Syntron Bioresearch, Inc.

QuikScreen® Multi X Drug Cup Test

ONE STEP ONSITE DRUG CUP WITH ADULTERATION

Catalog # 65xxx

Not for Diagnostic Use

— Instructions —

② CE

INTENDED USE

The **QuikScreen® Multi X Drug Cup Test** is an immunochromatographic assay for rapid, qualitative detection of drug combinations and their principal metabolites in urine at specified cut-off concentrations. In the **QuikScreen® Multi X Drug Cup Test** , X may denote any number of drugs, 1 through 14. These drug combinations may be composed from any of the following drugs, at the noted cut-off concentrations:

DRUG CLASS	ABBREVIATIONS	SENSITIVITY
AMPHETAMINE-I	AMP	500 ng/ml
AMPHETAMINE-II	AMP	1000 ng/ml
BARBITURATES-I	BAR	200 ng/ml
BARBITURATES-II	BAR	300 ng/ml
BENZODIAZEPINES-I	BZD	200 ng/ml
BENZODIAZEPINES-II	BZD	300 ng/ml
BUPRENORPHINE	BUP	10 ng/ml
COCAINE I	COC	150 ng/ml
COCAINE II	COC	300 ng/ml
COTININE	COT	200 ng/ml
COTININE	COT	500 ng/ml
2-ETHYLIDINE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE	EDDP	100 ng/ml
FLUNITRAZEPAM	FM II	300 ng/ml
KETAMINE	KET	1000 ng/ml
MARIJUANA	THC	50 ng/ml
METHADONE	MAD	300 ng/ml
METHAMPHETAMINE-I	MET	500 ng/ml
METHAMPHETAMINE-II	MET	1000 ng/ml
METHYLENEDIOXYMETHAMPHETAMINE-I	MDMA	500 ng/ml
METHYLENEDIOXYMETHAMPHETAMINE-II	MDMA	1000 ng/ml
OPIATES I	OPI	300 ng/ml
OPIATES II	OPI	2000 ng/ml
OXYCODONE	OXY	100 ng/ml
PHENCYCLIDINE	PCP	25 ng/ml
PROPOXYPHENE	PPX	300 ng/ml
TRICYCLIC ANTIDEPRESSANT	TCA	1000 ng/ml

An added feature to assess the integrity of the urine samples prior to drug testing, is a visual determination of ***Creatinine (CRE)***, ***Glutaraldehyde (GLU)***, ***pH***, ***Specific Gravity (SG)*** and ***Nitrite, Pyridinium Chlorochromate, Bleach (NPB)***. These adulteration strips are built into the test device which may provide information regarding urine sample tampering.

Note: *The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.*

SUMMARY AND EXPLANATION OF THE TEST

The **QuikScreen® Multi X Drug Cup Test** is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need of instrumentation. The method employs unique mixture of antibodies to selectively identify the drugs of abuse and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economical concern in many developed and developing countries throughout the world. The above stated drugs are among the most frequently abused illicit drugs, according to the U.S. Substance Abuse and Mental Health Services Administration. Opiates are among a class of heavily abused prescription drugs.

The sensitivity of the **QuikScreen® Multi X Drug Cup Test** is set as required for the screening immunoassays of these drugs in the reference guidelines set by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Department of Health and Human Services.

PRINCIPLE OF THE TEST

The **QuikScreen® Multi X Drug Cup Test** is a competitive binding immunoassay in which drug and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. By utilizing antibodies that are specific to different drug classes, the test permits independent, simultaneous detection of any of the drug combinations from a single sample. The approximate run time is 5 minutes.

In the assay procedure, urine mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a rose-pink color band in the appropriate Test Zone for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the immobilized antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen-antibody complex, preventing the development of a rose-pink color band.

Regardless of the drug levels in the sample, a rose pink-color band is produced in each Control Zone (top bands) by a parallel immunochemical reaction. These bands serve as built-in quality control measures by demonstrating antibody recognition, verifying that the reagents are chemically active.

Included in this device are any 4 of the following 5 different adulteration strips to determine whether the urine sample is adulterated: ***Creatinine***, ***Glutaraldehyde***, ***pH***, ***Specific Gravity*** and ***NPB*** the results of which can be achieved by comparing to the color chart provided.

REAGENTS AND MATERIAL PROVIDED

1. Test Devices	Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.
2. Test Instructions	*Catalog# PI-65XXX-NIVD*
3. Color Chart	*Catalog# COL-007*

Optional:

4. Negative Control I	*Cat.# 4010N*
5. Amphetamine-I Positive Control	*Cat.# 11120P*
6. Amphetamine-II Positive Control	*Cat.# 11120P-B*
7. Barbiturates-I & II Positive Control	*Cat.# 18040P*
8. Benzodiazepines-I & II Positive Control	*Cat.# 18020P*
9. Buprenorphine Positive Control	*Cat.# 19094P*
10. Cocaine-I & II Positive Control	*Cat.# 12000P*
11. Cotinine Positive Control	*Cat.# 19095P*
12. EDDP Positive Control	*Cat.# 191040P*
13. Flunitrazepam Positive Control	*Cat.# 18060P*
14. Ketamine Positive Control	*Cat.# 19100P*
15. Marijuana Positive Control	*Cat.# 13020P*
16. Methadone Positive Control	*Cat.# 19020P*
17. Methamphetamine-I Positive Control	*Cat.# 11320P*
18. Methamphetamine-II Positive Control	*Cat.# 11320P-B*
19. Methylenedioxymethamphetamine-I Positive Control	*Cat.# 19060P*
20. Methylenedioxymethamphetamine-II Positive Control	*Cat.# 19060P-B*
21. Opiates/Morphine-I Positive Control	*Cat.# 11220P*
22. Opiates/Morphine-II Positive Control	*Cat.# 11220P-B*
23. Oxycodone Positive Control	*Cat.# 19080P*
24. Phencyclidine Positive Control	*Cat.# 14020P*
25. Propoxyphene Positive Control	*Cat.# 13020P*
26. Tricyclic Antidepressant Positive Control	*Cat.# 19092P-B*

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.
2. Specimen collection containers.

WARNINGS AND PRECAUTIONS

1. Not for In-Vitro Diagnostic Use.
2. Do not use the test device beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of urine in the toilet by draining it out of the test device. Fasten cap on the device and throw the empty urine cup in the garbage.
4. Read the results at 5 minutes. Do not interpret results after 30 minutes.
5. Visually inspect the foil package to insure it is intact. If the package is not intact, the integrity of the device might be compromised.

STORAGE AND STABILITY

Store test kit below 28°C; **do not freeze**. If stored at 2°-8°C, allow the test kit to reach room temperature (15°-28°C) before performing the test. Refer to the expiration date for stability.

SPECIMEN COLLECTION AND PREPARATION

Fresh urine specimens should be collected directly into the cup. The **QuikScreen® Multi X Drug Cup Test** device employs a **thermal strip which should be checked immediately** after collection to validate urine specimen. SAMHSA regulations specify that any temperature below 90.5° F must be considered adulterated. No additives or preservatives are required.

