

DRUGS OF ABUSE TEST CUPS **14-DRUG PANEL WITH ADULTERANTS**Step by Step Instructions

For in vitro diagnostic use

The McKesson Consult® Drugs of Abuse Test Cup is a screening test for the rapid qualitative detection of multiple drugs and/or drug metabolites in human urine at or above the following cutoff concentrations:

THC	11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml
COC	Benzoylecgonine	150 ng/ml
OPI	Morphine	300 ng/ml
MET	d-Methamphetamine	500 ng/ml
AMP	d-Amphetamine	500 ng/ml
BZO	Oxazepam	300 ng/ml
BAR	Secobarbital	300 ng/ml
MTD	Methadone	300 ng/ml
BUPG	Buprenorphine Glucuronide	10 ng/ml
TCA	Nortriptyline	1000 ng/ml
MDMA	3,4-Methylenedioxymethamphetamine	500 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml

This test provides visual qualitative results and is intended for over-the-counter and prescription point-of-care use. The McKesson Consult Drugs of Abuse Test Cup is available in multiple drug analyte combinations.

This test provides only preliminary results and is the first step in a two-step process for identifying drugs in urine. The second step is confirming the results at a certified laboratory. To confirm preliminary positive results obtained by the McKesson Consult Drugs of Abuse Test Cup, a more specific alternative method such as Gas Chromatography-Mass Spectrometry (GC-MS) or Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) must be used. Clinical consideration and professional judgment must be applied to any drug test result, particularly when a preliminary positive result is indicated.

TESTING MATERIALS

The following materials are for testing an individual urine sample. Kits may contain supplies for testing 1 to 25 urine samples.

- ✓ Step-by-Step Test Instructions
- ✓ Individually Wrapped Test Lid
- ✓ Specimen Cup



Specimen
Collection Cup



Individually
Wrapped Test Lid

STORAGE

Store the McKesson Consult Drugs of Abuse Test Cup at room temperature 59°F to 86°F (15°C to 30°C).

INSTRUCTIONS

Step 1.

- a. Collect fresh urine in the specimen cup.
 Make sure the urine is above the minimum fill line.
- b. Open foil pouch. Remove test lid from pouch. Discard desiccant.





Step 2.

Twist the lid onto the cup. The cup lid must be closed tightly.

IMPORTANT: Cup lid must be secured tightly by twisting it a quarter turn AFTER lid is snug.



Step 3.

Tilt the cup on its legs to activate the test.

Read test results at 5 minutes. Do not read after 8 minutes.





Page **1** of **7**

INTERPRETATION OF RESULTS

Each strip contains two drug tests. The C region shows validity of a test result. The T1 region shows the result for Test 1. The T2 region shows the result for Test 2.

For C region:

The appearance of a line indicates a valid result.

No line means an **Invalid** result. If a test strip does not have a line in the C region, test results are **Invalid** for both T1 and T2 on that strip.

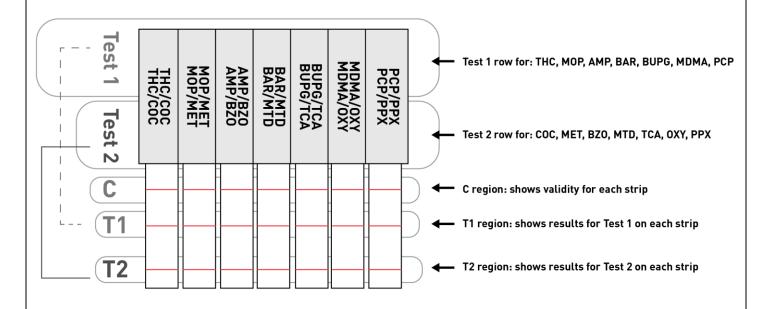
For T1 and T2 regions:

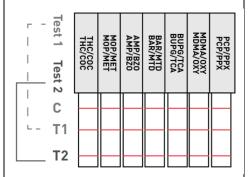
The appearance of a line indicates a **Negative** result.

