



DRUGS OF ABUSE

PANEL PLUS TCA

■ INTENDED USE

The Triage® Drugs of Abuse Panel plus Tricyclic Antidepressants is an immunoassay used for the qualitative determination of the presence of the major metabolites of drugs of abuse, (Phencyclidine, Benzodiazepines, Cocaine Metabolite, Amphetamines, THC, Opiates, Barbiturates), and Tricyclic Antidepressants in urine.

This test provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The tricyclic test is a qualitative screening test. A negative result does not eliminate the possibility of the presence of tricyclic antidepressants in the urine specimen at concentrations lower than 1000 ng/mL. Should confirmation of the test result for the parent compound or the metabolites be desired, an alternative method that is capable of identification and quantification should be used, eg. HPLC, GC or GC/MS. A positive screening result may be due to the sum of the reactivity of the parent tricyclic antidepressant and the various metabolites of the respective compound.

■ SUMMARY AND EXPLANATION OF THE TEST

Drug abuse in the United States continues to be an increasingly significant social and economic problem. Opiates, cocaine, THC, amphetamines, and phencyclidine are recognized as the most frequently abused illicit drugs by the Substance Abuse and Mental Health Services Administration (SAMHSA). Tranquilizers, anti-depressants, barbiturates and opiate compounds are among a group of prescription drugs that also are

frequently abused. The opiate class of compounds that may produce a positive result, include illicit opiates as well as codeine containing cough medications and antidiarrheal preparations.

These drugs, in addition to tricyclic antidepressants, are also associated with drug overdose and presentation in the emergency department. Additionally, accidental or intentional self-poisoning using tricyclic antidepressants is a condition that must be addressed by physicians. Serious toxicities have been estimated to begin at serum concentrations exceeding 1000 ng/mL⁽¹⁾, although serum concentrations as low as 329 ng/mL have been associated with toxicity⁽²⁾.

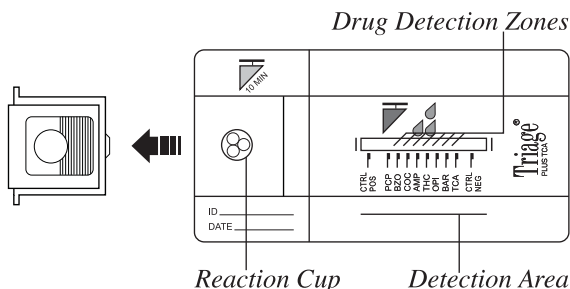
Numerous methods have been developed for the detection of tricyclic antidepressants in serum or plasma. The length of the procedures is not conducive to providing the physician with a timely result as to whether the patient has ingested tricyclic antidepressants. According to the Annual Report of the American Association of Poison Control Centers, tricyclic antidepressants account for a significant number of patients that are admitted to the emergency room and intensive care units and mortality rates are higher as compared to ingestion of other drugs.

Urine based screening tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most accepted method for screening urine for the presence of drugs. Visually read immunoassays eliminate the need for instrumentation.

The Triage® Drugs of Abuse Panel plus Tricyclic Antidepressants uses 8 discrete competitive immunoassay procedures for the simultaneous detection and identification of the major urinary metabolites of 8 different, single drug classes. The use of monoclonal antibodies that are specific for the metabolites of the 8 drug classes ensures a high degree of sensitivity and specificity.

■ PRINCIPLES OF PROCEDURE

TRIAGE® PLUS TRICYCLIC ANTIDEPRESSANTS TEST DEVICE



The Triage® Drugs of Abuse Panel plus Tricyclic Antidepressants utilizes a patented immunochemistry, ASCEND™ MULTIMMUNOASSAY® (AMIA™). Each AMIA™ assay is a competitive binding immunoassay in which a chemically labeled drug (drug conjugate) competes with drug which may be present in the urine for antibody binding sites. After a brief incubation, the reaction mixture is transferred to the membrane in the Detection Area. Free drug conjugate that is displaced from antibody binding sites by drug in the urine, binds to a zone of monoclonal antibody that is immobilized on the membrane. The membrane is washed to remove the unbound conjugate and clear the background. Test results are visually read.

A positive specimen produces a distinct colored bar in the Drug Detection Zone adjacent to the drug name. A negative specimen does not produce a colored bar.

■ REAGENTS

Triage® Drugs of Abuse Panel plus Tricyclic Antidepressants kit contains all the reagents necessary for the simultaneous detection and identification of the major urinary metabolites of 8 different, single drug classes.

