PRECISION DX

Panel Dip M2000

Catalogue NO.: See Box Label

Please read all instructions before use.

INTENDED USE

The Precision DX Panel Dip M2000 are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine(AMP)	1000 ng/mL
Barbiturates (BAR)	300 ng/mL
Buprenorphine(BUP)	10 ng/mL
Benzodiazepines(BZO)	300 ng/mL
Cocaine(COC)	300 ng/mL
Methadone metabolite(EDDP)	300ng/ml
Ecstasy(MDMA)	500 ng/mL
Methamphetamine(MET)	1000 ng/mL
Morphine(MOR)	2000 ng/mL
Methadone(MTD)	300 ng/mL
Oxycodone(OXY)	100 ng/mL
Phencyclidine(PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Notriptyline (TCA)	1000 ng/mL
Marijuana(THC)	50 ng/mL

Configuration of the Precision DX Panel Dip M2000 can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only.

What are the Precision DX Panel Dip M2000?

The Precision DX Panel Dip M2000 are drug-screening tests that will give you a result for the presence of abuse in human urine. During testing, a urine sample moves upward on the test strip. A drug-positive urine sample will not produce a colored line in the specified test line area of the strip. A drug-negative urine sample will produce a colored line in the test line area. A colored line will always show in the control line area.

Contents of the Kit

- One Test Device
- Shipping bag
- Labeled Vial for shipping sample
- Instruction for Use
- Mailing box (Prepaid)
- Urine collection cup

Not included in package

- Watch, timer or clock

PRECAUTIONS

- Do not use after the expiration date.
- The device should remain in the sealed pouch until use.
- Do not re-use the test.

STORAGE

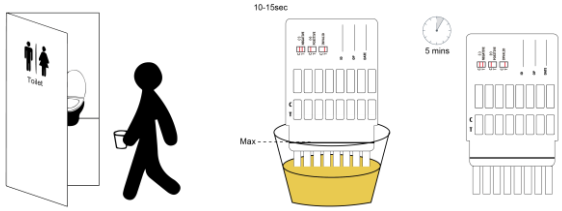
- Store between 39.2 ℉ and 86 ℉.
- DO NOT FREEZE.
- Keep away from direct sunlight, moisture and heat.

URINE COLLECTION

Collect urine specimen in the provided urine collection cup. Urine collected at any time of the day may be used.

PROCEDURE

1. Remove the Panel Dip Test from the sealed pouch and use it within the first hour after opening.
2. Collect a minimum of 2oz (the minimum mark) of urine in the cup.

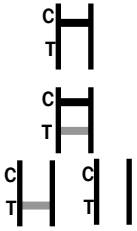


3. Hold the Panel Dip by the plastic casing. Dip the strip end of the Panel Dip Test in the urine specimen submerging only up to the "MAX" mark of the strip or until the edge of the plastic casing.
4. Keep the sample pad portion of the strip in the urine for 10-15 seconds, then place the Panel Dip Test on a flat, clean, dry surface for total of 5 minutes to read result.

Reading Result:

5. The result should be read at 5 minutes.

INTERPRETATION OF RESULTS



PRELIMINARY POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID: NO line appears in the C – Control region, then the result is Invalid.

UNDERSTANDING THE TEST RESULTS

A positive result does not mean a person took illegal drugs. A negative result does not mean a person did not take illegal drugs. There are many factors that affect the test. Certain drug tests are more accurate than others.

IMPORTANT: The results from the test are preliminary. The sample must be tested by a lab to confirm the result. Refer to the Confirmation Testing part of this insert.

1. What Is A False Positive Test?

A false positive test result means the drug is not present but shows as detected by the device. The most common causes for a false positive test are cross reactants. Certain food and medicines, diet plan drugs and nutritional supplements may cause a false positive result with this product.

2. What Is A False Negative Test?

A false negative test means the drug is present but is not detected by the device. If the sample is diluted, or the sample is contaminated that may cause a false negative result.

LIMITATIONS

- This test is for human urine only. Do NOT use this device to test any other fluids.
- Bleach or baking powder, in urine samples may produce incorrect results. If contamination is suspected, repeat the test with another urine sample.
- The test does not distinguish between drugs of abuse and certain medications.

