



National Collection Network

CRLstat™ Monitect® 7 Multi-Drug Screen Panel BAR300/BZO300/OPI2000/MET1000/

THC50/COC300/PCP25

Catalog # X04-SC10

Intended Use

The NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel is an *in vitro* screen test for the rapid detection of barbiturates, benzodiazepines, opiates, methamphetamine, THC, cocaine and phencyclidine, in human urine at or above the following cut-off concentrations:

BAR	Secobarbital	300 ng/ml
BZO	Oxazepam	300 ng/ml
OPI	Morphine	2000 ng/ml †
MET	Methamphetamine	1000 ng/ml †
THC	11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml †
COC	Benzoyllecgonine	300 ng/ml †
PCP	Phencyclidine	25 ng/ml †

† SAMSHA mandated cut-off concentration

The NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel provides visual qualitative results and is intended for professional *in vitro* diagnostic use only. It is not intended for over-the-counter sale to non-professionals.

The NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel provides only a preliminary screening test result. For a quantitative analytical result or to confirm positive results obtained by CRLstat™, a more specific alternative method must be used. The Substance Abuse Mental Health Sources Administration (SAMHSA), formerly the National Institute on Drug Abuse (NIDA) has established Gas Chromatography/Mass Spectrometry (GC/MS) as the preferred confirmatory method.

Summary and Explanation

BAR: Barbiturates are a class of central nervous system depressants. Phenobarbital has been used as a daytime sedative and extensively as an anticonvulsant. Phenobarbital is an example of long acting barbiturate derivative while pentobarbital and secobarbital are examples of short acting barbiturate sedatives. Barbiturate abuse can lead not only to impaired motor coordination and mental disorder, but also to respiratory collapse, coma and even death. Short acting barbiturates will generally be excreted in urine as metabolites, while long acting barbiturates will primarily appear unchanged. Barbiturates normally remain detectable in urine for 4 to 6 days after use (up to 30 days for phenobarbital).^{2,3}

BZO: Benzodiazepines are anxiolytic drugs that are most widely prescribed and used as anti-anxiety agents. They are also used as hypnotics, muscle relaxants and anti-convulsants. Some metabolites of benzodiazepines also exhibit pharmacological activities. Use of benzodiazepines can result in drowsiness and confusion; it also potentiates alcohol and other central nervous system depressants. Psychological and physical dependence on benzodiazepines can develop if higher doses of the drug are given over a prolonged period.^{1,2} Benzodiazepines are taken orally or by injection. The drug is metabolized in the liver and excreted in the urine as the parent compound or as oxazepam (in the case of chlorodiazepoxide and diazepam). Oxazepam is detectable in the urine for up to 7 days.^{2,3}

OPI: Heroin, morphine and codeine are opiates that are derived from the resin of the opium poppy. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide may both be found in the urine of a person who has taken only heroin. The body also converts codeine to morphine. Thus, the presence of morphine (or morphine metabolite) in the urine indicates heroin, morphine and/or codeine use. Generally, morphine and other opiates can be detected in the urine within 2 to 6 hours after use and remains detectable up to 3 days.^{2,3} However, the length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of usage, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity and diet.

MET: Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Methamphetamine use in acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. Methamphetamine is excreted in the urine as amphetamine and oxidized as deaminated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine can be detected in the urine within 4-6 hours after use and for 3-5 days, depending on urine pH level.^{2,3}

THC: THC use may impair short-term memory and inhibit learning capacity. It may also alter mood and sensory perceptions, cause loss of coordination, induce anxiety, paranoia, hallucinations, depression, confusion, and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur. Long-term THC use may be associated with behavioral disorders. Withdrawal from marijuana use may produce restlessness, insomnia, anorexia, and nausea.