Note: *Urine specimens can be transferred from a urine collection container into* ***QuikScreen® Multi X Drug Cup Test*** *cup, if necessary.*

TEST PROCEDURE

1. Do not break the seal of the pouch until ready to begin testing.
2. Remove the Test Cup from the foil pouch.
3. Collect urine specimen directly into the Test Cup. Ensure that the sample amount meets the minimum level as indicated on the side of the Test Cup.
4. **Wait 1 minute and immediately read the adulteration strips for pH and Specific Gravity. At 5 minutes read the adulteration strips for Creatinine, Glutaraldehyde and NPB.** Obtain results by comparing them to the color chart provided. Color comparison must be performed under a good light source. If results show that the urine sample was **adulterated, do not read the drug test result.**
5. If urine sample is found to be **unadulterated, read the drug test results**.

Note: *The results must be interpreted at five minutes, except for pH and Specific Gravity. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.*

DEVICE FEATURE:

Included in this device are any 4 of the following 5 different adulteration strips to determine whether the urine sample is adulterated:

Creatinine (CRE) interacts with a creatinine indicator in an alkaline medium and forms an orange-red complex. The color intensity is directly proportional to the concentration of creatinine when compared visually to the color chart to obtain result.

Glutaraldehyde (GLU) is based on the reaction of the aldehyde group of glutaraldehyde with aldehyde detecting reagent on the strip. A pink, purple, or light blue- purple color is obtained if glutaraldehyde is present in the urine.

pH is based on multiple indicators which give a broad range of colors covering the entire urinary pH range. Colors range from maroon to pinkish-red through orange, green and dark green.

Specific Gravity (SG) is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark green or green in urine of low ionic concentration and yellow-green in urine of higher ionic concentration.

Nitrite, Pyridinium Chlorochromate and Bleach (NPB) test is based on the development of colors ranging from cream, for negative reading, to a positive color of green, brownish-green, or brown when the chromogen is oxidized by nitrite, pyridinium chlorochromate or bleach.

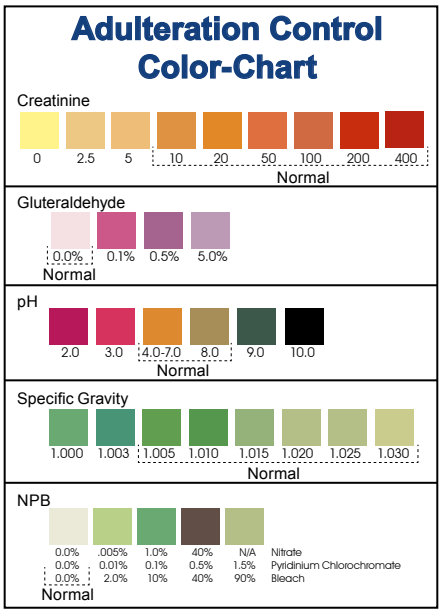
The **QuikScreen® Multi X Drug Cup Test** also provides internal control to determine adulteration of the urine sample in the form of up to 5 reagent strips, to test for CRE, GLU, pH, SG and NPB on urine samples submitted for drugs of abuse testing.

INTERPRETATION OF RESULTS

ADULTERATION STRIPS

Results are obtained by direct comparison of the reacted strip with the color chart provided, similar to the illustration below. An adulterated urine sample will show result colors under the **"Abnormal"** block colors of the chart. An unadulterated urine sample will show the strip colors similar to the **"Normal"** block colors of the color chart.

Based on the information gathered from a review of current clinical and forensic toxicology literature and recommendations made by the U.S. Substance Abuse and Mental Health Services Administration's Drug Testing Advisory Board, a specimen is defined to be:



a. ***Dilute*** if the Creatinine is <20 mg/dl unless the criteria for a substituted specimen are met.

b. ***Adulterated*** if the pH is ≤4 or ≥8.

c. ***Dilute*** if the Specific Gravity is <1.005 mg/dl, unless the criteria for a substituted specimen are met.

d. ***Adulterated*** if the Nitrite concentration is ≥5 mg/ml.

e. ***Adulterated*** if an exogenous substance (i.e., a substance which is not a normal constituent of urine such as CRE, GLU, pH, SG and NPB) or an endogenous substance at a higher concentration than normal physiological concentration is present in the specimen.

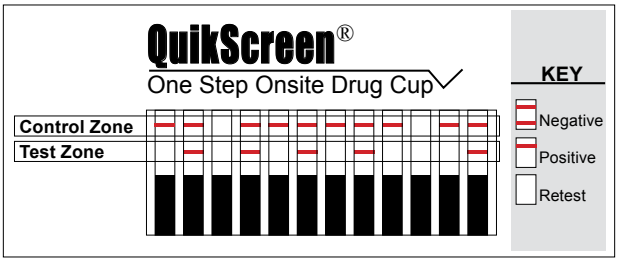
DRUG TEST STRIPS

Positive: A *rose-pink* band is visible in each control zone (top band). No color band appearing in the appropriate test zone (bottom band) indicates a preliminary positive result for the corresponding drug of that specific test zone. Send urine specimen to a certified laboratory for confirmation.

Negative: A *rose-pink* band is visible in each control zone and the appropriate test zone, indicating that the concentration of the corresponding drug of that specific test zone is below the detection limit of the test.

Invalid: If a color band is not visible in each of the control zones, the test is invalid. Another test should be run to re-evaluate the specimen.

Note: *There is no meaning attributed to line color intensity or width.*



QUALITY CONTROL

An internal procedure control has been incorporated into the test to insure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of drugs of abuse and their metabolites in human urine only.
2. Although the test is very accurate, there is the possibility false results will occur due to the presence of interfering substances in the specimen sample.
3. The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels in urine, or the level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens, can cause erroneous test results regardless of the analysis method used.
5. If adulteration is suspected, obtain another urine specimen.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity**. The **QuikScreen® Multi X Drug Cup Test** detects drugs of abuse and their major metabolites in urine at concentrations equal to or greater than the cut-off level for the specific drug, which is suggested by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) for the immunoassay method.
2. **Specificity**. A study was conducted with the **QuikScreen® Multi X Drug Cup Test** device to determine the cross-reactivity of drug-related compounds with the test. Substances listed in **Table I** produced results approximately equivalent to the cutoff levels. A separate study was conducted to determine the cross-reactivity of non-related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross reactivity was detected with the substances listed in **Table II**.

Table I: Concentrations of drug-related compounds showing positive response approximately equivalent to the cut-off set for the test:

The following Amphetamine-related substances yield a positive result for Amphetamine-I at 500 ng/ml cut-off level:

d-Amphetamine	*500 ng/ml*
l-Amphetamine	*25,000 ng/ml*
Δ-l-Amphetamine	*600 ng/ml*
Ephedrine	*250,000 ng/ml*
(±)3,4-Methylenedioxyamphetamine(MDA)	*600 ng/ml*
(±)Phenylpropanolamine (PPA)	*50,000 ng/ml*
β-Phenylethylamine	*90,000 ng/ml*
Pseudoephedrine	*100,000 ng/ml*
Thyramine	*100,000 ng/ml*

The following Amphetamine-related substances yield positive results for Amphetamine-II at 1000 ng/ml cut-off level:

d-Amphetamine	*1000 ng/ml*
l-Amphetamine	*25,000 ng/ml*
Δ-l-Amphetamine	*10,000 ng/ml*
β-Phenylethylamine	*180,000 ng/ml*
Tyramine	*100,000 ng/ml*
(±) 3,4-Methylenedioxyamphetamine-HCl (MDA)	*1200 ng/ml*

The following Barbiturate-related substances yield a positive result for Barbiturates-I at 200 ng/ml cut-off level:

