpropamide
Chlorprothixene
Chlorthalidone
Chlorzoxazone *(5-Chloro-2-Hydroxybenzoxazole)*
Cholesterol
Cimetidine
Cinchonidine
Cinoxacin
Ciprofloxacin
Citalopram*
Citalopram Hydrobromide*
Clarithromycin
Clemastine
Clenbuterol
Clindamycin
Clindamycin Phosphate
Clobazam *(except BZO)*
Clobetasone Butyrate
Clonazepam *(except BZO)*
Clonidine
Clorazepate(except BZO)
Clorazepate Dipotassium
Cloxacillin
Clozapine
Coca ethylene *(except COC)*
Cocaine *(Ecgonine Methyl Ester Benzoate) (except COC)*
Codeine *(Desferrioxamine Mesylate) (except BUP, OPI & OXY)*
Colchicine
Cortisone
β-Cortol
Creatinine
Cromolyn *(Cromoglycic Acid)*
Cyclobenzaprine *(except TCA)*
Clomipramine *(except TCA)*
Cyclophosphamide
Cyclosporin A
Cyproheptadine *(except TCA)*
Dantrolene
Deferoxamine Mesylate
Deoxyepinephrine
R-(-)-Deprenyl *(Selegiline)*
Desipramine *(except TCA)*
N-Desmethylclozapine *(Normethylclozapine)*
Desmethyldiazepam *(except BZO)*
Desoximetasone
Dexamethasone
Dexbrompheniramine
Dextromethorphan
4,4'-Diaminophenyl Sulfone *(Dapsone*
Diazepam *(except BZO)*
Diazoxide
Dichloromethane *(Methylene Chloride)*
Dichlorphenamide
Diclofenac
Dicyclomine
Dieldrin
Diethyldithiocarbamic Acid
N,N-Diethylnicotinamide *(Niacin Diethylamide; Nikethamide)*
Diflorasone Diacetate
Diflucortolone pivalate
Diflunisal
Digitoxin
Digoxin *(1,2 β-Hydroxydigitoxin)*
DL-3-4 Dihydroxymandelic Acid
DL-3-4 Dihydroxyphenyl Glycol
3,4 Dihydroxyphenylacetic Acid
(2,3-Dihydroxypropyl) Theophylline *(Dyphylline)*
Diltiazem
Diltiazem-cardzem
Dimenhydrinate