Note: Any test line, even a very faint test line, is considered a negative result.

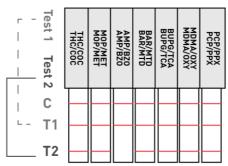
No line indicates a **Preliminary Positive** result.

Note: Any urine with preliminary positive results should be sent to a laboratory for confirmation.



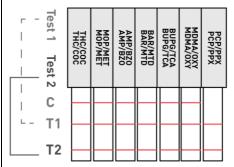


Example #1: There is a line appearing in both T1 and T2 regions on all test strips. Therefore, it is **Negative** for all tests.



Example #2: There is no line appearing in the T2 region on the third test strip.

Therefore, it is Preliminary Positive for BZO test. All other tests are Negative.



Example #3: There is no line appearing in the C region on the seventh test strip. Therefore, it is **Invalid** for both PCP and PPX tests. All other tests are **Negative**.

DETECTION LEVELS AND APPROXIMATE DETECTION TIMES

Drug	Test Identifier	Cut-off Level ¹	Minimum Detection Time ²	Maximum Detection Time ²
Marijuana	THC	50 ng/ml	1-3 hours	1-7 days
Cocaine	COC	150 ng/ml	2-6 hours	2-3 days
Opiates	MOP	300 ng/ml	2-6 hours	1-3 days
Methamphetamine	MET	500 ng/ml	4-6 hours	2-3 days
Amphetamine	AMP	500 ng/ml	4-6 hours	2-3 days
Ecstasy	MDMA	500 ng/ml	2-7 hours	2-4 days
Phencyclidine	PCP	25 ng/ml	4-6 hours	7-14 days
Propoxyphene	PPX	300 ng/ml	2-8 hours	2-7 days
Benzodiazepines	BZO	300 ng/ml	2-7 hours	1-4 days
Barbiturates	BAR	300 ng/ml	2-4 hours	1-3 weeks
Methadone	MTD	300 ng/ml	3-8 hours	1-3 days
Buprenorphine	BUPG	10 ng/ml	2-7 hours	1-6 days
Tricyclic Antidepressants	TCA	1000 ng/ml	8-12 hours	2-7 days
Oxycodone	OXY	100 ng/ml	1-3 hours	1-2 days

¹Cut-off level is the lowest drug concentration in the urine that can be detected by the McKesson Consult Drugs of Abuse Test Cup.

CONFIRMATION TESTING ITEMS

The following materials may be used to send an individual urine sample to a laboratory for confirmation testing. These items are included in over-the-counter kits.

✓ 1 Specimen Bag

✓ 2 Identification Labels

✓ 1 Mailing Label

Specimen Bag

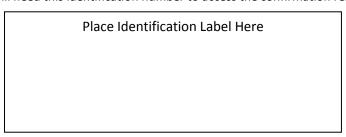
Identification Label

PROCEDURE FOR CONFIRMATION

The following procedure may be used for confirming preliminary positive results:

Step 1:

Make sure the lid is twisted tightly. Place a check mark in the box on both Identification Labels for the drug(s) with preliminary positive result. Place one Identification Label onto the McKesson Consult Drugs of Abuse Test Cup. Place the other Identification Label below for your record. You will need this identification number to access the confirmation result.



Step 2:

Place the labeled McKesson Consult Drugs of Abuse Test Cup into the Specimen Bag and seal the bag.

Step 3:

Place specimen into a shipping box and affix the Mailing Label. Drop the shipping box with POSTAGE into any mailbox. Specimen should be mailed within 24 hours of collection.

Step 4:

Obtain confirmation results:

 Results will be ready in 5 to 7 days after the sample is received in our laboratory (time for results may vary if using another laboratory).

² Drug clearance rates are dependent on many factors such as frequency of drug use, the amount of drug taken, metabolism rates, and even body fat content.