Amobarbital	*200 ng/ml*
Barbital	*200 ng/ml*
Bromocriptine	*200 ng/ml*
Butabarbital	*200 ng/ml*
Sodium Dodecylsulfate	*260 ng/ml*
Phenobarbital	*200 ng/ml*
Pentobarbital.	*200 ng/ml*
Secobarbital	*200 ng/ml*
Sertraline Hydrochloride(Zoloft)	*200 ng/ml*

The following Barbiturate-related substances yield a positive result for Barbiturates-II at 300 ng/ml cut-off level:

Allobarbital	*600 ng/ml*
Amobarbital	*600 ng/ml*
Barbital	*300 ng/ml*
Butabarbital	*300 ng/ml*
Butalbital	*300 ng/ml*
Pentobarbital.	*300 ng/ml*
Phenobarbital	*300 ng/ml*
Secobarbital	*300 ng/ml*

The following Benzodiazepine-related substances yield positive results for Benzodiazepines-I at 200 ng/ml cut-off level:

α-Hydroxytriazolam	*200 ng/ml*
α-Hydroxyalprazolam	*200 ng/ml*
Alprazolam	*62.5 ng/ml*
Bromazepam	*250 ng/ml*
Clorazepate	*50 ng/ml*
Chlordiazepoxide	*950 ng/ml*
Clobazam	*2,500 ng/ml*
Clonazepam	*500 ng/ml*
Clotiazepam	*460 ng/ml*
Daypro (Chemically not a Benzodiazepine)	*200 ng/ml*
Demoxepam	*600 ng/ml*
Desmethyldiazepam	*50 ng/ml*
Diazepam	*50 ng/ml*
Flunitrazepam	*250 ng/ml*
Flurazepam	*100 ng/ml*
1-N-Hydroxyethylflurazepam	*130 ng/ml*
Halazepam.	*160 ng/ml*
Ketazolam	*210 ng/ml*
Lorazepam.	*200 ng/ml*
Lormetazepam	*250 ng/ml*
Medazepam	*1000 ng/ml*
Midazolam.	*130 ng/ml*
N-Desalkyflurazepam	*300 ng/ml*
N-Desmethyldiazpam	*160 ng/ml*
Nitrazepam	*200 ng/ml*
Nordiazepam.	*200 ng/ml*
Oxazepam	*200 ng/ml*
Prazepam	*100 ng/ml*
Temazepam	*200 ng/ml*
Tetrazepam	*200 ng/ml*
Triazolam	*500 ng/ml*

The following Benzodiazepine-related substances yield positive results for Benzodiazepines-II at 300 ng/ml cut-off level:

Alprazolam	*600 ng/ml*
Bromazepam	*100 ng/ml*
Chlordiazepoxide	*300 ng/ml*
Clobazam	*300 ng/ml*
Clonazepam	*300 ng/ml*
Clorazepate	*200 ng/ml*
Delorazepam	*3,000 ng/ml*
Diazepam	*300 ng/ml*
Estazolam	*300 ng/ml*
Flunitrazepam	*300 ng/ml*
Flurazepam	*150 ng/ml*
Lorazepam.	*500 ng/ml*
Lormetazepam	*500 ng/ml*
Nitrazepam	*250 ng/ml*
Nordiazepam.	*150 ng/ml*
Oxazepam	*300 ng/ml*
Prazepam	*1,500 ng/ml*
Temazepam	*150 ng/ml*
Triazolam	*200 ng/ml*

The following Buprenorphine-related substances yield positive result for Buprenorphine at 10 ng/ml cut-off level:

Buprenorphine-3-β-D-Glucuronide.	*2.5 ng/ml*
Buprenorphine	*10 ng/ml*
Nalorphine.	*1000 ng/ml*
Norbuprenorphine.	*30000 ng/ml*
Norbuprenorphine-3-β-D-Glucuronide	*30000 ng/ml*

The following Cocaine-related substances yield positive results for Cocaine/Benzoylecgonine-I at 150 ng/ml cut-off level:

Benzoylecgonine	*150 ng/ml*
Cocaine	*150 ng/ml*
Isoxsuprine	*1,500 ng/ ml*

The following Cocaine-related substances yield positive results for Cocaine/Benzoylecgonine-II at 300 ng/ml cut-off level:

Benzoylecgonine	*300 ng/ml*
Cocaine	*300 ng/ml*

The following Cotinine-related substances yield positive results for Cotinine at 200 ng/ml cut-off level:

(-)-Nicotine	*300 ng/ml*

The following Cotinine-related substances yield positive results for Cotinine at 500 ng/ml cut-off level:

(-)-Nicotine	*500 µg/ml*

The following EDDP-related substances yield positive results for EDDP at 100 ng/ml cut-off level:

EDDP.	*100 ng/mL*
EMDP	*200,000 ng/mL*
Methadone	*500,000 ng/mL*

The following Flunitrazepam-related substances yield positive results for Flunitrazepam at 300 ng/ml cut-off level:

Alpha hydroxyaltriazolam	*200 ng/ml*
Alprazolam	*62.5 ng/ml*
Bromazepam	*250 ng/ml*
Clobazam	*2500 ng/ml*
Clorazepate	*50 ng/ml*
Clonazepam	*500 ng/ml*
Diazepam	*50 ng/ml*
Desmethyldiazepam	*50 ng/ml*
Benzodiazepine	*300 ng/ml*
Flurazepam	*100 ng/ml*

The following Ketamine-related substances yield positive results for Ketamine at 1000 ng/ml cut-off level:

Norketamine	*10,000 ng/ml*
Phencyclidine	*>200,000 ng/ml*

The following Marijuana-related substances yield positive results for Marijuana at 50 ng/ml cut-off level:

Cannabinol	*10,000 ng/ml*
11-nor-Δ-8-THC-9-COOH	*50 ng/ml*
11-nor-Δ-9-THC-9-COOH	*50 ng/ml*
Δ8-THC	*7500 ng/ml*
Δ9-THC	*10,000 ng/ml*
11-hydroxy-Δ-9-THC	*2500 ng/ml*

The following Methadone-related substances yield positive results for Methadone at 300 ng/ml cut-off level:

Doxylamine	*50,000 ng/ml*
EDDP (2 Ethylidene-1,5-dimethy 1-3,3-Diphenylpyrrolidin)	*100,000 ng/ml*
Methadol	*25,000 ng/ml*
Perphenazine	*75,000 ng/ml*
Protriptyline	*2,000 ng/ml*
Trimipramine	*10,000 ng/ml*

The following Methamphetamine-related substances yield positive results for Methamphetamine-I at 500 ng/ml cut-off level:

d-Amphetamine	*50,000 ng/ml*
Δ,l-Amphetamine	*10,000 ng/ml*
Ephedrine	*25,000 ng/ml*
(+) Methamphetamine	*500 ng/ml*
(±)3,4-Methylenedioxymethamphetamine(MDMA)	*500 ng/ml*
(±)3,4-Methylenedioxyamphetamine(MDA)	*50,000 ng/ml*
Pseudoephedrine	*1,000 ng/ml*
Phenyl Propanolamine (PPA)	*98,000 ng/ml*

The following Methamphetamine-related substances yield positive results for Methamphetamine-II at 1000 ng/ml cut-off level:

(+) Methamphetamine	*1000 ng/ml*
(±)3,4-Methylenedioxymethamphetamine (MDMA)	*1000 ng/ml*
(±)3,4-Methylenedioxyamphetamine (MDA)	*200,000 ng/ml*
d-Amphetamine Sulfate	*200,000 ng/ml*
l-Amphetamine Sulfate	*200,000 ng/ml*
Δ-,l-Amphetamine Sulfate	*200,000 ng/ml*

The following Methylenedioxymethamphetamine-related substances yield positive results for Methylenedioxymethamphetamine-I at 500 ng/ml cut-off level:

(±) 3,4-Methylenedioxymethamphetamine (MDMA)	*500 ng/ml*
Δ-Amphetamine	*50,000 ng/ml*
(±) 3,4-Methylenedioxyamphetamine (MDA)	*50,000 ng/ml*
(+) Methamphetamine	*500 ng/ml*
Δ-l-Amphetamine	*100,000 ng/ml*
Deoxyephedrine	*500 ng/ml*
Ephedrine	*2,500,000 ng/ml*
Phenylpropanolamine	*9,800,000 ng/ml*
Pseudoephedrine	*1,000 ng/ml*

The following Methylenedioxymethamphetamine-related substances yield positive results for Methylenedioxymethamphetamine-II at 1000 ng/ml cut-off level:

(±) 3,4-Methylenedioxymethamphetamine (MDMA)	*1000 ng/ml*
d-Amphetamine	*50,000 ng/ml*
(±) 3,4-Methylenedioxyamphetamine (MDA)	*50,000 ng/ml*
(+) Methamphetamine	*500 ng/ml*
Δ-l-Amphetamine	*100,000 ng/ml*
Deoxyephedrine	*500 ng/ml*
Ephedrine	*5,000,000 ng/ml*
Pseudoephedrine	*1,000 ng/ml*

The following Opiates-related substances yield a positive result for Opiates/Morphine-I at 300 ng/ml cut-off level:

Atropine	*100,000 ng/ml*
Codeine	*300 ng/ml*
Heroin	*300 ng/ml*
Hydrocodone	*500 ng/ml*
Hydromorphone	*300 ng/ml*
Imipramine	*50,000 ng/ml*
Levorphanol	*600 ng/ml*
Meperidinew	*100,000 ng/ml*
Morphine-3-β-D Glucuronide	*300 ng/ml*
Naloxone	*1000 ng/ml*
Norcodeine	*2,000 ng/ml*
Opiate	*300 ng/ml*
Oxycodone	*1000 ng/ml*
Ranitidine	*100,000 ng/ml*
Thebaine	*1,500 ng/ml*

The following Opiates/Morphine-related substances yield a positive result for Opiates/Morphine-II at 2000 ng/ml cut-off level:

Morphine	*2000 ng/ml*
Morphine Sulfate Pentahydrate	*2000 ng/ml*
Morphine-3-β-D Glucuronide	*2000 ng/ml*
Codeine	*2000 ng/ml*
Heroin	*2000 ng/ml*
Levorphanol	*4000 ng/ml*
Ranitidine	*100,000 ng/ml*
6-Acetylmorphine	*50 ng/ml*

The following Oxycodone-related substances yield positive results for Oxycodone at 100 ng/ml cut-off level:

Oxycodone-HCl	*100 ng/ml*
Codeine	*700 ng/ml*
Hydrocodone	*500 ng/ml*
Hydromorphone	*1,500 ng/ml*
Morphine-Sulfate	*7,000 ng/ml*
Morphine-3-b-D-Glucuronide	*40,000 ng/ml*
Norcodeine	*40,000 ng/ml*
Oxymorphone	*300 ng/ml*

The following Phencyclidine-related substances yield a positive result for Phencyclidine at 25 ng/ml cut-off level:

Phencyclidine	*25 ng/ml*
Tenocyclidine	*2000 ng/ml*

The following Propoxyphene-related substances yield positive results for Propoxyphene at 300ng/ml cut-off level:

Methadone	*1,350,000 ng/ml*
Norpropoxyphene	*1000 ng/ml*
Propoxyphene	*300 ng/ml*
2-ethyl-1,5-dimethyl-3,3-diphenylpyrroline (EDDP)	*200,000 ng/ml*

The following Tramadol-related substances yield positive results for Tramadol at 200 ng/ml cut-off level:

(+/-) Chlorpheniramine	*100,000 ng/ml*
Diphenhydramine	*46,000 ng/ml*
Pheniramine	*>100,000 ng/ml*
Paracetamol	*>50,000 ng/ml*

The following Tricyclic Antidepressant-related substances yield positive results for Tricyclic Antidepressant at 500 ng/ml cut-off level:

Amitriptyline	*500 ng/ml*
Desipramine	*500 ng/ml*
Imipramine	*500 ng/ml*

The following Tricyclic Antidepressant-related substances yield positive results for Tricyclic Antidepressant at 1000 ng/ml cut-off level:

Amitriptyline	*1,000 ng/ml*
Cyclobenzaprine	*1,500 ng/ml*
Clomipramine	*5,000 ng/ml*
Desipramine	*600 ng/ml*
Doxepin	*1,000 ng/ml*
Imipramine	*600 ng/ml*
Notriptyline	*1,000 ng/ml*
Nordoxepin	*1,000 ng/ml*

Table II: Compounds tested and found not to cross-react with the test at a 100 µg / ml concentrate in urine.

Acetaminophen	*Furosemide*
Acetone	*Glucosamine*
Acetyl Salicylic Acid	*Guaiacol Glyceryl Ether*
Amikacin	*Hydrochlorothiazide*
Amitriptyline	*Hydrocodone*
Ampicillin	*Ibuprofen*
l-Ascorbic Acid (Vitamin C)	*Ketamine*
Aspartame	*Lidocaine*

Aspirin	*Maprotiline*
Atropine	*Meperidine*
Benzocaine	*Methanol*
Benzoic Acid	*Methylphenidate*
(+)- Brompheniramine	*Naltrexone*
Buprenorphine	*(+/-) Naproxen*
Buprenorphine3-β-D-Glucuronide	*Nicotine*
Caffeine	*Nor-Buprenorphine*
(+)-Chlorpheniramine	*Noscapine Hydrochloride*
(+/-)-Chlorpheniramine	*Oxalic Acid*
Chlorpromazine	*Omega-3-Fatty Acid*
Cortisone	*Penicillin G*
(-)-Cotinine	*Phenalzine*
Creatinine	*l-Phenylephrine*
Dextromethorphan	*(+/-)-Phenylpropanolamine*
4-Dimethylaminoantipyrine	*Promethazine*
Diphenhydramine	*Pseudoephedrine*
5,5-Diphenylhydantoin	*Quinine*
Dopamine	*Quinidine*
EDDP	*Salicylic Acid*
+ Ephedrine	*Sulindac*
- Ephedrine	*Sustiva(efavirenz)*
(+/-) Epinephrine	*Theophyline*
Erythromycin	*Thioridazine*
Ethanol	*Tramadol*
Fentanyl	*d(+)-Trehalose*
Fluxetine	*Trifluoperazine*

In order to examine potential naturally occurring interfering substances normally contained in urine. Drug free urine and drug positive urine were spiked with various potential interfering substances. Both samples were tested with QuikScreen® Multi X Drug Screen Test Cup Device. No cross-reaction was noted by any of the following substances at the concentrations list in the following table.