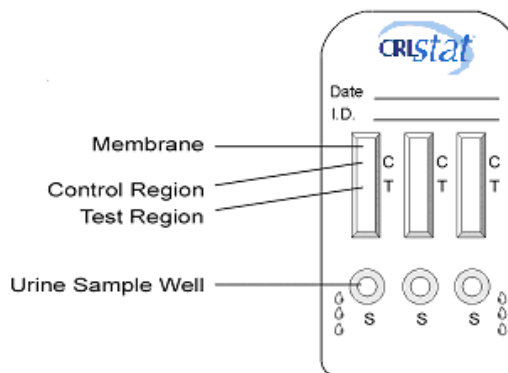
COC: Cocaine derived from the leaves of the coca plant, is a potent central nervous system stimulant, and has been used as a local anesthetic. Cocaine use induces euphoria, confidence, and a sense of increased energy; these psychological effects are accompanied by increased heart rate, pupil dilation, fever, tremors, and sweating. Cocaine is generally smoked or administered intravenously or orally. Cocaine base can be smoked in the form commonly known as "crack", which is likely to lead to dependence since the effect is more rapid and heightened. Cocaine is primarily excreted as benzoyllecgonine and can generally be detected for 24-60 hours after cocaine use or exposure.²

PCP: Phencyclidine is an atrychlohexylamine that is used as a veterinary anesthetic. It is used illegally as a hallucinogen, and is commonly referred to as PCP, angel dust, crystal cyclone, love boat, hog, or killer weed. PCP can produce lethargy, disorientation, and loss of coordination, visual distortion, euphoria, ataxia, and even coma. PCP can be taken orally, by nasal ingestion, smoking, or intravenous injection. It is metabolized in the liver and excreted through the kidneys. The half-life of phencyclidine is about three days.

Test Principle

Urine based screening tests for drugs of abuse are available from simple immunoassay tests to complex analytical procedures. Due to speed and sensitivity, immunoassays have become the most widely accepted method for urine-based drugs of abuse screening tests. The CRLstat™ family of urine drug screen tests is based on the principle of the highly specific immunochemical reactions between antigens and antibodies.¹ The NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel is based on a competitive immunoassay procedure in which an immobilized drug conjugate competes with the drug present in urine for limited antibody binding sites. The test device contains three membrane strips, onto which the drug conjugates are pre-coated at specific regions known as the test regions. Colored antibody-colloidal gold conjugates are coated onto a pad and placed at one end of each membrane. In the test procedure, a sample of urine is added to each of the sample wells and allowed to migrate across the membranes by capillary action. If any drug is present in the urine sample, it competes with the drug conjugate, which is immobilized on the membrane, for the limited binding sites on the colored antibody colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibodies, and the colored colloidal gold conjugate cannot bind to the drug conjugate on the membrane. The absence of a color band at the test region indicates a positive result for that particular test. If there is no drug or drug metabolite present to compete for the binding sites of the colored colloidal gold conjugate, it binds to the immobilized drug conjugate to form a visible band at the test region of the membrane. The presence of a color band at the test region indicates a negative result for the test.

A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip at the control region (C) to indicate that the test performed properly. This control band should always appear regardless of the presence of drug or metabolite.



Reagents

Protein conjugates for barbiturate, benzodiazepine, morphine, methamphetamine, THC, benzoyllecgonine and phencyclidine are coated onto the test regions of the membranes.

The colored conjugate pad for each strip contains monoclonal antibodies for barbiturate, benzodiazepine, morphine, methamphetamine, THC, benzoyllecgonine and phencyclidine.

Materials Provided

Each NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel Kit contains:

- 1 Package Insert (directions for use).
- 25 Test Cassettes (Test Cards). Each cassette test is packaged individually in a foil pouch with a disposable pipette and a desiccant.

Warnings and Precautions

- FOR *IN VITRO* DIAGNOSTIC USE ONLY
- For professional use only.
- The test device should remain in its original sealed pouch until ready for use. Discard the test device if package is ripped or torn.
- Handle all urine specimens as if potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container and dropper pipette for each urine sample.

Product Storage

The NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel pouch should be stored at room temperature (15°–30°C) until the expiration date on the pouch. Do not open pouch until ready to perform the assay.