- Call 1-800-340-4029 to obtain confirmation result (for over-the-counter kit).
- You will need the identification number to access the confirmation result.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only (not for internal use).
- The test is for one time use only. It is not reusable.
- Do not use the McKesson Consult Drugs of Abuse Test Cup after the expiration date printed on the pouch.
- Keep the McKesson Consult Drugs of Abuse Test Cup in its original sealed pouch until ready for use. Do not use the test if the pouch is ripped or torn.
- Certain foods or medications may cause the test to give false results.
- Contaminated or tainted urine sample may give false results.
- Send specimen with preliminary positive or uncertain results to a laboratory for confirmation.
- Urine may contain infectious diseases. Always wear gloves and wash hands with soap after handling.
- Do not use this test if you are color-blind.

UNDERSTANDING THE TEST RESULTS & FOLLOW UP

What is a Preliminary Positive Result?

The McKesson Consult Drugs of Abuse Test Cup is a screening test to detect the presence of drugs in human urine. This means that if a drug is present, you will usually get a preliminary positive test result. It is important to send out the specimen to confirm the preliminary positive result. This is because certain foods, supplements, beverages, or medicines can affect the results of the McKesson Consult Drugs of Abuse Test Cup.

If the test results are preliminary positive, does it mean that you found drugs of abuse?

No. Take no serious actions until you get the laboratory's result. Many factors may cause a false positive result in the screening test. A positive test for a prescription drug does not mean that a person is abusing the drug. This is because the test does not indicate acceptable levels compared to abusive levels of prescribed drugs. This test cannot be used for legal purposes. If you get a preliminary positive test result, you should send the urine to a laboratory to confirm the test result. The confirmation test is called gas chromatography-mass spectrometry (or GC-MS) or liquid chromatography-tandem mass spectrometry (LC-MS/MS).

Many things can affect the accuracy of the tests, including (but not limited to):

- The way you did the test.
- The way you stored the test or urine.
- What the person ate or drank before taking the test.
- Any other prescription or over-the-counter drugs the person may have taken before the test.
- Note: Some over-the-counter medications will produce the same test results as illegally-abused amphetamines.

Where can I get some help?

Consult with a counselor, doctor, or a qualified professional to help you address drug abuse problems. The following organizations provide helpful resources on drug abuse prevention and recovery programs. These resources are for information purposes only.

Alcohol and Drug Information http://store.samhsa.gov/home
Community Anti-Drug Coalitions of America http://www.cadca.org
National Institute on Drug Abuse http://www.drugabuse.gov.

LIMITATIONS OF THE TEST

- The assay is designed for use with human urine only.
- Positive results indicate the presence of drug/metabolites only and do not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well as other substances in certain foods and medication may interfere with the test and cause false results. See the Specificity section for a list of substances that may produce positive results, and the Interference section for a list of compounds that were tested and did not interfere with the test.
- A positive drug result does not indicate the frequency or time of drug use, nor does it distinguish between drugs and certain foods and/or medications.
- 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 with, a new specimen should be collected.

For Professional Use

PROFESSIONAL KIT CONTENTS

- 1 Step-by-Step Test Instructions
- 25 Individually Wrapped Test Lids
- 25 Specimen Cups
- 25 Tamper-evident seals

TEST PRINCIPLE

The McKesson Consult Drugs of Abuse Test Cup is based on the principle of the highly specific immunochemical reactions between antigens and antibodies, which are used for the analysis of specific substances in urine. The test is based on a competitive immunoassay procedure in which immobilized drug conjugates compete with the drug(s) present in urine for limited binding sites of the antibody conjugated to colloidal gold. If there is drug or drug metabolite in the urine sample, the binding sites of the antibody become saturated and the antibody-colloidal gold conjugate cannot bind to the specific test region. The absence of a color band 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, a visible color band forms at the specific test region indicating a negative result for that particular test. A control band with a different antigen/antibody reaction should always appear regardless of the presence of drug or metabolite.