FREQUENTLY ASKED QUESTIONS

1. *What does the Drug of Abuse Urine Test do?*

These tests indicate if one or more prescription or illegal drugs are present in urine.

The testing is done in two steps. First, you do a quick at-home test. Second, if the test suggests that drugs may be present, you send the sample to a laboratory for additional testing.

2. *What is "cut-off level"?*

The cut-off level is the specified concentration of a drug in a urine sample. Above that concentration the test is called positive, and below that concentration it is called negative.

3. *What are drugs of abuse?*

Drugs of abuse are illegal or prescription medicines that are taken for a non-medical purpose, including taking the medication for longer than your doctor prescribed it for or for a purpose other than what the doctor prescribed it for.

4. *Common Street Names for the Drugs to be detected?*

Drug	Common Street Names
Amphetamine (AMP)	Speed, Jelly Beans or Super Jellies , Hearts, Uppers, Pick me ups or Wake me ups, Wake ups, Get ups, Boot ups, Sparkles
Secobarbital(BAR)	Amytal, Downers, Nembutal, Phenobarbital, Reds, Red Birds, Red devils, Seconal, Tuninal, Yellowjackets
Oxazepam (BZO)	Benzos, Downers, Nerve Pills, Tranks
Cocaine (COC)	Blow, C, candy, coke, do a line, freeze, girl, happy dust, Mama coca, mojo, monster, nose, pimp, shot, smoking gun, snow, sugar, sweet stuff, and white powder.
Methamphetamine (MET)	Speed, Ice, Chalk, Meth, Crystal, Crank, Fire, Glass
Methylenedioxymethamphetamine (MDMA)	Ecstasy, E, X, XTC, Adam, Clarity, Lover's Speed
Buprenorphine(BUP)	Bupe, Subbies, Temmies
Morphine (MOR)	Aunt Hazel, big H, black pearl, brown sugar, capital H, charley, china white, dope, good horse, H, hard stuff, hero, heroina, little boy, mud, perfect high, smack, stuff and tar.
Methadone (MTD)	Amidone, Dolophine, Methadose
Phencyclidine (PCP)	Angel dust, belladonna, black whack, CJ, cliffhanger, crystal joint, Detroit pink, elephant tranquilizer, hog, magic, Peter Pan, sheets, soma, TAC, trank, white horizon and zoom.
Notriptyline (TCA)	Pamelor
Propoxyphene (PPX)	Darvon
Marijuana (THC)	420, Aunt Mary, baby, bobby, boom, chira, chronic, ditch, ganja, grass, greens, hash, herb, Mary Jane, nigra, Pot, reefer, rip, root, skunk, stack, torch, weed and zambi.
Oxycodone (OXY)	OC, Ocycotton, OX, and Kicker

5. *How accurate is the test?*

The tests are sensitive to drugs and accurate. These tests, however, are not as accurate as lab tests. In some cases, certain foods and drugs may cause false positives as well as false negatives for those who use drug-testing kits.

6. *If the test results are negative, can the conclusion be that the urine is free of drugs?*

This means that if the sample was collected properly and the test was performed according to the directions, either the urine sample is free of the drugs tested for, or the drug levels were below the detection limit of this test.

7. *Does a preliminary positive screen test mean that you have found of abuse?*

This means that the test has reacted with something in the sample and the sample must be sent to the lab for a more accurate test.

8. *What should I do, if the lab test confirms a positive result?*

If you have received a confirmed positive result, please consult with our staff on a proper course of action. We will help you identify counselors who can help you. It is important that you remain calm and do not react in a negative way to the situation. If you do not believe the test result, please consult with your physician. They will have your background medical history and be able to provide you with detailed information on both the test and the meaning of the result.