Specimen Collection and Handling

The NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel is formulated for use with urine specimens. Use only freshly voided, untreated urine.⁴ Do not centrifuge or add preservatives to urine. Urine samples should be collected so that testing may be performed as soon as possible, preferably during the same day. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

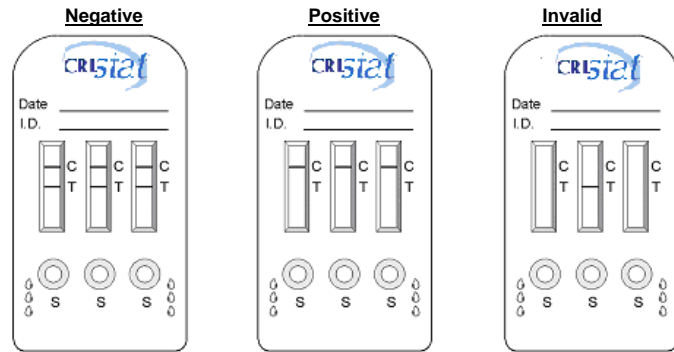
Note: All materials coming into contact with urine specimens should be handled and disposed of as if potentially infectious. Avoid direct contact and follow good laboratory practice.

Test Procedure

IMPORTANT: Donor sample (urine specimen) should be brought to room temperature prior to testing. Do not open pouch until ready to perform the assay.

1. Remove the test device from the sealed pouch.
2. Draw the urine sample up the pipette and dispense 3 drops (approximately 0.15 ml) into each of the sample wells. Avoid adding drops that contain air since air bubbles in the well may cause uneven flow or prevent the flow of the sample onto the test strip.
3. **Once the control bands (C) appear in 5 minutes or less, results are ready to interpret. Results are stable and may be interpreted up to 15 minutes after control bands form.**

Interpretation of Results



*Note: The above results are for illustration purposes only, see the explanations below for interpretation of results.

Negative: The presence of a colored band at the control region (C) and a colored band at a specific test region regardless of the intensity indicate that the result is negative for that particular test.

Positive: The presence of a colored band at the control region (C) and the absence of a colored band at the test region indicate a positive result for that particular test.

Invalid: No band appears at the control region (C). The test is inconclusive even if there is a band in the test region. If the test device does not produce a band at the control region, check testing procedures, samples, and/or control materials, and repeat the test using a new device.

Important: Read each test independently. Do not compare color intensity of one test to another. Samples with faint test bands at the test regions should be considered negative. The NCN CRLstat™ Monitect® 7 Multi-Drug Screen panel provides qualitative results for the presence of drug(s) at specified cut-off concentrations. It is recommended that samples with questionable test bands and positive results be confirmed with a more specific quantitative method (Gas Chromatography/Mass Spectrometry).

Quality Control

Internal control: The NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel device has a built-in internal procedural control. The appearance of the control band (C) is considered an internal procedural control. This band should always appear if adequate sample volume is used and the testing procedure is followed.

External control: It is recommended that negative and positive urine controls be used to initially test each new lot of product to ensure proper kit performance. The same assay procedure should be followed with external control materials as

with a urine specimen. When external controls do not produce the expected results, do not run test specimens. Follow the proper federal, state and local guidelines when running external controls.

Quality control testing at regular intervals is a good laboratory practice and may be required by federal, state or local guidelines. Always check with the appropriate licensing or accrediting bodies to ensure that the quality program employed meets the established standards.

Limitations of Procedure

- The assay is designed for use with human urine only.
- Positive results only indicate the presence of drug/metabolites and do not indicate or measure intoxication.
- There is a possibility that technical or procedural error as well as other substances in certain food and medication may interfere with the test and cause false results. See Specificity section for the list of substances that will produce either positive results, or that do not interfere with test performance.
- If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drugs of abuse and certain food and/or medication.
- If it is suspected that the sample may have been mislabeled a new specimen should be collected.
- If it is suspected that the sample may have been tampered, a new specimen should be collected.