SPECIMEN COLLECTION AND HANDLING

Fresh urine does not require any special handling or pretreatment. A fresh urine sample should be collected in the specimen container provided. Urine samples should be tested as soon as possible after collection, preferably within the same day. Specimens that have been refrigerated or frozen must be 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.

QUALITY CONTROL

Internal control: The McKesson Consult Drugs of Abuse test device has built-in internal procedural controls. 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. Additionally, the background color should become clear and provide distinct test result. If the control band (C) does not appear then the test is invalid. The test should be repeated using a new device.

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. If 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.

PERFORMANCE CHARACTERISITCS

PRECISION

A study was conducted at two laboratories and one physician office in an effort to determine the precision of the McKesson Consult Drugs of Abuse Test Cup over 12 or more consecutive days. Testing was conducted on the Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methamphetamine,

Methylenedioxymethamphetamine, Methadone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants assays by operators using three different lots of product to demonstrate the within-run, between-run and between-operator precision. An identical panel of coded samples, containing drugs at the concentration of $\pm\,50\%$ cut-off level was labeled as a blind and tested at each site. The correlation with expected results was >99% across all lots and sites (with a 95% confidence interval).

ACCURACY

The accuracy of the McKesson Consult Drugs of Abuse Test Cup was evaluated in comparison to the results from GC-MS or LC-MS analysis. Thirty-six (36) negative drug-free urine samples were collected from volunteer donors and tested with both the McKesson Consult Drugs of Abuse Test Cup and the GC-MS or LC-MS method. Of the 36 negative urine samples tested, all were found negative by both methods. Additionally, for each drug test, a minimum of 40 clinical urine samples previously analyzed by GC-MS or LC-MS method with known concentration(s) of drug(s) values were blind labeled and evaluated. The results are summarized below:

Drug Test		GC-MS		GC-MS -50% to	GC-MS Cutoff to	GC-MS	% Agreement w/ GC-MS	
		Neg.	< -50%	Cutoff	+50%	> +50%	Neg (-)	Pos (+)
THC 50	Pos. (+)	0	0	1	6	35	07.70/	100%
	Neg. (-)	36	2	4	0	0	97.7%	
COC 150	Pos. (+)	0	0	3	3	37	92.7%	97.6%
	Neg. (-)	36	0	2	1	0	32.770	97.6%
МОР	Pos. (+)	0	0	3	7	34	92.5%	100%
300	Neg. (-)	36	0	1	0	0		
MET	Pos. (+)	0	0	0	5	67	4000/	96.0%
500	Neg. (-)	36	2	4	3	0	100%	
AMP	Pos. (+)	0	0	2	5	36	95.1%	100%
500	Neg. (-)	36	1	2	0	0		
BZO	Pos. (+)	0	0	3	4	39	92.5%	100%
300	Neg. (-)	36	0	1	0	0		
BAR	Pos. (+)	0	0	1	6	33	97.5%	95.1%
300	Neg. (-)	36	0	3	2	0		
MTD	Pos. (+)	0	0	0	3	36	100%	97.5%
300	Neg. (-)	36	0	4	1	0		
BUPG	Pos. (+)	0	0	1	4	38	97.5%	97.7%
10	Neg. (-)	36	0	3	1	0		
TCA	Pos. (+)	0	0	0	27	11	100%	02.70/
1000	Neg. (-)	36	0	4	3	0		92.7%
MDMA	Pos. (+)	0	0	1	3	40	97.5%	97.7%
500	Neg. (-)	36	0	3	1	0		
OXY	Pos. (+)	0	0	2	6	38	95.2%	1000/
100	Neg. (-)	36	0	4	0	0		100%
PCP	Pos. (+)	0	0	0	3	36	100%	% 95.1%
25	Neg. (-)	36	0	4	2	0		
PPX	Pos. (+)	0	0	2	4	36	95.0%	100%
300	Neg. (-)	36	0	2	0	0		

SPECIFICITY

The specificity for the McKesson Consult Drugs of Abuse Test Cup was determined by testing various drugs, drug metabolites, structurally related compounds, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine. The effect of specimens with various pH (4.5–9) and specific gravity (1.005–1.030) ranges was also evaluated and found not to interfere with the McKesson Consult Drugs of Abuse Test Cup.