9. *How long can drugs be detected in the body with a urine drug test?*

Drug	Minimum detection time	Maximum detection time
Amphetamine (AMP)	2-7 hours	1-2 days
Secobarbital(BAR)	2-4 hours	1-4 days

Oxazepam (BZO)	2-7 hours	1-2 days
Cocaine (COC)	1-4 hours	2-4 days
Methamphetamine (MET)	2-7 hours	2-4 days
Methylenedioxymethamphetamine (MDMA)	2-7 hours	2-4 days
Buprenorphine(BUP)	4 hours	1-3 days
Morphine (MOR)	2 hours	2-3 days
Methadone (MTD)	3-8 hours	1-3 days
Phencyclidine (PCP)	4-6 hours	7-14days
Notriptyline (TCA)	8-12hours	2-7 days
Marijuana (THC)	2 hours	Up to 5+ days
Oxycodone(OXY)	4 hours	1-3 days
Propoxyphene (PPX)	2~4 hours	1-4 days
Methadone metabolite (EDDP)	2 hours	2 to 6 days

CONFIRMATION TESTING

- Write Identification Number on the label.
- Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds (2/3) full and tightly close the cap.
- Please fill out name, return address, and cell phone number on Mailing Box.
- Place labeled vial in shipping bag and seal the bag.
- Place the sealed Shipping bag in the Mailing Box.
- Mail the box using any US Postal Service.
- Contact the lab if you do not get the result in 5 days.

MORE INFORMATION AND RESOURCES

You can contact your health care provider, or any of the following organizations listed below for additional information and/or counseling regarding substance abuse prevention and treatment:

- American Council for Drug Education (ACDE)
  1-800-DRUGHELP / www.ade.org
- Center for Substance Abuse Treatment (CSAT)
  1-877-SAMHSA-7 / www.samhsa.gov
- The National Council on Alcoholism and Drug Dependence (NCADD)
  1-800-NCA-CALL / www.ncadd.org
- Pride Youth Program formerly Parent's Resource Institute for Drug Education , Inc. (PRIDE)
  1-800-668-9277 / www.prideyouthprogram.org
- The Treatment Center
  1-877-409-9043 / www.thetreatmentcenter.org

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the test was confirmed by testing 80 clinical urine specimens in parallel with LC-MS. The results are shown below. The test is accurate at least 96 percent.

AMP

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Operator B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Operator C	Positive	0	0	0	14	25
	Negative	10	20	10	1	0

% agreement among positives is 98.3%

% agreement among negatives is 99.2%

BAR

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Operator C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

% agreement among positives is 99.2%

% agreement among negatives is 97.5%

BUP

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Operator B	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Operator C	Positive	0	0	2	14	25
	Negative	10	20	8	1	0

% agreement among positives is 97.5%

% agreement among negatives is 95%

BZO

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Operator B	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Operator C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

% agreement among positives is 98.3%

% agreement among negatives is 99.2%

COC

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2	15	25
	Negative	10	20	8	0	0
Operator B	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Operator C	Positive	0	0	1	13	25
	Negative	10	20	9	2	0

% agreement among positives is 98.3%

% agreement among negatives is 97.5%

EDDP

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Operator B	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Operator C	Positive	0	0	1	14	25
	Negative	10	20	9	1	0

% agreement among positives is 98.3%

% agreement among negatives is 97.5%

MDMA

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

% agreement among positives is 98.3%

% agreement among negatives is 97.5%

MET

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Operator B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Operator C	Positive	0	0	1	14	25
	Negative	10	20	9	1	0

% agreement among positives is 99.2%

% agreement among negatives is 98.3%

MOR

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2	15	25
	Negative	10	20	8	0	0
Operator B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator C	Positive	0	0	0	14	25
	Negative	10	20	10	1	0

% agreement among positives is 98.3%

% agreement among negatives is 97.5%

MTD

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2	15	25
	Negative	10	20	8	0	0
Operator B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

% agreement among positives is 99.2%

% agreement among negatives is 96.7%

OXY

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Operator B	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Operator C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

% agreement among positives is 99.2%

% agreement among negatives is 98.3%

PCP

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Operator B	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Operator C	Positive	0	0	1	14	25
	Negative	10	20	9	1	0

% agreement among positives is97.5%

% agreement among negatives is 97.5%

PPX

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Operator B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Operator C	Positive	0	0	1	14	25
	Negative	10	20	10	0	0

% agreement among positives is 99.2%

% agreement among negatives is 98.3%

	Negative	10	20	9	0	0
Operator C	Positive	0	0	0	15	25
	Negative	10	20	10	0	0

% agreement among positives is 100%

% agreement among negatives is 98.3%

TCA

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Operator B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator C	Positive	0	0	0	14	25
	Negative	10	20	10	1	0

% agreement among positives is 98.3%

% agreement among negatives is 99.2%

THC

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Operator C	Positive	0	0	0	14	25
	Negative	10	20	10	1	0

% agreement among positives is 98.3%

% agreement among negatives is 98.3%

B. Specificity and Cross-reactivity

The following table lists compounds that are positively detected in Precision DX Panel Dip.