TEST DEVICE

- Mouse monoclonal antibodies against phencyclidine, benzodiazepine metabolites, benzoylecgonine, amphetamines, THC (11-nor- Δ^9 -THC-9-carboxylic acid), morphine, barbiturates and tricyclic antidepressants immobilized on a membrane
- Mouse monoclonal antibodies against phencyclidine, benzodiazepine metabolites, benzoylecgonine, amphetamines, THC (11-nor- Δ^9 -THC-9-carboxylic acid), morphine, barbiturates and tricyclic antidepressants lyophilized in a protein matrix containing <0.01% sodium azide
- Drugs and drug derivatives conjugated to colloidal gold, lyophilized in a protein matrix containing <0.01% sodium azide
- Lyophilized buffer

WASH SOLUTION

- Buffered solution containing preservative

■ WARNINGS AND PRECAUTIONS

- FOR IN VITRO DIAGNOSTIC USE.
- For professional use only.
- Urine specimens may be potentially infectious, proper handling and disposal methods should be established.
- Reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. Upon disposal of these reagents, always dilute the material with a large volume of water to prevent azide build up in the plumbing.

- Do NOT interchange, mix or combine reagents from kits with different lot numbers.
- This method has been tested using urine only. Other fluids have not been evaluated.
- The performance of this product has not been established when stored outside the recommended conditions.

■ STORAGE AND HANDLING REQUIREMENTS

The reagents contained in the Triage® Drugs of Abuse Panel plus Tricyclic Antidepressants are to be stored at room temperature (15°-25°C) and are stable until the date stamped on the box. The reagents in the foil pouch are moisture sensitive. Do not remove device from pouch until ready to use.

■ SAMPLE COLLECTION AND PREPARATION

Freshly voided urine specimens should be collected in a clean, previously unused glass or plastic container. If the specimen is not tested immediately, it should be refrigerated at 2°-8°C for a maximum of 2 days. If longer storage is required, specimens may be stored frozen (-20°C or colder). Specimens that were refrigerated must reach room temperature (15°-25°C) prior to testing. Specimens that were frozen must be thawed and mixed thoroughly prior to testing. Specimens containing a large amount of particulate matter may be clarified by centrifuging or allowing to settle before testing.

■ MATERIALS PROVIDED

Biosite® Triage® Drugs of Abuse Panel plus Tricyclic Antidepressants

Catalog No.	92010	92000
<u>Kit contains:</u>	<u>10 Test Kit</u>	<u>25 Test Kit</u>
Test Devices	10 each	25 each
Wash Solution	1 x 8 mL	1 x 8 mL
Pipet	1 each	1 each
Pipet Tips	50 each	50 each

■ MATERIALS REQUIRED BUT NOT PROVIDED

Timer or stopwatch

■ PIPETTING PROCEDURE

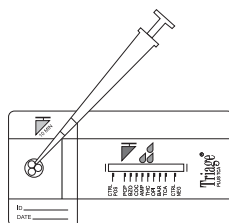
INSTRUCTIONS FOR USING THE BIOSITE PIPET

1. Before each use, attach a clean, disposable tip to the pipet.
2. Depress the plunger until it stops.
3. Holding the pipet vertically, place the end of the tip into the sample.
4. Release the plunger, allowing the tip to fill with sample. Withdraw the tip from the sample when the plunger is fully released.
5. To dispense the sample, gently depress the plunger until it stops.
6. Withdraw the tip and fully release the plunger.
7. Discard the pipet tip immediately after each use.

■ TEST PROCEDURE

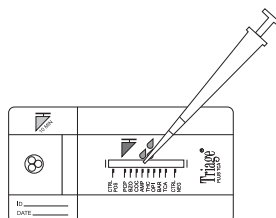
STEP 1 ADD SAMPLE

Check the reaction cup for one purple, one white and one yellow bead. Slide the cap from the reaction cup. Using the pipet provided and a clean pipet tip, pipet the urine sample (140 μ l) into the reaction cup and incubate 10 minutes at room temperature.