The following compounds produced positive results when tested at or above the concentrations listed below. The calibrator for each test is marked with an asterisk (*).

AMP 500 ng/ml			
Compound	ng/ml	Compound	ng/ml
d-Amphetamine *	500	Phentermine	1,000
I-Amphetamine	20,000	β-Phenylethylamine	80,000
d,l-3,4-MDA	1,500		
BAR 300 ng/ml		Commonwed	
Compound Allobarbital	ng/ml	Compound Butalbital	ng/ml 300
Alphenal	1,500 400	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
α-Hydroxy Alprazolam	50	Lorazepam	1,500
Alprazolam	150	Lormetazepam	1,000
Bromazepam	800	Medazepam	2,000
Chlordiazepoxide	2,000	Nitrazepam	1,000
Clobazam	200	Nordiazepam	100
Clonazepam Delorazepam	4,000	Oxazepam *	300 1,000
Diazepam	6,000 150	Phenazepam Prazepam	1,000
Estazolam	300	Temazepam	150
Flunitrazepam	1,000	Triazolam	1,500
Flurazepam	300		,
BUPG 10ng/ml			
Compound	ng/ml	Compound	ng/ml
Buprenorphine	100	Norbuprenorphine	100
Buprenorphine Glucuronide *	10	Norbuprenorphine Glucuronide	
			100
COC 150 ng/ml	, ,		, ,
Compound	ng/ml	Compound	ng/ml
Benzoylecgonine *	150	Ecgonine	65,000
MDMA 500 ng/ml	ng/ml	Compound	ng/ml
Compound	ng/ml	Compound	ng/ml
•	ng/ml 2,000 250	Compound d,I-3,4-MDMA* d-Methamphetamine	ng/ml 500 50,000
Compound d,l-3,4-MDA d,l-3,4-MDEA	2,000	d,l-3,4-MDMA*	500
Compound d,l-3,4-MDA	2,000	d,l-3,4-MDMA*	500
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml	2,000 250	d,l-3,4-MDMA* d-Methamphetamine	500 50,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound	2,000 250 ng/ml	d,l-3,4-MDMA* d-Methamphetamine	500 50,000 ng/ml
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA	2,000 250 ng/ml 10,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine	500 50,000 ng/ml 500 25,000 50,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine	2,000 250 ng/ml 10,000 1,750	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine	500 50,000 ng/ml 500 25,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA	2,000 250 ng/ml 10,000 1,750 1,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine	500 50,000 ng/ml 500 25,000 50,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml	2,000 250 ng/ml 10,000 1,750 1,000 20,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide	500 50,000 ng/ml 500 25,000 50,000 75,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound	2,000 250 ng/ml 10,000 1,750 1,000 20,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound	500 50,000 ng/ml 500 25,000 50,000 75,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine	2,000 250 ng/ml 10,000 1,750 1,000 20,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone *	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl-	2,000 250 ng/ml 10,000 1,750 1,000 20,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound	500 50,000 ng/ml 500 25,000 50,000 75,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone *	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 ng/ml	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound Compound 6-Acetylmorphine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 ng/ml 500	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 ng/ml 500 600	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydromorphone	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 50,000 ng/ml 500 600 300 500 300	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydromorphone Morphine *	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 solution of the control of the co	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 500
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 50,000 ng/ml 500 600 300 500 300 100	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 500
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound Compound	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 50,000 ng/ml 500 600 300 500 300 100	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide Nalorphine Compound	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 500 5,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 ng/ml 500 600 300 500 300 100 ng/ml 15,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydromorphone Morphine * Morphine * Morphine-3-β-D-Glucuronide Nalorphine Compound Oxymorphone	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 5,000 ng/ml 3,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Codeine Codeine Compound	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 ng/ml 500 600 300 500 300 100 ng/ml 15,000 5,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide Nalorphine Compound Oxymorphone Oxycodone *	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 5,000 ng/ml 3,000 100
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Codeine Dihydrocodeine Codeine Dihydrocodeine Codeine Dihydrocodeine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 ng/ml 500 600 300 500 300 100 ng/ml 15,000 2,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide Nalorphine Compound Oxymorphone Oxycodone * Hydromorphone	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 5,000 ng/ml 3,000 100 25,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Lihydrocodeine Codeine Dihydrocodeine Hydrocodone	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 ng/ml 500 600 300 500 300 100 ng/ml 15,000 5,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide Nalorphine Compound Oxymorphone Oxycodone *	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 5,000 ng/ml 3,000 100
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Hydrocodone PCP 25 ng/ml	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 solution 500 300 500 300 100 ng/ml 15,000 2,000 300 2,000 300	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide Nalorphine Compound Oxymorphone Oxycodone * Hydromorphone Ethyl Morphine	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 5,000 ng/ml 3,000 5,000
Compound d,l-3,4-MDA d,l-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,l-3,4-MDMA d,l-3,4-MDMA d,l-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Lihydrocodeine Codeine Dihydrocodeine Hydrocodone	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 ng/ml 500 600 300 500 300 100 ng/ml 15,000 2,000	d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide Nalorphine Compound Oxymorphone Oxycodone * Hydromorphone	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 5,000 ng/ml 3,000 100 25,000