AMP

Amphetamine (Cut-off=1000 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
D - Amphetamine	1000	100%
L - Amphetamine	20000	5%
DL - Amphetamine	3000	33%
Phentermine	30000	3.3%
Hydroxyamphetamine	8000	12.5%
Methylenedioxyamphetamine (MDA)	20000	5%
d-Methamphetamine	＞100000	＜1%
1-Methamphetamine	＞100000	＜1%
Ephedrine	＞100000	＜1%
Methylenedioxyethylamphetamine (MDE)	＞100000	＜1%
3,4-methylenedioxy-methamphetamine (MDMA)	＞100000	＜1%

BAR

Secobarbital (Cut-off=300 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
Secobarbital	300	100%
Amobarbital	1000	30%
Alphenal	62.5	480%
Aprobarbital	250	120%
Butabarbital	100	300%
Butethal	500	60%
Butalbital	5000	6%
Cyclopentobarbital	500	60%
Pentobarbital	200	150%
Phenobarbital	300	100%

BUP

Buprenorphine (Cut-off=10 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	10	100%
Norbuprenorphine	50	20%
Norbuprenorphine-3-D-Glucuronide	100	10%
Morphine	＞100000	<0.01%
Oxymorphone	＞100000	<0.01%
Hydromorphone	＞100000	<0.01%

BZO

Oxazepam (Cut-off=300 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
Oxazepam	300	100%
Alprazolam	150	200%
a-Hydroxyalprazolam	1000	30%
Bromazepam	1000	30%
Chlordiazepoxide	63	476.2%
Clonazepam	2500	12%
Clobazam	75	400%
Clorazepate dipotassium	100	300%
Desalkylflurazepam	500	60%
Diazepam	500	60%
Estazolam	500	60%
Flunitrazepam	＞50000	＜0.6%
D,L-Lorazepam	10000	3%
Midazolam	10000	3%
Nitrazepam	75	400%
Norchlordiazepoxide	62.5	480%
Nordiazepam	125	240%
Temazepam	75	400%
Triazolam	1000	30%

COC

Cocaine (Cut-off=300 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
Benzoylecgonine	300	100%
Cocaine HCl	750	40%
Cocaethylene	12500	2.4%
Ecgonine	32000	0.9%
Norcocaine	100000	0.3%

EDDP

EDDP(Cut-off=300 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
EDDP(2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine)	300	100%
EMDP(2-Ethyl-5-methyl-3,3-diphenylpyrroline)	＞100000	<0.3%
Disopyramide	75	400%
Methadone	＞100000	<0.3%
LAAM (Levo-alpha-acetylmethadol) HCl	＞100000	<0.3%
Alpha Methadol	＞100000	<0.3%
Doxylamine	＞100000	<0.3%

MDMA

MDMA (Cut-off=500 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
Methylenedioxymethamphetamine (MDMA)	500	100%
3,4-Methylenedioxyamphetamine (MDA)	5000	10%
3,4-Methylenedioxyethylamphetamine	300	166.7%
d-methamphetamine	>50000	＜1%
d-amphetamine	>50000	＜1%
l-amphetamine	>50000	＜1%
l-methamphetamine	>50000	＜1%

MET

Methamphetamine (Cut-off=1000 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
D(+)-Methamphetamine	1000	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	10000	10%
D/L-Methamphetamine	1000	100%
p-Hydroxymethamphetamine	10000	10%
D-Amphetamine	＞100000	＜1%
L-Amphetamine	＞100000	＜1%
Chloroquine	50000	2%
(+/-)-Ephedrine	4000	25%
L-Methamphetamine	10000	10%
(+/-)3,4-Methylenedioxyamphetamine	＞100000	＜1%
β-Phenylethylamine	7500	13.3%
Trimethobenzamide	20000	5%
(+/-)3,4-methylenedioxymethamphetamine(MDMA)	500	200%