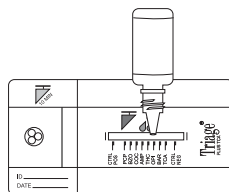
STEP 2 TRANSFER SOLUTION

Using the pipet provided and a clean pipet tip, transfer the reaction mixture from the cup to the point in the Detection Area indicated by the pipet graphic. **Allow the contents to soak through completely.**



STEP 3 WASH AND READ

As soon as the mixture has soaked through, add 3 drops of Wash Solution onto the center of the Detection Area. **Allow the Wash Solution to soak through completely.** Read the *CTRL NEG* Zone, the *CTRL POS* Zone and the Drug Detection Zones. Results may be read anytime within 5 minutes of completion.



■ RESULTS

INTERPRETATION OF RESULTS

The Triage® Drugs of Abuse Panel plus Tricyclic Antidepressants is a qualitative immunoassay. The exact concentration of drug and/or drug metabolites present in the urine specimen cannot be estimated.

The assay thresholds are minimally targeted to yield a positive result with 95% confidence at 120% of the following cutoff concentrations.

The following cut-off concentrations are established for the eight drugs:

PCP	Phencyclidine	25	ng/mL*
BZO	Benzodiazepines	300	ng/mL
COC	Cocaine (Benzoylecgonine)	300	ng/mL*
AMP	Amphetamines	1000	ng/mL*
THC	THC (11-nor- Δ^9 -THC-9-carboxylic acid)	50	ng/mL*
OPI	Opiates (Morphine)	300	ng/mL
BAR	Barbiturates	300	ng/mL
TCA	Tricyclic Antidepressants	1000	ng/mL

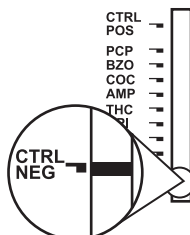
* Recommended Screening cut-off concentrations by the Substance Abuse and Mental Health Services Administration.

See section on PERFORMANCE CHARACTERISTICS for expected accuracy and specificity.

STEP 1 READ THE *CTRL NEG* ZONE

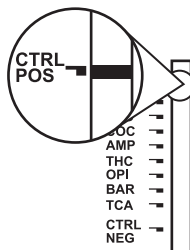
If a color bar appears in the *CTRL NEG* Zone, discard the device and retest the sample using a new device.

If the same results are observed upon repeat analysis, another specimen should be obtained and tested. If the same results are observed upon analysis of the new specimen, contact Biosite Technical Services.

**STEP 2** READ THE *CTRL POS* ZONE

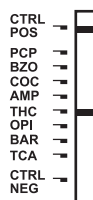
Results are valid if a color bar appears in the *CTRL POS* Zone. If no color bar appears in the *CTRL POS* Zone, discard the device and retest the sample using a new device.

If the same results are observed upon repeat analysis, another specimen should be obtained and tested. If the same results are observed upon analysis of the new specimen, contact Biosite Technical Services.

**STEP 3** READ THE DRUG DETECTION ZONES**POSITIVE RESULTS**

A sample is positive if a distinct colored bar appears in any of the Drug Detection Zones adjacent to the drug names. A bar of any discernible intensity is interpreted as positive. The device should remain on a flat surface.

If a color bar appears, the sample is presumed to contain drug at a level equal to or greater than the cut-off concentration for that drug. **The color intensity of the positive internal control zone is not to be used as a reference color bar.**



NEGATIVE RESULTS

A sample is negative if no color bar appears in any of the Drug Detection Zones adjacent to the drug names.



QUALITY CONTROL AND ACCEPTABILITY OF RESULTS

The Control Negative (CTRL NEG) Zone ensures that the antibody reagent bead is present and reactive. A color bar **should not** appear in this zone.

The Control Positive (CTRL POS) Zone ensures that the conjugate reagent bead and membrane are present and reactive. A color bar **should** appear in this zone.

A Positive Control above the specified threshold for each drug should produce a color bar on the membrane adjacent to the name of the specified drug designated on the Test Device.

Negative Controls should not produce a color bar adjacent to the names of any of the drugs at the Detection Zone.

If a positive result is NOT observed adjacent to the *CTRL POS* zone and/or a negative result is NOT observed adjacent to the *CTRL NEG* zone the test should be discarded. The test should be repeated using another device. If the same results are observed upon repeat analysis another specimen should be obtained and retested.

The use of a positive control urine, approximately 25% greater than the cut-off concentration, is recommended to initially test each shipment of product, every 30 days thereafter, and if the product is stored under conditions outside the manufacturer's recommendations.

The Positive (*CTRL POS*) and Negative (*CTRL NEG*) controls contained in this product satisfy the requirements of testing a positive control and a negative control on a daily basis.