Performance Characteristics

Precision

For each specific drug test, drug-free normal urine was spiked with a drug standard to various concentrations (-50%, -25%, +25% and +50%). For each concentration, a total of 25 tests were performed to validate the test performance around the cut-off concentration. The results for each of the NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panels are summarized below:

Drug Test	Total # of Test / Conc.	Concentration							
		-50%		-25%		+25%		+50%	
		-	+	-	+	-	+	-	+
BAR in BAR/BZO strip	25	25	0	25	0	3	22	0	25
BZO in BAR/BZO strip	25	25	0	25	0	5	20	0	25
OPI in OPI/MET strip	25	25	0	25	0	3	22	0	25
MET in OPI/MET strip	25	25	0	25	0	3	22	0	25
THC in THC/COC/PCP strip	25	25	0	25	0	4	21	0	25
COC in THC/COC/PCP strip	25	25	0	25	0	4	21	2	23
PCP in THC/COC/PCP strip	25	25	0	25	0	4	21	1	24

Accuracy

The accuracy of the NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel was evaluated in comparison to the results from GC/MS analysis or predicate method using commercially available immunoassay. 40 presumed negative urine samples were collected from volunteer donors and tested with both the NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel and the predicate method. Of the 40 presumed negative urine samples tested, all were found negative by both methods (100% agreement).

Additionally, for each drug test, a minimum of 40 clinical urine samples previously analyzed by GC/MS method with known concentration(s) of drug(s) were blind labeled and evaluated. The results are summarized below:

Drug Test		GC/MS Neg. (below C/O)	GC/MS Near Pos. (+25% to C/O)	GC/MS Pos. (> +25%)	% Agreement w/ GC/MS	
					Neg (-)	Pos (+)
BAR in BAR/BZO strip	Pos. (+)	0	4	35	100%	98%
	Neg. (-)	15	1	0		
BZO in BAR/BZO strip	Pos. (+)	0	5	34	100%	98%
	Neg. (-)	20	1	0		
OPI in OPI/MET strip	Pos. (+)	0	5	35	100%	100%
	Neg. (-)	5	0	0		
MET in OPI/MET strip	Pos. (+)	0	4	36	100%	100%
	Neg. (-)	3	0	0		
THC in THC/COC/PCP strip	Pos. (+)	0	5	34	100%	98%
	Neg. (-)	5	1	0		
COC in THC/COC/PCP strip	Pos. (+)	0	4	35	100%	98%
	Neg. (-)	5	1	0		
PCP in THC/COC/PCP strip	Pos. (+)	0	9	30	100%	98%
	Neg. (-)	7	1	0		

Specificity

The NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel performance at cut-off level is not affected by any urine samples with pH range of 4.5 to 8.5 and specific gravity range of 1.005 to 1.030.

The specificity study for each drug test was evaluated by adding structurally related compounds to normal human urine. The results are expressed as the amount of the compound, in ng/ml, that produced a positive result.

BAR 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Alphenal	400	Butalbital	3,000
Allobarbital	1,500	Butethal	400

Amobarbital	1,500	Pentobarbital	400
Aprobarbital	400	Phenobarbital	400
Barbital	400	Secobarbital	300
Butabarbital	400		

BZO 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Alprazolam	150	Lorazepam	1,500
Bromazepam	800	Lormetazepam	1,000
Chlordiazepoxide	2,000	Medazepam	2,000
Clobazam	200	Nitrazepam	1,000
Clonazepam	4,000	Nordiazepam	100
Delorazepam	6,000	Oxazepam	300
Diazepam	150	Prazepam	1,000
Estazolam	300	Temazepam	150
Flunitrazepam	1,000	Triazolam	1,500
Flurazepam	300		

OPI 2000 ng/ml

Compound	ng/ml	Compound	ng/ml
6-Acetylmorphine	2,000	Hydrocodone	5,000
Codeine	2,000	Hydromorphone	2,500
Dihydrocodeine	2,000	Morphine	2,000
Ethyl morphine	2,000	Morphine-3-β-D-Glucuronide	5,000
Heroin	2,000	Nalorphine	20,000