MOR

Morphine (Cut-off=2000 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
Morphine	2000	100%
Acetylmorphine	2500	80%
Codeine	1000	200%
Ethyl Morphine	250	800%
Heroin	5000	40%
Hydromorphone	2500	80%
Hydrocodone	5000	40%
Thebaine	13000	15.4%
Morphine-3- β-glucuronide	Negative at 200000	<1%
Procaine	Negative at 400000	<0.5%
Levorphanol	Negative at 400000	<0.5%
Oxycodone	Negative at 400000	<0.5%
Oxymorphine	Negative at 400000	<0.5%

MTD

Methadone (Cut-off=300 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
Methadone	300	100%
Doxylamine	5000	6%
LAAM HCl	10000	3%
Alpha Methadol	2000	15%
EDDP	＞100000	<0.3%
EMDP	＞100000	<0.3%

OXY

Oxycodone (Cut-off=100 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
Oxycodone	100	100%
Dihydrocodeine	>100000	<0.1%
Codeine	>100000	<0.1%
Hydromorphone	>100000	<0.1%
Morphine	>100000	<0.1%
Buprenorphine	>100000	<0.1%
Ethylmorphine	>100000	<0.1%
Oxymorphone	250	40%
Hydrocodone	3125	3.2%

PCP

Phencyclidine (Cut-off=25 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	75	33.3%

PPX

Propoxyphene (Cut-off=300 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
d-Propoxyphene	300	100%
D-Norpropoxyphene	333	90.1%

TCA

Nortriptyline (Cut-off=1000 ng/mL)	Concentration(ng/ml)	%Cross-Reactivity
Nortriptyline	1000	100%
Amitriptyline	750	133.3%
Clomipramine	10000	10%
Desipramine	200	500%
Doxepin	1250	80%
Imipramine	625	160%
Maprotiline	2000	50%
Nordoxepin	1000	100%
Promazine	1500	66.7%
Promethazine	25000	4%

Trimipramine	3000	33.3%
Cyclobenzaprine Hydrochloride	5000	20%
Norclomipramine	3000	33.3%

THC

Drug	Concentration(ng/ml)	% Cross-Reactivity
11-Nor-Δ^9-Tetrahydrocannabinol-9-COOH	50	100%
11-Hydroxy-Δ^9-Tetrahydrocannabinol	50	100%
11-Nor-Δ^8-Tetrahydrocannabinol-9-COOH	50	100%
Cannabinol	20000	0.25%
Δ^8-Tetrahydrocannabinol	15000	0.33%
Δ^9-Tetrahydrocannabinol	15000	0.33%
Cannabidiol	＞100000	＜0.05%
11-Nor-Δ^9-THC-carboxy glucuronide	75	66.7%
(-)-11-nor-9-carboxy-Δ 9-THC	50	100%

C. Precision

This study was performed 2 runs/day over 25 days. Three operators tested 450 samples. All samples were randomly marked. The results are given below.

AMP

Amphetamine concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
250	50	50	0	50	0	50	0
500	50	50	0	50	0	50	0
750	50	50	0	50	0	50	0
1000	50	11	39	13	37	10	40
1250	50	0	50	0	50	0	50
1500	50	0	50	0	50	0	50
1750	50	0	50	0	50	0	50
2000	50	0	50	0	50	0	50

BAR

Secobarbital concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
75	50	50	0	50	0	50	0
150	50	50	0	50	0	50	0
225	50	50	0	50	0	50	0
300	50	2	48	2	48	3	47
375	50	0	50	0	50	0	50
450	50	0	50	0	50	0	50
525	50	0	50	0	50	0	50
600	50	0	50	0	50	0	50