(Continued from previous page)
Dimercaprol (2,3-Dimercaptopropanol)
4-Dimethylaminoantipyrine *(Aminopyrine)*
1,1-Dimethylbiguanide *(Metformin)*
Dimethyl isosorbide
Dimethyl Sulfoxide *(DMSO)*
1,3-Dimethyluric Acid
1,7-Dimethylxanthine
Diphenhydramine *(except MTD)*
5,5-Diphenylhydantoin *(Phenytoin) (except BAR)*
Dipyridamole
Dipyrone
Disopyramide *(except MTD)*
Divalproex
Dobutamine
Doxepin *(except TCA)*
Doxycycline
Doxylamine
Droperidol
Ecgonine
Ecgonine Methyl Ester
Efavirenz
Emetine
Enalapril
(-)-ψEphedrine
(+)-ψ-Ephedrine
(+)Ephedrine
(+/-)Ephedrine
(-)Epinephrine
(+/-)Epinephrine
Erythromycin
Escitalopram
Eserine *(Physostigmine) (except OPI)*
Estazolam *(except BZO)*
ß-Estradiol
Estriol
Estrone
Estrone-β-D-Glucuronide
Estrone-3-Sulfate
Ethacrynic Acid
Ethambutol
Ethamivan *(N,N-Diethylvanillamide)*
Ethanol, Standard
Ethopropazine
Ethosuxuximide *(2-Ethyl-2-Methylsuccinimide)*
2-Ethyl –2-Phenylmalonamide
Ethylene Glycol
Ethylenediaminetetraacetic Acid *(EDTA)*
2-Ethylidine-1,5-Dimethyl-3,3-diphenylpyrolidine
Ethylmorphine* *(except OPI & OXY)*
17-α-Ethynylestradiol
Etodolac
Etoposide
Ezetimbe
Famotidine
Felodipine
Fenfluramine
Fenoprofen *[(+/-)-2-(3-Phenoxyphenyl) Propionic Acid]*
Fentanyl*
Ferrous Sulfate
Fexophenadine
Fluoxetine
Flurbiprofen
Flufenamic Acid
Flunisolide
Flunitrazepam *(except BZO)*
Fluphenazine
Flurandrenolide
Flurazepam *(except BZO)*
Flurbiprofen
Formaldehyde
Furosemide
Gabapentin
Gemfibrozil
Gentamicin Sulfate
Gentisic Acid
Glucose
(D)-(+)-Glucose *(Dextrose)*
Glibenclamide
Griseofulvin
Guaiacol Glyceryl Ether
Guaifenesin
Guanethidine
Halazepam
Halcinonide
Haloperidol
Hemoglobin
Heroin *(Diacetylmorphine)* (except OPI)*
Hexachlorocyclohexane
Hexachlorophene
Hexobarbital
Hippuric Acid
Histamine *[2 (4-Imidazoyl) Ethylamine]*
DL-Homatropine
Hydralazine *(1-Hydrazinophthalazine)*
(1S,9R)- β-Hydrastine
Hydrochlorothiazide
Hydrocodone *(except BUP,OPI& OXY)*
Hydrocortisone
Hydroflumethiazide
Hydromorphone *(except OPI & OXY)*
Hydroxocobalamin
O-Hydroxyhippuric Acid
5-Hydroxyindole-3-Acetic Acid
5-Hydroxy-2-indole-2-Carboxylic Acid
4-Hydroxy-3-Methoxyphenylacetic Acid *(Homovanillic Acid)*
4-Hydroxy Phencyclidine *(except PCP)*
11-Hydroxy-∆9-Tetrahydrocannabinol* *(except THC)*
5-Hydroxytryptamine *(Serotonin)*
3-Hydroxytyramine
Hydroxyzine *(Atarax)*
L-Hyoscyamine
Ibuprofen
Irbesartan
Imidazole-4-Acetic acid
Imipramine *(except TCA)*
Indapamide
Indole-3-Acetic acid
Indole-3-Butyric Acid
DL-Indole-3-Lactic Acid
Indomethacin
Interferon
Ipratropium Bromide
Iproniazid
Isonicotinic Acid *(Pyridine-4-Carboxylic Acid)*
Isonicotinic Acid Hydrazide
Isopropamide *(except MTD)*
(+)Isoproterenol
(-)Isoproterenol
(+/-)Isoproterenol
Isoxsuprine
Kanamycin
Ketamine
Ketoprofen
Kynurenic Acid
Labetalol
Lamotrigine
Lanoprazole
Lansoprazole
Levorphanol
Levothyroxine
Lidocaine
Linoleic Acid-Conjugated (CLA), Gamma, Alpha; Eicosaphentaoic,docahexaenoic acid; omega 369
Lisinopril
Lithium Carbonate
Loperamide
Loratadine
(+/-)Lorazepam *(except BZO)*
Lormetazepam *(except BZO)*
Lysergic Acid Diethylamide *(LSD) (except BUP)*
Mebendazole
Meclizine
Meclofenamic Acid
Medazepam
Mefenamic Acid
Melanin
Meloxicam
Melphalan
(-)Menthol
Meperidine
Mephenesin
Mephentermine
Meprobamate
6-Mercaptopurine
Mersalyl Acid
Mescaline *(3,4,5-Trimethoxyphenyethylamine)*
DL-Metanephrine
Metaproterenol
Metaraminol *[(-)-m-Hydroxyphenylpropanolamine]*
(+/-) Methadone *(except MTD)*
(+) Methamphetamine *(Methylamphetamine; d-Desoxyephedrine) (except MDMA & MET)*
(+/-) Methamphetamine *(except MDMA & MET)*
Methanol, Absolute
Methaqualone
Methazolamide
Methotrimeprazine
Methoxamine
Methoxamine
(S)-6-Methoxy-α-Methyl-2-Napthalene Acetic Acid *(Naproxen)*
Methoxyphenamine
5-Methoxytryptamine
3-Methoxytyramine
2-Methyl-3-(3,4-dihydroxyphenyl)-DL-Alanine
2-Methyl-3-(3,4-dihydroxypheyl)-L-Alanine
3,3'-Methylene-bis-(4-Hydroxycoumarin) *(Dicumarol)*
Methylene Blue
(+/-) 3,4-Methylenedioxyamphetamine *(MDA) (except AMP)*
(+/-) 3,4-Methylenedioxymethamphetamine *(MDMA) (except MET & MDMA)*
(+/-) 3,4-methylenedioxy-n-ethylamphetamine *(MDEA) (except MET & MDMA)*
1-Methylhistamine
6 α-Methyl-17 α-Hydroxyprogesterone *(Medroxyprogesterone)*
6 α-Methylprednisolone *(Medrol)*
Methylphenidate *(Ritalin)*
Methyl Salicylate
Methyl Viologen *(Gramoxone;Paraquat Dichloride)*
Meticrane
Metoclopramide *(except BUP & COC)*