MET 1000 ng/ml

Compound	ng/ml	Compound	ng/ml
Ephedrine	50,000	d-Methamphetamine	1,000
p-Hydroxymethamphetamine	10,000	l-Methamphetamine	50,000
3,4-MDMA	1000	Procaine	100,000

THC 50 ng/ml

Compound	ng/ml	Compound	ng/ml
Cannabidiol	100,000	11-hydroxy-Δ9-THC	2,500
Cannabinol	50,000	Δ-8-tetrahydrocannabinol	7,000
11-nor-Δ-8-THC-9-COOH	50	Δ-9-tetrahydrocannabinol	10,500
11-nor-Δ-9-THC-9-COOH	50		

COC 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Benzoylcegonine	300	Ecgonine	100,000

PCP 25 ng/ml

Compound	ng/ml
Phencyclidine	25

Interference

The following compounds were found not to cross-react with the NCN CRLstat™ Monitect® 7 Multi-Drug Screen Panel when tested at concentration of 100 µg/ml (100,000 ng/ml):

Acetaminophen (4-Acetamidophenol; APAP; N-Acetyl-p-aminophenol)	3-Hydroxyptiramine
Acetone	11-Hydroxy-Δ-9-THC (except THC assay)
6-Acetylmorphine (except OPI assay)	11-nor-Δ-9-THC-9-Carboxylic Acid (except THC assay)
Acetylsalicylic acid (Aspirin)	lbutrofen
Albumin	Imipramine
Allobarbital (except BAR assay)	(-) Isoproterenol
Alphenal (except BAR assay)	(+/-) Isoproterenol
Alprazolam (except BZO assay)	Lidocaine
Aminopyrine	Lorazepam (except BZO assay)
Amiripryline	Lormetazepam (except BZO assay)
Amobarbital (except BAR assay)	Medazepam (except BZO assay)
Amoxapine	Meperidine
Amoxicillin	Methadone
Aprobarbital (except BAR assay)	(+/-) Methadone
d-Amphetamine (except MET assay)	Methamphetamine (except MET assay)
l-Amphetamine (except MET assay)	Methaqualone
Ampicillin	Methoxyphenamine
Apomorphine	N-Methyl-Ephedrine
l-Ascorbic Acid (Vitamin C)	(1R,2S) N-Methyl-Ephedrine
Aspartame	2-Methylamine-Propiophenone
Aspartamine	(+/-) 3,4-Methylenedioxyamphetamine (except MET assay)
Atropine	(+/-) 3,4-Methylenedioxyamphetamine (except AMP assay)
Barbital (except BAR assay)	Methylphenidate
Benzilic acid	Morphine (except OPI assay)
Benzocaine (Ethyl p-Aminobenzoate)	Morphine-3-β-D-Glucuronide (except OPI assay)
Benzoic acid	Nalidixic acid
Benzoylcegonine (except COC assay)	Nalorphine (except for OPI assay)
Benzphetamine	Naloxone
Bilirubin	(+) Naproxen
Bromazepam (except BZO assay)	Niacinamide
(+) Brompheniramine	Nitrazepam (except BZO assay)
Butabarbital (except BAR assay)	Nordiazepam (except BZO assay)
Butalbital (except BAR assay)	
Butethal (except BAR assay)	
Caffeine	
Cannabidiol (except THC assay)	
Cannabinol (except THC assay)	
Chloralhydrate	