BUP

Buprenorphine concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
2.5	50	50	0	50	0	50	0
5	50	50	0	50	0	50	0
7.5	50	50	0	50	0	50	0
10	50	3	47	2	48	2	48
12.5	50	0	50	0	50	0	50
15.0	50	0	50	0	50	0	50
17.5	50	0	50	0	50	0	50
20	50	0	50	0	50	0	50

BZO

Benzodiazepines concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
75	50	50	0	50	0	50	0
150	50	50	0	50	0	50	0
225	50	50	0	50	0	50	0
300	50	9	41	10	40	10	40
375	50	0	50	0	50	0	50
450	50	0	50	0	50	0	50
525	50	0	50	0	50	0	50
600	50	0	50	0	50	0	50

COC

Cocaine concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
75	50	50	0	50	0	50	0
150	50	50	0	50	0	50	0
225	50	50	0	50	0	50	0
300	50	11	39	8	42	11	39
375	50	0	50	0	50	0	50
450	50	0	50	0	50	0	50
525	50	0	50	0	50	0	50
600	50	0	50	0	50	0	50

EDDP

EDDP concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
75	50	50	0	50	0	50	0
150	50	50	0	50	0	50	0
225	50	50	0	50	0	50	0
300	50	9	41	10	40	9	41
375	50	0	50	0	50	0	50
450	50	0	50	0	50	0	50
525	50	0	50	0	50	0	50
600	50	0	50	0	50	0	50

MDMA

Ecstacy concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
125	50	50	0	50	0	50	0
250	50	50	0	50	0	50	0
375	50	50	0	50	0	50	0
500	50	13	37	11	39	11	39
625	50	0	50	0	50	0	50
750	50	0	50	0	50	0	50
875	50	0	50	0	50	0	50
1000	50	0	50	0	50	0	50

MET

Methamphetamine concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
250	50	50	0	50	0	50	0
500	50	50	0	50	0	50	0
750	50	50	0	50	0	50	0
1000	50	12	38	10	40	11	39
1250	50	0	50	0	50	0	50
1500	50	0	50	0	50	0	50
1750	50	0	50	0	50	0	50
2000	50	0	50	0	50	0	50

MOR

Morphine concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
500	50	50	0	50	0	50	0
1000	50	50	0	50	0	50	0
1500	50	50	0	50	0	50	0
2000	50	11	39	10	40	10	40
2500	50	0	50	0	50	0	50
3000	50	0	50	0	50	0	50
3500	50	0	50	0	50	0	50
4000	50	0	50	0	50	0	50

MTD

Methadone concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
75	50	50	0	50	0	50	0
150	50	50	0	50	0	50	0
225	50	50	0	50	0	50	0
300	50	2	48	3	47	2	48
375	50	0	50	0	50	0	50
450	50	0	50	0	50	0	50
525	50	0	50	0	50	0	50
600	50	0	50	0	50	0	50

OXY

Oxycodone concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
25	50	50	0	50	0	50	0
50	50	50	0	50	0	50	0
75	50	50	0	50	0	50	0
100	50	1	49	2	48	2	48
125	50	0	50	0	50	0	50
150	50	0	50	0	50	0	50
175	50	0	50	0	50	0	50
200	50	0	50	0	50	0	50

PCP

Phencyclidine concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
6.25	50	50	0	50	0	50	0
12.5	50	50	0	50	0	50	0
18.75	50	50	0	50	0	50	0
25	50	11	39	10	40	11	39
31.25	50	0	50	0	50	0	50
37.5	50	0	50	0	50	0	50
43.75	50	0	50	0	50	0	50
50	50	0	50	0	50	0	50

PPX

Propoxyphene concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
75	50	50	0	50	0	50	0
150	50	50	0	50	0	50	0
225	50	50	0	50	0	50	0
300	50	12	38	9	41	11	39
375	50	0	50	0	50	0	50
450	50	0	50	0	50	0	50
525	50	0	50	0	50	0	50
600	50	0	50	0	50	0	50

TCA

Nortriptyline concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
250	50	50	0	50	0	50	0
500	50	50	0	50	0	50	0
750	50	50	0	50	0	50	0
1000	50	10	40	9	41	10	40
1250	50	0	50	0	50	0	50
1500	50	0	50	0	50	0	50
1750	50	0	50	0	50	0	50
2000	50	0	50	0	50	0	50

THC

Marijuana concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
12.5	50	50	0	50	0	50	0
25	50	50	0	50	0	50	0
37.5	50	50	0	50	0	50	0
50	50	8	42	10	40	11	39
62.5	50	0	50	0	50	0	50
75	50	0	50	0	50	0	50
87.5	50	0	50	0	50	0	50
100	50	0	50	0	50	0	50

D. Interference

Over 100 commonly used medications were tested. It found that they have no influence on the test.

