CLIA*waived*™ *Inc.* Multiple Drug Cup Test

ONE STEP ONSITE DRUG CUP

REF *6xxxx*

CLIA-Waived — Instructions — IVD

INTENDED USE

The **CLIA*waived* Multidrug** cup is an immunochromatographic assay for rapid, qualitative detection of drug combinations and their principal metabolites in urine at specified cut-off concentrations. In the **CLIA*waived*** Multidrug cup may denote any number of drugs, 1 through 11. These drug combinations may be composed from any of the following drugs, at the noted cut-off concentrations:

DRUG CLASS	ABBREVIATIONS	SENSITIVITY
AMPHETAMINE	AMP	1000 ng/ml
BARBITURATES	BAR	300 ng/ml
BENZODIAZEPINES	BZD	300 ng/ml
COCAINE/BENZOYLECGONINE	COC/BEG	300 ng/ml
MARIJUANA	THC	50 ng/ml
METHADONE	MAD	300 ng/ml
METHAMPHETAMINE	MET	1000 ng/ml
OPIATES/MORPHINE	OPI/MOR	2000 ng/ml
OXYCODONE	OXY	100 ng/ml
PHENCYCLIDINE	PCP	25 ng/ml
TRICYCLIC ANTIDEPRESSANT	TCA	1000 ng/ml

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 **CLIA*waived* Multidrug** cup 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 **CLIA*waived* Multidrug** 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 **CLIA*waived* Multidrug** 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.

REAGENTS AND MATERIAL PROVIDED

1. Test Devices	Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.
2. Test Instructions	REF *PI-6xxxx*
Optional:	
3. Negative Control I	Contains buffered protein solution with sodium azide. REF 4010N
4. Amphetamine Positive Control	Contains AMP at 3000 ng/ml in a buffered protein solution with sodium azide. REF 11120P-B
5. Barbiturates Positive Control	Contains BAR at 1000 ng/ml in a buffered protein solution with sodium azide. REF 18040P
6. Benzodiazepines Positive Control	Contains BZD at 1000 ng/ml in a buffered protein solution with sodium azide. REF 18020P
7. Cocaine Positive Control	Contains COC/BEG at 1000 ng/ml in a buffered protein solution with sodium azide. REF 12000P
8. Marijuana Positive Control	Contains THC at 150 ng/ml in a buffered protein solution with sodium azide. REF 13020P
9. Methadone Positive Control	Contains MAD at 1000 ng/ml in a buffered protein solution with sodium azide. REF 19020P
10. Methamphetamine Positive Control	Contains MET at 3000 ng/ml in a buffered protein solution with sodium azide. REF 11320P-B
11. Opiates Positive Control	Contains OPI/MOR at 5000 ng/ml in a buffered protein solution with sodium azide. REF 11220P-B
12. Oxycodone Positive Control	Contains OXY at 300 ng/ml in a buffered protein solution with sodium azide. REF 19080P
13. Phencyclidine Positive Control	Contains PCP at 100 ng/ml in a buffered protein solution with sodium azide. REF 14020P
14. Tricyclic Antidepressant Positive Control	Contains TCA at 3000 ng/ml in a buffered protein solution with sodium azide. REF 19092P-B

MATERIALS REQUIRED BUT NOT PROVIDED

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

WARNINGS AND PRECAUTIONS

1. Do not use the test device beyond the expiration date.
2. 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.
3. 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

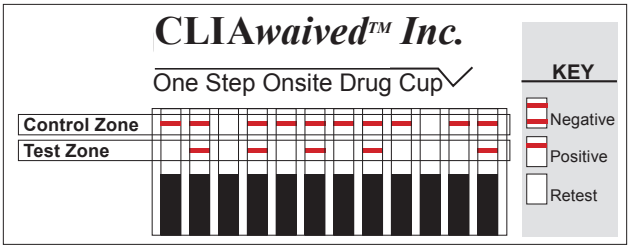
Fresh urine specimens should be collected directly into the cup. The **CLIA*waived* Multidrug** device employs a **thermal strip which should be checked immediately** after collection to validate urine specimen. SAMHSA regulations specify that any temperature below 90.5° F must be considered adulterated.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

Note: *Urine specimens can be transferred from a urine collection container into* **CLIA*waived* Multidrug** *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. Read the results at 5 minutes. Do not interpret results after 30 minutes.