Chlordiazepam-HCl-Di(H ₂ O)	Nordoxepin
Chlordiazepoxide (except BZO assay)	(+/-) Norephedrine
Chloroquine	(+/-) Norephedrine-(+)
(+) Chlorpheniramine	Phenylpropanolamine
(+/-) Chlorpheniramine	Norethindrone
l-Chlorpheniramine	D-Norpropoxyphene
Chlorpromazine	Nortriptyline
Cholesterol	Oxalic Acid
Clobazam (except BZO assay)	Oxazepam (except BZO assay)
Clomipramine	Oxolinic acid
Clonazepam (except BZO assay)	Oxycodone
Codeine (except OPI assay)	Papaverine
Cortisone	Penicillin-G (Benzylpenicillin)
(-) Cotinine	Penicillin-G Phentermine
Creatine	Pentazocaine
Creatinine	Pentobarbital (except BAR assay)
Cyclobenzaprine	Perphenazine
Delorazepam (except BZO assay)	Phencyclidine (except PCP assay)
Deoxycorticosterone	Pheniramine
Desipramine	Phenobarbital (except BAR assay)
Desmethyldiazepam	Phenothiazine (Thiodiphenylamine)
Dexbrompheniramine	Phentermine (except AMP assay)
Dextromethorphan	Phenylephrine
Diazepam (except BZO assay)	β-Phenylethylamine
4-Dimethylaminoantipyrine	Prednisolone
Diphenhydramine	Prazepam (except BZO assay)
Dopamine (3-Hydroxytyramine)	Procaine
Doxepin	Promazine
Doxylamine	Promethazine
Dihydrocodeine (except OPI assay)	d-Propoxyphene
Ecgonine (except COC assay)	Protryptiline
Ecgonine Methyl Ester	d-Pseudoephedrine
(-) Ephedrine	Pyroliidine
(-) Epinephrine	Quinidine
(+) Epinephrine	Quinine
(+/-) Ephedrine (except MET assay)	Ranitidine
Erythromycin	Riboflavin
Estazolam (except BZO assay)	Salicylic acid
β-Estradiol	Secobarbital (except BAR assay)
Estrone-3-Sulfate	Serotonin
Ethanol	Sodium Chloride
Ethyl Morphine (except OPI assay)	Sulfamethazine
Ethyl-p-aminobenzoate	Sulindac
2-Ethylidene-1.5-Dimethyl-1-3.3-Diphenylpyrrolidone (except MTD assay)	Temazepam (except BZO assay)
Flunitrazepam (except BZO assay)	Tetracycline
Flurazepam (except BZO assay)	Δ8-THC (except THC assay)
Furosemide	Δ9-THC (except THC assay)
Gentisic acid	11-Nor-Δ8-THC-9-Carboxylic Acid (except THC assay)
Glucose	Tetrahydrocortisone
Glutethimide	Thiamine
Guaiacol Glyceryl Ether	Thioridazine
Hemoglobin	Triazolam (except BZO assay)
Heroin (except OPI assay)	Trifluoperazine
Hippuric acid	Trimethobenzamide
Hydrochlorothizide	Trimipramine Maleate
Hydrocodone (except OPI assay)	Tryptamine
Hydrocortisone	d,l-Tryptophan
Hydromorphone (except OPI assay)	Tyramine
p-Hydroxymethamphetamine (except MET assay)	d,l-Tyrosine
	Uric Acid
	Verapamil
	Zomepirac

Bibliography of Suggested Reading

1. Wong, R., The Current Status of Drug Testing in the US Workforce, Am. Clin. Lab., 2002; 21(1): 21-23
2. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, Davis, CA, 1982.
3. Urine testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.
4. Wong, R., The Effect of Adulterants on Urine Screen for Drugs of Abuse: Detection by an On-site Dipstick Device, Am. Clin. Lab., 2002; 21(3); 14-18
5. Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970-11979, 1988.
6. McBay, A.J. Clin. Chem. 33, 33B-40B, 1987.
7. Gilman, A.G., and Goodman, L.S. The Pharmacological Basis of Therapeutics, Eds. MacMillan Publishing, New York, NY, 1980.
8. Ringsrud, K.M and Linne, J.J., Urinalysis and Body Fluids, A color Text and Atlas, Mosby-Year Book, Inc., 1995.
9. U.S Department of Transportation, Drug Testing Procedures Handbook

Distributed by:
Clinical Reference Lab
8433 Quivira Road
Lenexa, KS 66215