■ LIMITATIONS OF THE PROCEDURE

There is the possibility that factors such as technical or procedural errors, as well as additional substances in the urine sample that are not listed below, may interfere with the test and cause erroneous results.

Adulterants, such as bleach, added to urine specimens may produce erroneous results regardless of the method of analysis. If adulteration is suspected, obtain an additional specimen and retest.

Addition of a strong oxidizing agent, eg. bleach (hypochlorite), to a urine specimen can oxidize the analyte, reducing the concentration of analyte that can be detected regardless of the method of analysis.

A positive result indicates the presence of the drug or drug metabolites and does not indicate the level of intoxication, route of administration or urinary concentration. **The serum concentration of tricyclic antidepressants cannot be determined using this test. If a quantitative result for total tricyclic antidepressants or a specific tricyclic antidepressant is desired, a confirmatory method such as HPLC or GC/MS should be performed. Similarly, if a negative result is obtained and ingestion of tricyclic antidepressants is suspected, a serum sample should be obtained and tested using an appropriate method.**

A negative result does not eliminate the possibility of the presence of tricyclic antidepressants in the urine specimen at concentrations lower than 1000 ng/mL.

Refer to the specific performance characteristics for information regarding the test specificity, a list of drugs and drug metabolites that produce a positive result in this test, and other potentially interfering substances.

■ PERFORMANCE CHARACTERISTICS

Accuracy

The performance of the Triage® Drugs of Abuse Panel plus Tricyclic Antidepressants was evaluated on 787 urine specimens and compared to the commercially available tests using the stated cut-off concentrations.

Positive specimens (687) that were previously evaluated for the presence of each of the 8 specific drugs were re-evaluated using the Triage® Test Device, thin layer chromatography and Gas Chromatography/Mass Spectroscopy. An additional 100 specimens were obtained from persons who were not taking prescription medication, over the counter medication or other drugs. The results are presented below.

	<u>Triage® Result</u>	<u>Triage® v. GC/MS</u>	<u>Triage® v. Syva®EMIT®</u>	<u>Triage® v. Toxilab® ††</u>
		Pos/Neg	Pos/Neg	Pos/Neg
PCP	>25 ng/mL	52/0	52/0	*
	<25 ng/mL	0/192	0/100	*
Benzodiazepines	>300 ng/mL	74/5	67/12	*
	<300 ng/mL	1/207	7/109	*
Cocaine	>300 ng/mL	50/0	50/0	*
	<300 ng/mL	0/193	1/100	*
Amphetamines	>1000 ng/mL	63/8	64/2	*
	<1000 ng/mL	0/194	2/111	*
THC †	>50 ng/mL	67/0	68/1	*
	<50 ng/mL	0/193	0/101	*
Opiates	>300 ng/mL	55/0	55/0	*
	<300 ng/mL	0/198	0/100	*

Barbiturates	>300 ng/mL	58/0	57/1	*
	<300 ng/mL	0/192	0/100	*
Tricyclic Antidepressants	>1000 ng/mL	**	**	224/0
	<1000 ng/mL	**	**	1/211

† GC/MS confirmation is done at 15 ng/mL of 11-nor-9carboxy- Δ^9 -THC

†† Toxilab TLC sensitivity is 500 ng/mL

* Not evaluated using TLC

** Not evaluated using GC/MS or Syva®

SPECIFICITY

The specificity of each of the eight drug classes in the Triage® Drugs of Abuse Panel plus Tricyclic Antidepressants test has been extensively tested with over 700 drugs and closely related compounds. A portion of the compounds representative of each class are listed below and are expressed as the threshold concentration that produces a positive result⁸.

PCP	ng/mL
PCE	500
PCP	25
PCPy	50
TCM	5,000
TCP	25
TCPy	125

Benzodiazepines

Alprazolam	450
Alprazolam, α -OH	400
Alprazolam glucuronide, α -OH	400
Bromazepam	400
Clorazepate	5,000
Chlordiazepoxide	1,250
Clobazam	700
Clonazepam	350
Demoxepam	2,000
Diazepam	350
Estazolam	300
Flunitrazepam	350
Flurazepam	450
Halazepam	750
Hydroxyethyl flurazepam	350
Lorazepam	550
Lorazepam glucuronide	400
Nitrazepam	750
Nordiazepam	300
Nordiazepam glucuronide	300