Table III - Natural Occurring Compounds in Urine and the Effect on QuikScreen® Multi X Drug Cup test

Analyte	Range	Effect	
		Positive*	Negative**
Ascorbic	300 mg/dl		
Bilirubin	1.0 mg/dl	None	None
Creatine	500 mg/dl	None	None
Glucose	1500 mg/dl	None	None
Hemoglobin	300 mg/dl	None	None
Potassium	110 mEq/dl	None	None
Human Serum Albumin	500 mg/dl	None	None
Globulin	1500 mg/dl	None	None
Sodium chloride	6000 mg/dl	None	None
Uric Acid	23 mg/dl	None	None
Cholesterol	500 mg/dl	None	None

*Concentration of Positive Drug Control = Amphetamine 1250 ng/ml, Methamphetamine 1250 ng/ml, Opiates 2500 ng/ml, Cocaine 375ng/ml, THC 63 ng/ml, Phencyclidine (PCP) 32 ng/ml, Benzodiazepine (450 ng/ml), Barbiturate (450 ng/ml), Methadone (450 ng/ml), TCA (1250 ng/ml), Oxycodone (100 ng/ml), Propoxyphene (300 ng/ml).

** Concentration of Drug [Drug Free urine] = 0 ng/ml

Effects of prolonged specimen exposure to the test device: In order to determine if there were any significant affects on the specimen by prolonged exposure to the test device, a study on the **QuikScreen® Multi X Drug Cup test** was performed using in-house urine control with GC/MS value assignment. The test specimens were subjected to a time zero (0) GC/MS evaluation. The test specimens were then applied to the **QuikScreen® Multi X Drug Cup test** such that the fluid level was midway between urine level marks and moderately shaken for a period of 10 minutes. The **QuikScreen® Multi X Drug Cup test** with the test specimens were stored for 50 hours at room temperature(15-30°) C.

Samples for GC/MS analysis were taken at times 0, 12, 36 and 60 hours. Statistically there was no significant change in the concentrations reported for any of the analytes at any time period. Based upon the GC/MS data, it may safe to conclude that there were no significant changes in the analyte concentrations of specimens that could be related to the device or the test strips contained in the device.

Accuracy: The accuracy of the **QuikScreen® Multi X Drug Cup Test** was tested in a clinical trial of urine samples submitted to a SAMHSA certified laboratory. The laboratory used Syva® EMIT II as their screening procedure. All positive samples by either screening method were confirmed by GC/MS. The relative sensitivity results by either GCMS is summarized as follows:

3.1 Amphetamine-I (AMP) 500 ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	**188**	**0**
QuikScreen® Negative	**0**	**340**

When compared to Syva EMIT II the relative sensitivity was computed to be 188/188 or 100%. The relative specificity was computed to be 340/340 or 100%. The concordance of the combined data with respect to Syva EMIT II was 528/528 or 100%.

3.2 Amphetamine-II (AMP) 1000 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**47**	**2**
QuikScreen® Negative	**0**	**61**

When compared to GC/MS the relative sensitivity was computed to be 47/47 or 100%. The relative specificity was computed to be 61/63 or 96.8%. The concordance of the combined data with respect to GC/MS was 108/110 or 98.2%.

3.3 Barbiturates-I (BAR) 200 ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	**185**	**2**
QuikScreen® Negative	**0**	**335**

When compared to Syva EMIT II the relative sensitivity was computed to be 185/185 or 100%. The relative specificity was computed to be 335/337 or 99.4%. The concordance of the combined data with respect to Syva EMIT II was 520/522 or 99.6%.

3.4 Barbiturates-II (BAR) 300 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**39**	**2**
QuikScreen® Negative	**0**	**52**

When compared to GC/MS the relative sensitivity was computed to be 39/39 or 100%. The relative specificity was computed to be 52/54 or 96.3%. The concordance of the combined data with respect to GC/MS was 91/93 or 97.8%.

3.5 Benzodiazepine-I (BZD) 200ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	**210**	**0**
QuikScreen® Negative	**9**	**221**

When compared to Syva EMIT II the relative sensitivity was computed to be 210/219 or 95.9%. The relative specificity was computed to be 221/221 or 100%. The concordance of the combined data with respect to Syva EMIT II was 431/440 or 98%.

3.6 Benzodiazepine-II (BZD) 300ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**42**	**2**
QuikScreen® Negative	**0**	**52**

When compared to GC/MS the relative sensitivity was computed to be 42/42 or 100%. The relative specificity was computed to be 52/54 or 96%. The concordance of the combined data with respect to GC/MS was 94/96 or 98%.

3.7 Buprenorphine (BUP) 10ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**33**	**15**
QuikScreen® Negative	**0**	**55**

When compared to GC/MS the relative sensitivity was computed to be 33/33 or 100%. The relative specificity was computed to be 55/70 or 78.6%. The concordance of the combined data with respect to GC/MS was 88/103 or 85.4%.

3.8 Cocaine/I (COC) 150 ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	**194**	**1**
QuikScreen® Negative	**0**	**212**

When compared to Syva EMIT II the relative sensitivity was computed to be 194/194 or 100%. The relative specificity was computed to be 212/213 or 99.5%. The concordance of the combined data with respect to Syva EMIT II was 406/407 or 99.8%.

3.9 Cocaine-II (COC 300 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**42**	**1**
QuikScreen® Negative	**0**	**53**

When compared to GC/MS the relative sensitivity was computed to be 42/42 or 100%. The relative specificity was computed to be 53/54 or 98%. The concordance of the combined data with respect to GC/MS was 95/96 or 99%.

3.10 Cotinine (COT) 200 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**36**	**0**
QuikScreen® Negative	**0**	**110**

When compared to GC/MS the relative sensitivity between positive samples was 36/36 or 100% . The relative specificity between negative samples was 100/100 or 100%. The concordance of the combined data with respect to GC/MS was 146/146 or 100%.

3.11 Cotinine (COT) 500 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**24**	**0**
QuikScreen® Negative	**2**	**122**

When compared to GC/MS the relative sensitivity between positive samples was 24/24 or 100% . The relative specificity between negative samples was 122/124 or 99 %. The concordance of the combined data with respect to GC/MS was 144/146 or 98.6 %.

3.12 EDDP 100 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**50**	**0**
QuikScreen® Negative	**2**	**108**

When compared to GC/MS the relative sensitivity was computed to be 50/50 or 100%. The relative specificity was computed to be 106/108 or 98.1%. The concordance of the combined data with respect to GC/MS was 158/160 or 98.7%.

3.13 Flunitrazepam (COC) 300 ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	**60**	**0**
QuikScreen® Negative	**2**	**75**

When compared to GC/MS the relative sensitivity was computed to be 58/60 or 96.6%. The relative specificity was computed to be 73/75 or 97.3%. The concordance of the combined data with respect to GC/MS was 131/135 or 97.03%.

3.14 Ketamine (KET) 1000 ng/ml Cut-Off Level

	LC/MS Positive	LC/MS Negative
QuikScreen® Positive	**21**	**0**
QuikScreen® Negative	**2**	**119**

When compared to LC/MS the relative sensitivity was computed to be 21/23 or 91.3%. The relative specificity was computed to be 119/119 or 100%. The concordance of the combined data with respect to LC/MS was 140/142 or 98.6%.

3.15 Marijuana (THC) 50 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**42**	**1**
QuikScreen® Negative	**0**	**53**

When compared to GC/MS the relative sensitivity was computed to be 42/42 or 100%. The relative specificity was computed to be 53/54 or 98%. The concordance of the combined data with respect to GC/MS was 95/96 or 99%.