(+/-)Metoprolol
Metronidazole
Mexiletine *(except AMP)*
Mianserin
Midazolam
Milrinone
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
Nialamide
Nicotic Acid *(Niacin)*
Nifedipine
Nitrazepam *(except BZO)*
Nitrofurantoin
Nomifensine
11-Nor-∆8-Tetrahydrocannabinol-9-Carboxylic Acid* *(except THC)*
11-Nor-∆9-Tetrahydrocannabinol-9-Carboxylic Acid* *except THC)*
11-Nor-∆9-THC-9-Carboxylic Acid Glucuronide* (*except THC)*
Norclomipramine *(except TCA)*
NorcocaineNorcodeine *(except OPI)*
Nordoxepin *(except TCA)*
Nordiazepam *(except BZO)*
Norethindrone
Norfloxacin
DL-Normetanephrine
Normorphine
d-Norpopoxyphene *(except PPX)*
Nortriptyline *(except TCA)*
Noscapine
Nylidrin
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
Oxyprenolol
Oxypurinol
Paclitaxel
Pancuronium Bromide
Pantoprazole
Papaverine
Pargyline
Paroxetine HCL
Phenazopyridine
Phencyclidine Morpholine *(except PCP)*
Penicillin G *(Benzylpenicillin)*
Pentachlorophenol
Pentobarbital *(Nembutal) (except BAR)*
Pentoxifylline *(Trental)*
Pentylenetetrazole
Phencyclidine *(except PCP)*
Phendimetrazine
p-Phenylenediamine
Phenelzine
Phenformin
Pheniramine
Phenobarbital *(except BAR)*
Phenol
Phenolphthalein
Phenothiazine *(Thiodiphenylamine)*
Phenoxymethyl 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
Procyclidine *(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)*
∆8-Tetrahydrocannabinol *(except THC)*
∆9-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-Methly-2-Isopropylphenol)*
Timolol
Tobramycin
Tolazamide
Tolbutamide
Tolmetin
Toluene
cis-Tramadol
Trans-2-Phenylcyclopropylamine *(Tranylcypromine-mine)*
Tramadol HCl
Trazodone
Triamcinolone *(Fluoxiprednisolone)*
Triamterene
Triazolam* *(except BZO)*
Trichlormethiazide
Trichloroacetic acid
2,2,2 Trichloroethanol
Trifluoperazine
Triflupromazine
DL-Trihexyphenidyl
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 Actions
No Control Line(s) appears	Insufficient quantity of specimen drops applied to sample well when using the pipette procedure. Insufficient specimen volume or shortened dipping time when using the dip procedure. Specimen was dropped with pipette into the test channel instead of the sample well. Specimen volume exceeds the dip line on the device when using the dip procedure.	Follow product instructions and quick reference guide for correct specimen collection and test procedure.
No flow or the sample does not completely flow up the strip	Insufficient quantity of specimen drops applied to sample well when using the pipette procedure. Insufficient specimen volume or shortened dipping time when using the dip procedure.	Follow product instructions and quick reference guide for correct specimen collection and procedure. When using the pipette procedure ensure full drops are counted. When using the dip procedure allow sufficient dipping time.
Washed out results or smeared lines	Flooding the strips with too much specimen: Excessive drops are applied to sample well when using the pipette procedure. Specimen volume exceeds the dip line on the device when using the dip procedure.	Follow product instructions and quick reference guide for correct specimen collection and test procedure. When using the pipette procedure ensure full drops are counted. When using the dip procedure ensure specimen does not reach above dip line.
Color blindness (For analyte result interpretation)	Result and control line(s) are colored.	Color is insignificant, as a line does not require color differentiation to interpret the test results. Once the control line(s) have formed the results are read by the appearance or lack of a line.
Improper placement of test device	When conducting the pipette procedure the device is not laying on a flat surface.	Follow product instructions and quick reference guide for correct test procedure. Testing has demonstrated that laying the device at an improper angle has minimal effects on the final results.
Questionable results	Physical degradation of device, improper storage, opening package too long prior to testing, read results too late.	Follow product instructions for correct product storage, handling and result interpretation.
Questionable results/ excessive invalid results	Specimen adulteration	Specimen validity testing can be conducted to ensure specimen integrity
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.