	ng/mL
Oxazepam	700
Oxazepam glucuronide	800
Temazepam	550
Temazepam glucuronide	500
Triazolam	400
Triazolam, α -OH	700
Cocaine	
Benzoylcegonine	300
Cocaethylene	100,000
Ecgonine	15,000
Amphetamines	
d-Amphetamine	650
l-Amphetamine	40,000
MDA	1,200
MDEA	2,500
MDMA	2,000
d-Methamphetamine	1,000
l-Methamphetamine	30,000
Phenethylamine	750,000
THC	
11-nor-9 carboxy- Δ^9 -THC	50
Opiates	
Acetylmorphine, 6-	400
Codeine	300
Diacetylmorphine	400
Ethylmorphine	400
Hydrocodone	500
Hydromorphone	500
Meperidine	75,000
Morphine	300
Morphine 3- β glucuronide	490
Nalorphine	2,500
Oxycodone	20,000
Oxymorphone	40,000
Thebaine	2,000
Barbiturates	
Allobarbitol	300
Aminoglutethimide	10,000
Amobarbitol	300
Aprobarbitol	300
Barbitol	500
Butabarbitol	300
Butalbital	300
Cyclobarbitol	300
Cyclopentobarbitol	300
Pentobarbitol	300
Phenobarbitol	400
Secobarbitol	300
Talbutal	300

Tricyclic Antidepressants	ng/mL
Amitriptyline	1,000
Chlorpromazine*	50,000
Chlorprothixene*	12,500
Clomipramine	4,000
Cyclobenzaprine*	2,000
Desipramine	1,000
Doxepin	1,750
Imipramine	1,000
Maprotiline*	25,000
Nordoxepin	2,000
Nortriptyline	1,000
Perphenazine*	40,000
Phenothiazine*	60,000
Promazine*	10,000
Protriptyline	2,000
Thiothixene*	20,000
Trimipramine	3,500

* Structurally Related Compounds

The following compounds were found not to cross-react when tested at concentrations up to at least 100 $\mu\text{g/mL}$ (unless otherwise indicated in parenthesis)⁸.

Acebutolol	Acetaldehyde	Acetaminophen
Acetanilide	Acetazolamide	Acetohexamide
Acetone	Acetopromazine	Acetyl-L-cysteine, N-
Acetylmethadol	Acetylprocainamide, N-	Acetylsalicylic acid
Albumin	Albuterol	Aldrin
Allopurinol	Alprenolol	Amantadine
Amcinonide	Amikacin	Amiloride
Amineptine	Amino-benzoic acid, p-	Aminopyrine, l-
Amiodarone	Ammonium chloride	Amoxapine
Amoxicillin	Amphotericin	Ampicillin
Amygdalin	Aniline	Antipyrine
Apocodeine	Apomorphine	Ascorbic acid
Aspartame	Aspirin	Astemizole
Atenolol	Atropine	Azatadine
Azathioprine	Baclofen	Barbituric acid
Beclomethasone	Bemegride	Benactyzine
Bendroflumethiazide	Benzidine	Benzocaine
Benzoic acid	Benzonate	Benzphetamine
Benzthiazide	Benzyl alcohol	Benzylamine
Berberine	Betamethasone	Bilirubin (2.5)
Bisacodyl	Bromoergocryptine, 2- α -	Brompheniramine
Bufotenine	Bumetanide	Bupivacaine
Buprenorphine	Buspirone	Butenoic acid
Butorphanol	Butyric acid	Butyraldehyde
Butyrophenone	Caffeine	Camphor
Cannabidiol	Canrenoic Acid	Captopril