500	Phencyclidine Morpholine	50,000
ng/ml	Compound	ng/ml
300	Norpropoxyphene	500
ng/ml	Compound	ng/ml
1,000	Nordoxepin	1,000
7,500	Nortriptyline *	1,000
1,500	Perphenazine	50,000
750	Promazine	10,000
1,000	Protriptyline	350
750	Trimipramine	1,500
ng/ml	Compound	ng/ml
100,000	11-Hydroxy-Δ9-THC	2,500
50,000	Δ-8-Tetrahydrocannabinol	7,000
50	Δ-9-Tetrahydrocannabinol	10,500
50		
	ng/ml 300 ng/ml 1,000 7,500 1,500 750 1,000 750 ng/ml 100,000 50,000 50	ng/ml Compound 300 Norpropoxyphene ng/ml Compound 1,000 Nordoxepin 7,500 Nortriptyline * 1,500 Perphenazine 750 Promazine 1,000 Protriptyline 750 Trimipramine ng/ml Compound 100,000 11-Hydroxy-Δ9-THC 50,000 Δ-8-Tetrahydrocannabinol 50 Δ-9-Tetrahydrocannabinol

CONSUMER STUDY

A consumer study was conducted to determine the performance of the device when used by untrained, laypersons following only the instructions in the product labeling. A total of 153 participants read a total of 5460 assays during the study and 5228 of those 5460 assays (95.8%) was interpreted correctly. Each assay was tested by these participants using spiked solutions targeted to 0%, 25%, 50%, 75%, 125%, 150%, and 175% of the assay cutoff level.

INTERFERENCE

The following compounds were found not to cross-react when tested at concentrations up to $100 \mu g/ml$ (100,000 ng/ml).