3.16 Methadone (MAD) 300 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**42**	**0**
QuikScreen® Negative	**0**	**52**

When compared to GC/MS the relative sensitivity was computed to be 42/42 or 100%. The relative specificity was computed to be 52/52 or 100%. The concordance of the combined data with respect to GC/MS was 94/94 or 100%.

3.17 Methamphetamine-I (MET) 500 ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	**193**	**0**
QuikScreen® Negative	**6**	**256**

When compared to Syva EMIT II the relative sensitivity was computed to be 193/199 or 97%. The relative specificity was computed to be 256/256 or 100%. The concordance of the combined data with respect to Syva EMIT II was 449/455 or 98.7%.

3.18 Methamphetamine-II (MET) 1000 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**41**	**1**
QuikScreen® Negative	**0**	**59**

When compared to GC/MS the relative sensitivity was computed to be 41/41 or 100%. The relative specificity was computed to be 59/60 or 98%. The concordance of the combined data with respect to GC/MS was 100/101 or 99%.

3.19 Methylenedioxymethamphetamine-I (MDMA) 500 ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	**193**	**0**
QuikScreen® Negative	**6**	**256**

When compared to Syva EMIT II the relative sensitivity was computed to be 193/199 or 97%. The relative specificity was computed to be 256/256 or 100%. The concordance of the combined data with respect to Syva EMIT II was 449/455 or 98.7%

3.20 Methylenedioxymethamphetamine-II (MDMA) 1000 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**41**	**1**
QuikScreen® Negative	**0**	**59**

When compared to GC/MS the relative sensitivity was computed to be 41/41 or 100%. The relative specificity was computed to be 59/60 or 98.3%. The concordance of the combined data with respect to GC/MS was 100/101 or 99%.

3.21 Opiates-I (OPI/) 300 ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	**172**	**0**
QuikScreen® Negative	**0**	**190**

When compared to Syva EMIT II the relative sensitivity was computed to be 172/172 or 100%. The relative specificity was computed to be 190/190 or 100%. The concordance of the combined data with respect to Syva EMIT II was 362/362 or 100%.

3.22 Opiates-II (OPI) 2000 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**41**	**1**
QuikScreen® Negative	**0**	**54**

When compared to GC/M the relative sensitivity was computed to be 41/41 or 100%. The relative specificity was computed to be 54/55 or 98.2%. The concordance of the combined data with respect to GC/MS was 95/96 or 99%.

3.23 Oxycodone (OXY) 100 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**55**	**1**
QuikScreen® Negative	**0**	**43**

When compared to GC/MS the relative sensitivity was computed to be 55/55 or 100%. The relative specificity was computed to be 43/44 or 98%. The concordance of the combined data with respect to GC/MS was 98/99 or 99%.

3.24 Phencyclidine (PCP) 25 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**40**	**4**
QuikScreen® Negative	**0**	**53**

When compared to GC/MS the relative sensitivity was computed to be 40/40 or 100%. The relative specificity was computed to be 53/57 or 93%. The concordance of the combined data with respect to GC/MS was 93/97 or 96%.

3.25 Propoxyphene (PPX) 300 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**26**	**2**
QuikScreen® Negative	**0**	**32**

When compared to GC/MS the relative sensitivity was computed to be 26/26 or 100%. The relative specificity was computed to be 32/34 or 94%. The concordance of the combined data with respect to GC/MS was 58/60 or 96.6%.

3.26 Tricyclic Antidepressant (TCA) 500 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**16**	**1**
QuikScreen® Negative	**0**	**22**

When compared to GC/MS the relative sensitivity was computed to be 16/16 or 100%. The relative specificity was computed to be 22/23 or 95.6%. The concordance of the combined data with respect to GC/MS was 38/39 or 97.4%.

3.27 Tricyclic Antidepressant (TCA) 1000 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**41**	**1**
QuikScreen® Negative	**0**	**42**

When compared to GC/MS the relative sensitivity was computed to be 41/41 or 100%. The relative specificity was computed to be 42/43 or 98%. The concordance of the combined data with respect to GC/MS was 83/84 or 99%.

BIBLIOGRAPHY

General

1. Baselt, R.C., Disposition of Toxic Drugs and Chemicals in Man, 2nd Ed., *Biomedical Publ.*, Davis, CA, p.488 (1982).
2. Cody, J.T., Schwarzhoff, R., *J. Anal. Toxicol.*, 17: 2630 (1993).
3. Urine Testing for Drugs of Abuse, *NIDA Research Monograph* 73, (1986).
4. Dasguspta, A., Saldana, S., Kinnaman, G., Smith M., Johansen, K., *Clin. Chem.*, 39(1):104-108 (1993).
5. Department of Health and Human Services, *Fed. Regist.*, 53(69): 11970-11989 (1988), (1989).
6. *FDA Guidance for Labeling Urine Drugs of Abuse Screening Testing*, Kshitij Mohan, 7/21/1987.
7. Blum, K., *Handbook of Abusable Drugs*, Gardner Press, Inc., New York, 1st Ed., (1984).
8. Tietz, N.W.; *Clinical Guide to Laboratory Tests*; W.B. Saunders Company, (1976).

Amphetamine/Methamphetamine Test

1. Ellerbe, P., Long, T.,Welch, M.J., *J. Anal. Toxicol.*, 17: 165-170 (1993).

Barbiturate Test

1. Hoffmann, F.E. *A Handbook of Drug and Alcohol Abuse: The Biomedical Aspects. Oxford University Press*, New York, 1983.
2. Wyngarrden, J.B., Smith, L.H. (eds.) *Cecil Textbook of Medicine.* W.B. Saunders Co., Philadelphia, 1988, pp. 53-54.
3. Ellenhorn, M.J., Barceloux, D.*J. Medical Toxicology.* Elsevier Science Publishing Co., New York, 1988, pp. 575-580.
4. Gorodetzky, Z.V. *Detection of Drugs of Abuse in Biological Fluids.* In: Martin, W.R. (ed.) Drug Addiction. I. Springer-Verlag, New York, 1977, pp. 319-409.

Benzodiazepines Test

1. S.J., Mule and G.A. Gasella. "Quantitation and Confirmation of the Diazolo and Triazolobenzodiazepines in Human Urine by GC/MS," *J. Anal. Toxicol.*, Vol. 13 (1989), pp. 179-184.
2. C. Drouet-Coassolo, C. Aubert, P. Coassolo, and J. Cano. "Capillary GC/MS Method for the Identification and qualification of some Benzodiazepines and Their Unconjugated Metabolites in Plasma," *J. Chromatogr.*, Vol. 487 (1989), pp. 295-311.
3. C. Ballanto, V. Reggi, G. Tognoni, et al., "Benzodiazepines: Clinical Pharmacology and Therapeutic Use," *Drugs,* Vol. 19 (1980): 195-219.
4. A.J. Giannini and E.A. Slaby. *Drugs of Abuse* (MEDEC Books: 1989), Ch. 4, pp. 59-80.
5. M.A. Pear and L. Kopjak, "The Screening and Quantitation of Diazepam, Flurazepam, Chlordiazepoxide, and Their Metabolites in Blood and Plasma by Electron-Capture Gas Chromatography and High Pressure Liquid Chromatography," *J. Forensic Sci.*, Vol. 24(1979) pp. 46-54.
6. H. Schultz, "Modern Screening Strategies in Analytical Toxicology with Special Regard to New Benzodiazepines," *J. Legal. Med.*, Vol. 100 (1988) pp. 19-37.
7. J.G. Langner, B.K. Gan, R.H. Liu, L.D. Baugh, P. Chand, J.L. Weng, et.al. "Enzymatic Digestion, Solid Phase Extraction, and GC/MS of Derivatized Intact Oxazepam in Urine," *Clin. Chem.*, Vol. 37 (1991) pp.1596-1601.
8. R.L. Fitzgerald, D.A. Rexin, and D.A. Herold. "Benzodiazepine Analysis by Negative Chemical Ionization GC/MS," *J. Anal. Toxicol.*, Vol. 17, pp.342-347.