Carbamazepine	Carbamyl- β -methylcholine	Carbidopa
Carboplatin	Carbromal	Carisoprodo
Cathinone	Cefaclor	Cefadroxil
Cefotaxime	Cefoxitin	Ceftriaxone
Cefuroxime	Cephalexin	Cephaloridine
Cephadrine	Chloral hydrate	Chloralose, α -
Chloramphenicol	Chlorcyclizine	Chlordecone
Chlormezanone	Chloroquine	Chlorothiazide
Chlorotrianisene	Chlorpheniramine	Chlorpropamide
Chlorpyrifos	Chlorthalidone	Chlorzoxazone
Cholesterol	Cimetidine	Cinchonidine
Cinoxacin	Ciprofloxacin	Clemastine
Clenbuterol	Clindamycin	Clobetasone
Clofibrate	Clonidine	Cloxacillin
Clozapine	Colchicine	Cortisone
Cortol, β -	Cortolone, β -	Cotinine, 1-
Creatinine	Cromolyn	Cyclazocine
Cyclizine	Cyclophosphamide	Cyproheptadine
Dantrolene	Dapsone	Desferoxamine
Deoxyepinephrine	Deprenyl	Desmethylozapine
Desmethylsertraline	Desoximetasone	Despropionyl fentanyl (10)
Dexamethasone	Dextropropoxyphene	Dextromethorphan
Dextrorphan	Diazinon	Diazoxide
Dichloralphenazone	Dichloromethane	Dichlorophenamide
Diclofenac	Dicumaryl	Dicyclomine
Dieldrin	Diethylthiocarbamic acid	Diethylnicotinamide N,N
Diethylpropion	Diflorasone	Diflucortolone
Diflunisal	Digitoxin	Digoxin
Dihydroxymandelic acid,dl3,4-	Dihydroxyphenylacetic acid	Dimethoxy-4-bromoamphetamine
Dimethoxy-4-methylamphetamine	Dihydroxyphenylglycol,dl 3,4-	Diltiazem
Dimenhydrinate	Dimercaprol	Dimethylbiguanide, 1,1-
Dimethyl sulfoxide	Dimethyluric acid, 1,3-	Diphenhydramine
Diphenoxylate	Diphenylhydantoin, 5,5-	Dipyridamole
Dipyron	Diquat (10)	Disopyramide
Disulfiram	Dobutamine	Domperidone
Dopa, l-	Dopamine	Doxapram
Doxycycline	Doxylamine	Droperidol
Dyphylline	Ecgonidine methyl ester	Ecgonine methyl ester
EDDP	EDTA	EMDP
Emetine	Endrin	Enflurane
Ephedrine, (+/d)	Ephedrine, (-/l)	Epinephrine, l-
Ergotamine	Erythromycin, l-	Estradiol, β -
Estriol	Estrone	Estrone-3-glucuronide
Estrone-3-sulfate	Ethacrynic acid	Ethambutol
Ethamivan	Ethanol	Ethchlorvynol
Ethinyl Estradiol	Ethinamate	Ethopropazine
Ethosuximide	Ethotoin	Ethylene glycol
Ethyl p-aminobenzoate	Ethyl-2-phenylmalonamide, 2-	Etodolac
Etoposide	Famotidine	Fencamfamine
Fenfluramine (10)	Fenoprofen	Fenproporex
Fentanyl	Ferrous sulfate	Fluconazole
Flufenamic acid	Flumazenil	Flunisolide

Fluothane	Fluoxetine	Fluoxymesterone
Fluphenazine	Flurandrenolide	Flurbiprofen
Formaldehyde	Furosemide	Gemfibrozil
Gentamicin	Gentisic acid	Glucose
Glyburide	Glycopyrrolate	Griseofulvin
Guaiacol glyceryl ether	Guanethidine	Halcinonide
Haloperidol	Haloperidol metab. I	Haloperidol metab. II
Haloperidol metab. III	Hemoglobin	Hexachlorobenzene
Hexachlorophene	Hippuric acid	Histamine
Homatropine	Homovanillic acid	Hydralazine
Hydrastine	Hydrochlorothiazide	Hydrocortisone
Hydroflumethiazide	OH(5)indole-2-carboxylic acid	OH(5)indole-3-acetic acid
OH-3-methoxyphenylglycol,dl4-	Hydroxocobalamin	Hydroxynicotinic acid, 6-
Hydroxynorephedrine, p-	Hydroxyzine	Hyoscyamine
8-Hydroxybutyric Acid, γ -	Ibuprofen	Imidazole-4-acetic acid
Indapamide	Indole-3-lactic acid, dl-	Indole-3-acetic acid
Indole-3-butyric acid	Indomethacin	Insulin
Ipratropium	Iproniazid	Isoniazid
Isopropamide	Isopropanol	Isoproterenol, dl-
Isosorbide	Isoxsuprine	Kanamycin
Ketamine	Ketoconazole	Ketoprofen
Ketorolac tromethamine	Kynurenic acid	Labetalol
Lidocaine	Lindane	Lisinopril
Lithium carbonate	Loperamide	Loxapine
Lysergic acid diethylamide(2.5)	Malathion	Mebendazole
Meclizine	Meclofenamic acid	Medroxyprogesterone
Mefenamic acid	Melanin	Melphalan
Menthol	Mephenesin	Mephentermine
Mephenytoin	Mepivacaine	Meprobamate
Mercaptopurine, 6-	Mersalyl acid	Mescaline
Mesoridazine	Metanephrine	Metaproterenol
Metaraminol	Methadone, dl-	Methanol
Methaqualone	Methazolamide	Methcathinone
Methenamine	Methenolone	Methocarbamol
Methohexital	Methotrexate	Methotrimeprazine
Methoxamine	Methoxyamine	Methoxyflurane
Methoxyphenamine	Methoxytryptamine, 5-	Methoxytyramine, 3-
Methylene Blue	Methyl histamine, 1-	Methyl-l-dopa, α -
Methyl dopamine, 3-o-	Methylephedrine, N-(+)	Methylephedrine,N-(-)
Methylphenidate	Methylprednisolone, 6- α -	Methylpseudoephedrine(+)
Methylpseudoephedrine(-)	Methyl salicylate	Methyltestosterone, 17 α -
Methyprylon	Metricrane	Metoclopramide
Metolazone	Metoprolol, dl-	Metronidazole
Mianserin	Milrinone	Minaprine
Monoethylglycinexylidide	Nabumetone	Nadolol
Naficillin	Nalbuphine	Nalidixic acid
Nalmefene	Naloxone	Naltrexone
Naphazoline	Naphthol, α -	Naphthoxyacetic acid, 2-
Naproxen	Neomycin	Nialamide
Nicotinamide	Nicotine	Nicotinic acid
Nifedipine	Nitrofurantoin	Nitrophenol, p-
Nomifensine	Norcocaine	Norepinephrine, l-