If the test does not perform as expected, or if repeated invalid results are obtained, call ABMC Technical Service at 1.800.227.1244 / Outside the U.S.: +1.518.758.8158 extension 3.

EXPECTED WAIVER PERFORMANCE BY UNTRAINED USERS

A total of 75 lay-users having no laboratory experience were recruited to perform the testing. Each participant was provided thirteen (13) artificial urine specimens as well as, nine (9) Rapid TOX ten (10) test devices, four (4) Rapid TOX three (3) test devices, four (4) each of BUP, TCA, OXY tests and study-specific instructions and forms. Based on the set of thirteen (13) samples, each drug had twenty (20) measurements on weak negative (80% of cutoff), weak positive (120% of cutoff) where the professional obtained the correct result 95/99% of the time, strong negative (no drug present) and strong positive (150% of cutoff) for each site. Participants performed testing on both specimen application methods (dip and drop), using one method at a time. Lay-users were asked to read the whole instruction and perform the tests.
The data demonstrated the following:

The percent of correct results of the sixteen (16) drugs for strong negative (0% of cutoff) were all 100% (95% CI: 95% to 100%) for both methods.
The percent of correct results for strong positive (150% of cutoff) for the Dip method from 98.7% (95% CI: 93% to 99.9%) (MTD) to 100% (95% CI: 95% to 100%) all other drugs and for the Drop method from 98.7% (95% CI: 93% to 99.9%) (BAR and BZO) to 100% (95% CI: 95% to 100%) all other drugs.

The percent correct results for the weak negative (80% of cutoff) for the Dip method were from 93.3% (95% CI: 85.1% to 97.8%) (AMP, BAR, BZO, COC-150, COC-300, MTD, OPI-300, OPI-2000, PCP, PPX and THC) to 94.7% (95% CI: 86.9% to 98.5%) (BUP, MDMA, MET, OXY and TCA) and for the Drop method were from 93.3% (95% CI: 85.1% to 97.8%) (AMP, BZO, BUP, COC-150, COC-300, MTD, MET, OPI-2000, OXY, PCP, PPX, TCA and THC) to 94.7% (95% CI: 86.9% to 98.5%), (BAR, MDMA, OPI-300).

The percent correct results for the weak positive (120% of cutoff) for the Dip method were from 93.3% (95% CI: 85.1% to 97.8%) (MDMA, PCP, PPX and TCA) to 96% (95% CI: 88.8% to 99.2%) (AMP, BZO and BUP) and for the Drop method were from 93.3% (95% CI: 85.1% to 97.8%) (BUP, MDMA, MET, OPI-300 and PCP) to 94.7% (95% CI: 86.9% to 98.5%), (AMP, BAR, BZO, COC-150, COC-300, MTD, OPI-2000, OXY, PPX, TCA and THC).

The data demonstrated that there was no statistically significant difference in the percent of correct results for both methods and among the three sites for strong negative, weak negative, weak positive and strong positive concentrations for sixteen (16) drugs.

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