Buprenorphine

1. Huang, W., Andollo, W., Hearn W.L. *J. Anal. Toxicol.*, 16: 307-310 (1992).
2. Cody, J.T., and Schwarzhoff, R., *J. Anal. Toxicol.*, 17: 2630 (1993).
3. Glare, P.A., Walsh, T.D., and Pippenger, C.E., *Ther. Drug Monit.*, 13: 226-232 (1991).
4. Walsh, T.D., Cheater, F.M., Pharm. J., 10: 525-527 (1983).
5. Mitchell, J.M., Paul, B.D., Welch, P., Cone, E.J. *J. Anal. Toxicol.*, 15: 49-53 (1991).
6. Department of Health and Human Services, *Fed. Regist.*, 53(69): 11970-11989 (1988), (1989).
7. Cone, E.J., Dickerson, S., Paul, B.D., Mitchell, J.M., *J. Anal. Toxicol.*, 17: 156-164 (1993).
8. Baselt, R.C., Disposition of Toxic Drugs and Chemicals in Man, *2nd. Ed., Biomedical Publ., Davis*, CA, p. 488 (1982).
9. Urine Testing for Drugs of Abuse, *SAMHSA Research Monograph*, 73, (1986).
10. FDA Guidance for Labeling Urine Drugs of Abuse Screening Testing, Kshitij Mohan, 7/21/1987.

Cocaine Test

1. D.W. Hoyt et al., *J. Am. Med. Assoc.*, Vol. 258 (1987), pp. 504-509.
2. R.R. MacGregor, J.S. Fowler, and A.P. Wolf. *J. of Chromatography*, Vol. 590 (1992), pp. 354-58.
3. E.J. Cone, D. Yousefnejad, and S.L. Dickerson. *J. of Forensic Sciences*, Vol. 35, No.4 (1990), pp. 786-91.
4. E.J. Cone et al., *J. of Forensic Sciences*, Vol. 34, No. 1 (1989), pp. 15-31.
5. B. Holmstedt and A. Fredga. *J. of Ethnopharmacology*, Vol. 3 (1981), pp. 113-47.
6. T. Inaba and J. Can. *Physiol. Pharmacol.*, Vol. 67 (1989), pp. 1154-57
7. A.R. Jeffcoat et al., *Drug Metabolism and Disposition*, Vol. 17, No. 2 (1989), pp. 153-59.

Cotinine

1. The Merck Index. 13th ed. Whitehouse Station: Merck & Co., Inc., 2001.
2. Drug Facts and Comparisons. 55th ed. St. Louis: Facts and Comparisons, 2001.
3. "Ultram brand of Tramadol Hydrochloride." http://opioids.com/tramadol/prescribe.html.
4. Raffa, R. et al. "Mechanism of action study." *J. of Pharmacol. Exp. Ther.* vol. 267. 331 (1993).
5. Elsing, B. and G. Blaschke. "HPLC determination in urine." *J. of Chomatog.* vol. 612. 223 (1993).
6. US Pharmacopia, The National Formulary. Taunton: US PharmaZevin S, Jacob P and Benowitz N. Cotinine Effectson nicotine metabolism. *Clinical Pharmacology & Therapeutics*, 1997 June 61(6):649-54
7. Zuccaro P, Pichini S, Alteri I, Rosa M, Pellegrini M and Pacifici R. Interference of nicotine metabolites in cotinine determinationby RIA. *Clinical Chemistry*, 1997 Jan 43(1):180-1

7. Benowitz NL. Cotinine as blomarker of enviromental tabacco smoke exposure. Epidemiologic Reviews, 1996 18(2):188-204.
8. Curvall M and Vala FK Nicotine and metabolites: analysis and levels in body fluids. Nicotine and related alkaloids: absorption, distribution, metabolism and excretion. Edited by Gorrod J.W. and Wahren J. Published in 1993 by Chapman & Hall, London. ISBN 0 142 55740 1.opeial Convention, Inc., 1995.

2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)

1. Urine Testing for Drugs of Abuse, NIDA Research Monograph 73, (1986).
2. Critical Issues in Urinalysis of Abused Substances: Report of the Substance Abuse
3. Testing committee, clinical chemistry, 34(3), 617 (1988).
4. Blum, K., Handbook of Abusable drugs, Gardener Press, Inc. New York, NY, 1st Ed., (1984)
5. Baselet, R.C., Disposition of Toxic Drugs and Chemicals in Man, 3rd Ed., Chicago, IL. Year Book Medical Publishers Inc., 780-783, (1990)
6. Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Reg.53(69):11970-89 (1988)
7. Stewart, D.J., et al.: Cocaine and norcocaine hydrolosis by liver and serum esterase. Clin. PharmaCOL. Ther., 25:464-468 (1978)
8. Goldman FR and Thistel CI, Diversion of methadone: illicit methadone use among applicants to two metropolitan drug abuse programs. Int J Addict. 13:855-862 (1978)
9. Brodin K. et al., Monitoring of methadone does intake. The Drug Monit. 19:591 (1997)

Flunitrazepam

1. S.J. Mule and G.A. Gasella. "Quantitation and Confirmation of the Diazolo- and Triazolobenzodiazepines in Human Urine by Gas Chromatography/Mass Spectrometry," *J. Anal. Toxicol*., Vol. 13 (1989), pgs. 179-184.
2. A.J. Giannini and E.A. Slaby. Drugs of Abuse (MEDEC Books: 1989), Chapter 4, pp. 59-80.
3. M.A. Peat and L. Kopjak. "The Screening and Quantitation of Diazepam, Flurazepam, Chlordiazepoxide, and Their Metabolites in Blood and Plasma by Electron-Capture Gas. Chromatography and High Pressure Liquid Chromatography," *J. Forensic Sci*., Vol. 24 (1979), pgs. 46-54.
4. H. Schultz. "Modern Screening Strategies in Analytical Toxicology with Special Regard to New Benzodiazepines," *J. Legal. Med*., Vol. 100 (1988), pgs. 19-37.
5. J.G. Langner, B.K. Gan, R.H. Liu, L.D. Baugh, P. Chand, J.L. Weng, et al. "Enzymatic Digestion, Solid-Phase Extraction, and Gas Chromatography/Mass Spectrometry of Derivatized Intact Oxazepam in Urine," *Clin. Chem*., Vol. 37 (1991), pgs. 1596-1601.
6. R.L. Fitzgerald, D.A. Rexin, and D.A. Herold. "Benzodiazepine Analysis by Negative Chemical Ionization Gas Chromatography/Mass Spectrometry," *J. Anal. Toxicol*., Vol. 17, pgs. 342-347.