Acetaminophen	Alprazolam (except BZO assay)
Acetone	Amitriptyline (except TCA assay)
Acetylsalicylic acid (Aspirin)	Amobarbital (except BAR assay)
6-Acetylcodeine (except MOP & OXY	Amoxapine
assay)	d-Amphetamine (except AMP assay)
6-Acetylmorphine (except MOP assay)	I-Amphetamine (except AMP assay)
Amoxicillin	Ampicillin
Albumin	Apomorphine
Allobarbital (except BAR assay)	Aprobarbital (except BAR assay)
Alphenal (except BAR assay)	I-Ascorbic Acid (Vitamin C)
Aspartame	α-Hydroxy Alprazolam (except BZO
Atropine	assay)
Barbital (except BAR assay)	4-Hydroxy Phencyclidine (except PCP
Benzilic acid	assay)
Benzocaine (Ethyl p-Aminobenzoate)	p-Hydroxymethamphetamine (except
Benzoic acid	MET assay)
Benzoylecgonine (except COC assay)	11-Hydroxy-Δ-9-THC (except THC assay)
Benzphetamine	Ibuprofen
Bilirubin	Imipramine (except TCA assay)
Bromazepam (except BZO assay)	d,l-Isoproterenol
d-Brompheniramine	Ketamine
Buprenorphine (except BUPG assay)	Lidocaine
Butabarbital (except BAR assay)	Lorazepam (except BZO assay)
Butalbital (except BAR assay)	Lormetazepam (except BZO assay)
Butethal (except BAR assay)	Medazepam (except BZO assay)
Caffeine	Meperidine
Cannabidiol (except THC assay)	Metaphit (except PCP assay)
Cannabinol (except THC assay)	Methadone (except MTD assay)
Chlordiazepoxide (except BZO assay)	d-Methamphetamine (except MET &
Chloroquine	MDMA assay)
d,I-Chlorpheniramine	I-Methamphetamine (except MET
Chlorpromazine	assay)
Cholesterol	Methagualone
Clobazam (except BZO assay)	Methoxyphenamine
Clomipramine (except TCA assay)	(1R,2S) N-Methyl-Ephedrine
Clonazepam (except BZO assay)	2-Methylamine-Propiophenone
Cocaine	d,l-3,4-Methylenedioxyamphetamine
Codeine (except MOP & OXY assays)	(except AMP & MDMA assays)
Cortisone	d,l-3,4-methylenedioxyethylamphet
I-Cotinine	(except MET & MDMA assays)
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

Creatine Creatinine

Cyclobenzaprine (except TCA assay)

Delorazepam (except BZO assay) Deoxycorticosterone

Desipramine (except TCA assay) Dextromethorphan

Diazepam (except BZO assay)

Dihydrocodeine (except MOP & OXY

assay)

4-Dimethylaminoantipyrine

Diphenhydramine

Dopamine (3-Hydroxytyramine) Doxepin (except TCA assay) Doxylamine (except MTD assay) Ecgonine (except COC assay) Ecgonine Methyl Ester

I-Epinephrine

d,l-Ephedrine (except MET assay)

Erythromycin

Estazolam (except BZO assay)

β-Estradiol Estrone-3-Sulfate

Ethyl Morphine (except MOP & OXY

assay)

Ethanol

Ethyl-p-aminobenzoate

2-Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrolidone (except MTD

Flunitrazepam (except BZO assay) Flurazepam (except BZO assay)

Furosemide Glucose Gentisic acid Glutethimide **Guaiacol Glyceryl Ether**

Hemoglobin Heroin (except MOP assay)

Hippuric acid Hydrochlorothizide

Hydrocodone (except MOP & OXY

assavs) Hydrocortisone

Hydromorphone (except MOP & OXY

assays)

Protriptyline (except TCA assay)

d-Pseudoephedrine

Pyrrolidine

Quinidine

Quinine

Ranitidine Riboflavin

Sertraline

Salicylic acid

Secobarbital (except BAR assay)

Serotonin

Sodium Chloride Sulfamethazine Sulindac

Temazepam (except BZO assay) Tetracycline Δ8-THC (except THC assay) Δ9-THC (except THC assay)

d,I-3,4-

Methylenedioxymethamphetamine (except MET& MDMA assays)