Norethandrolone	Norethindrone	Norfentanyl (10)
Norflouxacin	Norfluoxetine	Normeperidine
Normetanephrine	Noroxymorphone	Norpropoxyphene
Norpseudoephedrine	Nortestosterone, 19-	Norverapamil
Noscapine	Nylidrin	Octopamine
Orotic acid	Orphenadrine	Oxalic acid
Oxandrolone	Oxazolam	Oxolinic acid
Oxprenolol	Oxybutynin	Oxymetazoline
Oxymetholone	Oxyphenbutazone	Oxypurinol
Oxytocin	Pancuronium	Papaverine
Paraldehyde	Paramethadione	Paraquat
Parathion	Paraxanthine	Pargyline
Paroxetine	PCA	PCC
Pemoline	Penicillamine	Penicillin G
Penicillin V	Pentachlorophenol	Pentazocine
Pentoxifylline	Pentylentetrazole	Phenacetin
Phendimetrazine	Phenformin	Pheniramine
Phenol	Phenolphthalein	Phenoxybenzamine
Phensuximide	Phentolamine	Phenylacetone
Phenylalanine, dl-	Phenylbutazone	Phenylenediamine, m-
Phenylenediamine, p-	Phenylephrine	Phenylpropanolamine
Phentoloxamine	Phthalic acid	Physostigmine
Picrotoxin	Pilocarpine	Pimozide
Pinacidil	Pindolol	Pipecolic acid, l-
Pipemidic acid	Piromidic acid	Piroxicam
Potassium chloride	Potassium iodide	Pralidoxime
Prazosin	Prednisolone	Pregnene -3 β -ol-20-one, 5-
Pregnanediol glucuronide	Prilocaine	Primaquine
Primidone	Proadifen	Probenecid
Procaine	Procyclidine	Promethazine
Propiomazine	Propionylpromazine	Propoxyphene
Propranolol, dl-	Propylbenzene	Pseudoephedrine
Pseudoephedrine, l-	Psilocybin	Psilocyn
Pyridium	Pyridoxine	Pyrilamine
Quinidine	Quinine	Quinolinic acid
Ranitidine	Rescinnamine	Reserpine
Retinoic Acid	Riboflavin (75)	Ritodrine
Salicylamide	Salicylic acid	Salicylic acid
Serotonin	Sertraline	Salicylic acid
Sodium Borate	Sodium chloride	Salicylic acid
Sodium Formate	Sorbital	Salicylic acid
Spirolactone	Stanozolol	Salicylic acid
Succinylcholine	Sulfadiazine	Salicylic acid
Sulfamethazine	Sulfamethoxazole	Salicylic acid
Sulfathiazole	Sulfisoxazole	Salicylic acid
Sulpiride	Suxibuzone	Salicylic acid
Tannic acid	Taxol	Salicylic acid
Terbutaline	Terfenadine	Salicylic acid
Tetrahydrocortisone	Tetrahydrozoline	Salicylic acid
Theophylline	Thiamine	Salicylic acid
Thioridazine	Thymol	Salicylic acid
Timolol	Tobramycin	Salicylic acid