Ketamine

1. The Merck Index. 13th ed. Whitehouse Station: Merck & Co., Inc., 2001.
2. Drug Facts and Comparisons. 55th ed. St. Louis: Facts and Comparisons, 2001.
3. White, Will E. "This is Your Brain on Dissociatives" Oct. 1998. http://www.erowid.org/chemicals/dxm/dxm_health1.shtml
4. Sass, W. and Fusari, S. "Comprehensive Description." Anal. Profiles Drugs Subs. vol. 6. ppg 297-322 (1977).
5. Goldenthal, E. "Toxicity." Toxicol. Appl. Pharmacol. vol 18. pg 185 (1980).
6. Geisslinger, G. et al. "Enantioselective HPLC determination in plasma." J. of Chromatog. vol. 568. pg 165 (1991).
7. US Pharmacopia, The National Formulary. Taunton: US Pharmacopeial Convention, Inc., 1995.

Marijuana Test

1. Johansson, E., Gillespie, H.K., Halldin, M.M., *J. Anal. Toxicol*., 14: 176-180 (1990).
2. El Sohly, M.A., Jones, A.B., El Sohly, H.N., *J. Anal. Toxicol*., 14: 277-279 (1990)14: 227-279 (1990).
3. Foltz, R.L., Sunshine, I., *J. Anal. Toxicol*., 14: 375-378 (1990).
4. Wimbish, G.H., Johnson, K.D., *J. Anal. Toxicol*., 14: 292-295 (1990).
5. Nakamura, G.R., Meeks, R.D., Stall, W.J., *J. Forensic Sci*., 35(4): 792-796 (1990).
6. Jenkins, A.J., Mills, L.C., Darwin, W.D., Huestis, M.A., Cone, E.J., Mitchell, J.M., *J. Anal. Toxicol*., 17:6.
7. Hollister, L.E., Kanter, S.L., Board, R.D., Green D.E. *Res. Com. Chem. Pathol. Pharmacol*, 8: 579-584 (1974).

Methadone Test

1. B.J. Rounsaville, M.M. Weissman, P.H. Rosenberger, et.al. "Diagnosis and Symptoms of Depression in Opiate Addicts: Course and Relationship to Treatment Outcome," *Arch. Gen. Psychiatry* 39 (1982): 151-56.
2. B.J. Rounsaville and H.D. Kleber, "Psychiatric Disorders and the Course of Diagnostic Stability," in S.M. Mirin, e.d., *Substance Abuse and Psychopathology* (American Psychiatric Press, Washington, D.C., 1984): 134-51.
3. C.A. Dackis and M.S. Gold. "Depression in Opiate Addicts," ibid, pp. 20-40.
4. J.B. Wyngarrden, LH Jr., eds., *Cecil Textbook of Medicine* (WB Saunders Co.: Philadelphia, 1988), pp. 57 and 60.11970-89 (1988).

3,4 Methylenedioxymethamphetamine Test

1. Mandatory Guidelines for Federal Workplace Drug Testing Programs, *Fed. Regist*., 53(69): 11970-89 (1988).
2. Cody, J.T., Schwarzhoff, R., *J. Anal. Toxicol*., 17: 26-30 (1993).
3. Urine Testing for Drugs of Abuse, *NIDA Research Monograph* 73, (1986).
4. Blum, K., Handbook of Abusable Drugs, *Gardner Press*, Inc., New York, 1st Ed., (1984)
5. Dasgupta, A., Saldana, S., Kinnaman, G., Smith, M., Johansen, K., *Clin. Chem*., 39:104-108 (1993).
6. *FDA Guidance for labeling Urine Drugs of Abuse Screening Testing*, Kshitij Mohan, 7/21/1987.
7. Baselt, R.C., Disposition of Toxic Drugs and Chemicals in Man, 2nd Ed., *Biomedical Publ*., Davis, CA. p. 488 (1982).
8. Tietz, N.W.: *Clinical Guide to Laboratory Tests;* W.B. Saunders Company, (1976).
9. Ellerbe, P., Long, T., Welch, M.J., *J. Anal. Toxicol*., 17: 165-170 (1993).

Opiate Test

1. Huang, W., Andollo, W., Hearn W.L., *J. Anal. Toxicol*., 16: 307-310 (1992).
2. Cone, E.J., Dickerson, S., Paul, B.D., Mitchell, J.M., *J. Anal. Toxicol*., 17: 156-164 (1993).
3. Glare, P.A., Walsh, T.D., and Pippenger, C.E., *Ther. Drug Monit*., 13: 226-232 (1991).
4. Walsh, T.D., Cheater, F.M., *Pharm. J*., 10: 525-527 (1983).
5. Mitchell, J.M., Paul, B.D., Welch, P., Cone, E.J., *J. Anal. Toxicol*., 15: 49-53 (1991).

Oxycodone Test

1. Bolan, E.A., et al., Synergy between opioid ligands: evidence for functional interactions among opioid receptor subtypes. *J. Pharmacol. Exp. Ther.* 303, 557-562 (2002).
2. Ross, F.B., and Smith, M.T., The intrinsic antinociceptive effects of oxycodone appear to opioid receptor mediated. *Pain* 73, 151-157 (1997).

Phencyclidine Test

1. Froelich, P.E., Gross, G.: Separation and Detection of Phencyclidine in Urine by Gas Chromatography, *J. Chromatograph* 1977; 137; 135-143.
2. Gupta R.C. et al: Determination of Phencyclidine in Urine and Illicit Street Drug Samples, *Clin. Toxicol* 1975; 8:611-621.
3. Oellerich, M.: Enzyme Immunoassays In Clinical Chemistry: Present Status and Trends, *J. Clin. Chem. Biochem*., 1980;18:197-208.
4. Anilineo, Pitts, F.N.: Phencyclidine (PCP): A Review and Perspectives. *CRC Crit. Rev. Toxicol* 1982; 10:145-177.

Propoxyphene Test

1. Gilman AG, Rall TW, Nies AS, Taylor P eds., Goodman and Gilman's the Pharmacological Basis of Therapeutics, 8th ed., New York, Pergamon Press, 1990, p509.
2. Wilson J, Abused Drugs II – A Laboratory Pocket Guide, *AACC Press*, Washington, DC, 1994, p64.

Tramadol

1. The Merck Index. 13th ed. Whitehouse Station: Merck & Co., Inc., 2001.
2. Drug Facts and Comparisons. 55th ed. St. Louis: Facts and Comparisons, 2001.
3. "Ultram brand of Tramadol Hydrochloride." http://opioids.com/tramadol/prescribe.html.
4. Raffa, R. et al. "Mechanism of action study." *J. of Pharmacol. Exp. Ther.* vol. 267. 331 (1993).
5. Elsing, B. and G. Blaschke. "HPLC determination in urine." *J. of Chomatog.* vol. 612. 223 (1993).
6. US Pharmacopia, The National Formulary. Taunton: US Pharmacopeial Convention, Inc., 1995.

Tricyclic Antidepressant Test

1. Drug Facts and Comparisons, 55th edition, *St. Louis, A. Wolters Kluwer Co. 2001*., 902-911.
2. Wong R., The Effect of adulterants on urine screen for drug of abuse: Detection by an on-site dipstick Device, *Am. Clin. Lab*., 2002: 21(3); 14-18.
3. Fed. Register. Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs: 53, 69, 11970-11979 (1988).
4. U.S. Department of Transportation, Drug Testing Procedures Handbook.

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