Methylphenidate

Morphine (except MOP assay) Morphine-3-ß-D-Glucuronide (except MOP assay)

Nalidixic acid

Nalorphine (except for MOP assay)

Naloxone d-Naproxen Niacinamide

Nitrazepam (except BZO assay) Nordiazepam (except BZO assay)

Nordoxepin (except TCA assay)

Nicotine, (S)-Norepinephrine Norethindrone

Norpropoxyphene (except PPX assay) Nortriptyline (except TCA assay)

Oxalic Acid

Oxazepam (except BZO assay)

Oxolinic acid

Oxycodone (except OXY assay) Oxymorphone (except OXY assay)

Papaverine

Penicillin-G (Benzylpenicillin)

Pentazocine

Pentobarbital (except BAR assay) Perphenazine (except TCA assay) Phenazepam (except BZO assay)

Phencyclidine (except PCP assay) Phencyclidine Morpholine (except PCP

assay)

Pheniramine (except MTD assay) Phenobarbital (except BAR assay) Phenothiazine (Thiodiphenylamine) Phentermine (except AMP assay)

Phenylephrine

β-Phenylethylamine (except AMP assay)

Prednisolone

Prazepam (except BZO assay) Procaine (except MET assay) Promazine (except TCA assay)

Promethazine

Propoxyphene (except PPX assay) 11-nor-Δ8-THC-9-Carboxylic Acid

(except THC assay)

11-nor-Δ-9-THC-9-Carboxylic Acid

(except THC assay)

Thiamine Thioridazine

Triazolam (except BZO assay)

Trifluoperazine

Trimethobenzamide (except MET assay)

Trimipramine (except TCA assay)

Tryptamine d,l-Tryptophan Tyramine d,I-Tyrosine Uric Acid Verapamil Zomepirac

- U.S. Dept. of Transportation, Procedures for Transportation Workplace Drug and Alcohol Testing Programs. Federal Register, 1999 Dec.; 64(236); 69076
- U.S. Dept. of Health and Human Services, Mandatory Guidelines for Federal 7. Workplace Drug Testing Programs. Federal Register, 2001 Aug.; 66(162): 43876
- Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970-11979, 1988.
- 9. Liu, Ray H. and Goldberger, Bruce A., Handbook of Workplace Drug Testing, AACC Press (1995).
- 10. Gilman, A. G. and Goodman, L. S., The Pharmacological Basis of Therapeutics, eds. MacMillan Publishing, New York, NY, 1980.
- 11. McBay, A.J. Clin. Chem. 33, 33B-40B, 1987.
- Ringsrud, K.M and Linne, J.J., Urinalysis and Body Fluids, A color Text and Atlas, Mosby-Year Book, Inc., 1995.
- 13. Baselt RC. Disposition of toxic Drugs and chemicals in Man. 6th Ed. Biomedical Publ., Davis, CA. 2002; 129

GLOSSARY OF SYMBOLS

Symbol	Description	ISO 15223-1* Reference #	ISO 7000* Reference #
<u> </u>	Caution- consult accompanying documents symbol	5.4.3	1641
(2)	Do not reuse	5.4.2	1051
IVD	In vitro diagnostic medical device	5.5.1	Not applicable

ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements

ISO 7000: Graphical symbols for use on equipment – Registered symbols

General Questions? Call 1-800-777-4908 Technical Support? Call 1-800-340-4029

Distributed by McKesson Medical-Surgical Inc.

Richmond, VA 23233 **PVN A0916**

Made in USA

Part No.: PI-164-DXA14 Rev: 0, 10/2017

BIBLIOGRAPHY OF SUGGESTED READING

- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, Davis, CA, 1982.
- Urine testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.
- Wong, R., The Current Status of Drug Testing in the US Workforce, Am. Clin. Lab., 2002; 21(1): 21-23
- 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
- Young, D.S. et. al., Clinical Chemistry, 21 (9), 1975.