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



INTERPRETATION OF RESULTS

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 ensure 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 **CLIA*waived* Multidrug** cup 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 **CLIA*waived* X Multidrug** 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 positive results for Amphetamine at 1000 ng/ml cut-off level:

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

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

Cocaine	*300 ng/ml*
Benzoylecgonine	*300 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*
Δ 8-THC.	*7500 ng/ml*
Δ 9-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:

Methadone	*300 ng/ml*
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 at 1000 ng/ml cut-off level:

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

The following Opiates-related substances yield a positive result for Opiates 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 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	*Nicotene*
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	*Promathazine*
Diphenhydramine	*Pseudoephedrine*
5,5-Diphenylhydantoin	*Quinine*
Dopamine	*Quinidine*
EDDP	*Salicylic Acid*
+ Ephedrine	*Sulindac*
- Ephedrine	*Sustiva*
(+/-) Epinephrine	*Theophyline*
Erythromycin	*Thioridazine*
Ethanol	*Tramadol*
Fentanyl	*d(+)-Trehalose*
Fluxetine	*Trifluoperazine*

3. Accuracy: The accuracy of the **CLIA*waived* Multidrug** 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 (AMP) 1000 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
CLIA*waived* Positive	**47**	**3**
CLIA*waived* Negative	**0**	**40**

When compared to GC/Mass the relative sensitivity was computed to be 47/47 or 100%. The relative specificity was computed to be 40/43 or 93%. The concordance of the combined data with respect to GC/Mass was 87/90 or 96.6 %.

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

	GC/MS Positive	GC/MS Negative
CLIA*waived* Positive	**27**	**2**
CLIA*waived* Negative	**0**	**31**

When compared to GC/Mass the relative sensitivity was computed to be 27/27 or 100%. The relative specificity was computed to be 31/33 or 94%. The concordance of the combined data with respect to GC/Mass was 58/60 or 97%.

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

	GC/MS Positive	GC/MS Negative
CLIA*waived* Positive	**29**	**1**
CLIA*waived* Negative	**0**	**30**

When compared to GC/Mass the relative sensitivity was computed to be 29/29 or 100%. The relative specificity was computed to be 30/31 or 96.7%. The concordance of the combined data with respect to GC/Mass was 59/60 or 98.3%.

3.4 Cocaine (COC) 300 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
CLIA*waived* Positive	**30**	**0**
CLIA*waived* Negative	**0**	**30**

When compared to GC/Mass the relative sensitivity was computed to be 30/30 or 100%. The relative specificity was computed to be 30/30 or 100%. The concordance of the combined data with respect to GC/Mass was 60/60 or 100%.

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

	GC/MS Positive	GC/MS Negative
CLIA*waived* Positive	**32**	**0**
CLIA*waived* Negative	**0**	**31**

When compared to GC/Mass the relative sensitivity was computed to be 32/32 or 100%. The relative specificity was computed to be 31/31 or 100%. The concordance of the combined data with respect to GC/Mass was 63/63 or 100%.

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

	GC/MS Positive	GC/MS Negative
CLIA*waived* Positive	**30**	**0**
CLIA*waived* Negative	**0**	**30**

When compared to GC/Mass the relative sensitivity was computed to be 30/30 or 100%. The relative specificity was computed to be 30/30 or 100%. The concordance of the combined data with respect to GC/Mass was 60/60 or 100%.

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

	GC/MS Positive	GC/MS Negative
CLIA*waived* Positive	**30**	**0**
CLIA*waived* Negative	**0**	**30**

When compared to GC/Mass the relative sensitivity was computed to be 30/30 or 100%. The relative specificity was computed to be 30/30 or 100%. The concordance of the combined data with respect to GC/Mass was 60/60 or 100%.

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

	GC/MS Positive	GC/MS Negative
CLIA*waived* Positive	**29**	**0**
CLIA*waived* Negative	**0**	**31**

When compared to GC/Mass the relative sensitivity was computed to be 29/29 or 100%. The relative specificity was computed to be 31/31 or 100%. The concordance of the combined data with respect to GC/Mass was 60/60 or 100%.

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

	GC/MS Positive	GC/MS Negative
CLIA*waived* Positive	**50**	**0**
CLIA*waived* Negative	**0**	**20**

When compared to GC/Mass the relative sensitivity was computed to be 50/50 or 100%. The relative specificity was computed to be 20/20 or 100%. The concordance of the combined data with respect to GC/Mass was 70/70 or 100%.

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

	GC/MS Positive	GC/MS Negative
CLIA*waived* Positive	**22**	**4**
CLIA*waived* Negative	**0**	**34**

When compared to GC/Mass the relative sensitivity was computed to be 22/22 or 100%. The relative specificity was computed to be 34/38 or 90%. The concordance of the combined data with respect to GC/Mass was 56/60 or 93.3%.

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

	GC/MS Positive	GC/MS Negative
CLIA*waived* Positive	**16**	**1**
CLIA*waived* Negative	**0**	**22**

When compared to GC/Mass 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/Mass was 38/39 or 97.4%.

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 Benzodi-azepines 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. 5.M.A. Pear and L. Kopjak, "The Screening and Quantitation of Diaz-epam, 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.

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.

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.
5. M.J. Ellenhorn and D.G. Barceloux. *Medical Toxicology* (Elsevier Science Publishing Co., Inc., NY, 1988), pp. 714-18.

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 betweenμ 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 bek-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.

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.