Tolazamide	Tolbutamide	Tolmetin
Toluene	Toluic acid, p-	Tracazolate
Tramadol	Tranlycypromine	Trazadone
Triamcinlone	Triamterene	Tribenzylamine
Trichlormethiazide	Trichloroacetic acid	Trichloroethanol
Trifluoperazine	Trifluoromethylbenzoic acid, m-	Triflupromazine
Trihexyphenidyl	Trimethadione	Trimethoprim
Trinitroglycerin	Tripelennamine	Tripolidine
Tropacocaine	Tropic acid	Tropine
Tryptamine	Tryptophan	Tubocurarine
Tyrosine, dl-	Urea	Uric acid
Valproic acid	Vancomycin	Vanillylmandelic acid, dl-
Venlafaxine	Verapamil	Vincamine
Vitamin K	Warfarin	Xylometazoline
Yohimbine	Zearalenone	Zidovudine
Zimelidine	Zolpidem	Zomepirac
Zopiclone	Zoxazolamine	

PRECISION

The precision of the Triage® Drugs of Abuse Panel plus Tricyclic Antidepressants was determined using various concentrations of drug standards for each principal drug detected in this system. According to the minimum standard of performance established by SAMHSA, the 95% confidence level for positive results is established at 120% of the designated cut-off concentration for each drug⁶. Therefore the precision of the Triage® Drugs of Abuse Panel plus Tricyclic Antidepressants is minimally targeted to produce a positive result with 95% confidence levels for the principal drugs at 120% of the cut-off concentration for each drug.

■ BIBLIOGRAPHY OF SUGGESTED READING

1. Wells, B.G., Tricyclic Antidepressants. In: A Text Book for the Clinical Application of Therapeutic Drug Monitoring, Abbott Laboratories, Irving, TX. 1986, pp 458.
2. Boehmert, MT. and Lovejoy P.H., Value of the QRS Duration versus the Serum Drug Level in Predicting Seizures and Ventricular Arrhythmias After an Acute Overdose of Tricyclic Antidepressants. *New Eng. J. Med.* 313: 474-479, 1985.
3. The Pharmacological Basis of Therapeutics, A.G. Gilman, L.S. Goodman and A. Gilman eds. MacMillan Publishing, New York, NY., 1990.
4. Baselt, R.C., In: Disposition of Toxic Drugs and Chemicals in Man. Davis, CA Biomedical Communication., 1982.
5. Urine Testing for Drugs of Abuse, NIDA Research Monograph 73, 1986.
6. Federal Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs. 59, 110, 29908-29931, 1994, 11970-11979, 1988.
7. Clarke's Isolation and Identification of Drugs, Second Edition, A.C. Moffat eds. The Pharmaceutical Press, London, 1986.
8. Data on file at Biosite Incorporated

For Technical Assistance call
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Biosite Incorporated
9975 Summers Ridge Road
San Diego, California 92121 USA
+1 (858) 805-4808
www.biosite.com

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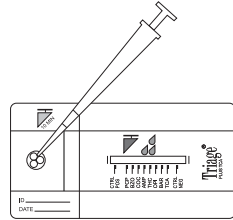
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TEST PROCEDURE

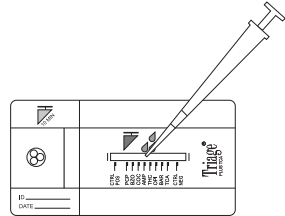
STEP 1: Add Sample

Slide the cap from the reaction cup. Using the pipet provided, pipet the urine sample (140 μ l) into the reaction cup and incubate **10 minutes** at room temperature.



STEP 2: Transfer Solution

Using the pipet provided and a clean pipet tip, transfer the reaction mixture from the cup to the point in the Detection Area indicated by the pipet graphic. **Allow the contents to soak through completely.**



STEP 3: Wash and Read

As soon as the mixture has soaked through, add 3 drops of Wash Solution into the center of the detection area. **Allow to soak through completely.** Read the CTRL NEG Zone, the CTRL POS Zone and the Drug Detection Zones. Results may be read anytime within 5 minutes of completion.