Acetaminophen	β-Estradiol	Oxalic acid
Acetophenetidin	Erythromycin	Oxolinic acid
N-Acetylprocainamide	Fenoprofen	Oxymetazoline
Acetylsalicylic acid	Furosemide	Papaverine
Albumin	Gentisic acid	Penicillin G
Aminopyrine	Hemoglobin	Perphenazine
Amoxicillin	Hydralazine	Phenelzine
Ampicillin	Hydrochlorothiazide	Prednisone
Apomorphine	Hydrocortisone	(±)-Propranolol
Ascorbic acid	O-Hydroxyhippuric	Pseudoephedrine
Aspartame	3-Hydroxytyramine	Quinine
Atropine	Ibuprofen	Ranitidine
Benzilic acid	Isoproterenol	Salicylic acid
Benzoic acid	Isoxsuprine	Serotonin (5- Hydroxytyramine)
Bilirubin	Ketamine	Sulfamethazine
Chloral hydrate	Ketoprofen	Sulindac
Chloramphenicol	Labetalol	Tetrahydrocortisone 3-(β-Dglucuronide)
Chlorothiazide	Loperamide	Tetrahydrocortisone 3-acetate
Chlorpromazine	Meperidine	Tetrahydrozoline
Cholesterol	Meprobamate	Thiamine
Clonidine	Methoxyphenamine	Thioridazine
Cortisone	Nalidixic acid	Triamterene
(-)-Cotinine	Naloxone	Trifluoperazine
Creatinine	Naltrexone	Trimethoprim
Deoxycorticosterone	Naproxen	DL-Tryptophan
Dextromethorphan	Niacinamide	Tyramine
Diclofenac	Nifedipine	DL-Tyrosine
Diflunisal	Norethindrone	Uric acid
Digoxin	Noscapine	Verapamil
Diphenhydramine	(±)-Octopamine	Zomepirac
Ecgonine methyl ester		

E. Lay User Study

A study was done at three sites with 310 people. They had different educations and skills. Their ages are from 18 to over 50. Samples were prepared at seven different concentrations. For nearly all samples tested, 90 percent or more were correct.

AMP

% of Cutoff	Number of samples	Amphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%	20	0	0	20	100
-75% Cutoff	20	252	0	20	100
-50% Cutoff	170	506	0	170	100
-25% Cutoff	20	748	1	19	95
+25% Cutoff	20	1254	20	0	100
+50% Cutoff	40	1506	40	0	100
+75% Cutoff	20	1747	20	0	100

BAR

% of Cutoff	Number	Secobarbital	Lay person results		The
	of samples	Concentration by GC/MS(ng/mL)	No. of Positive	No. of Negative	percentage of correct results (%)
-100%	20	0	0	20	100
-75% Cutoff	20	74	0	20	100
-50% Cutoff	170	153	0	170	100
-25% Cutoff	20	224	1	19	95
+25% Cutoff	20	376	19	1	95
+50% Cutoff	40	453	40	0	100
+75% Cutoff	20	527	20	0	100

BUP

% Cutoff	No of samples	Buprenorphine Concentration by GC/MS(ng/mL)	Lay person results		Correct Results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	2.7	0	20	100
-50% Cutoff	170	4.9	0	170	100
-25% Cutoff	20	7.2	1	19	95
+25% Cutoff	20	12.6	19	1	95
+50% Cutoff	40	15.4	40	0	100
+75% Cutoff	20	17.3	20	0	100

BZO

% Cutoff	No of samples	Benzodiazepines Concentration by GC/MS(ng/mL)	Lay person results		Correct Results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	76	0	20	100
-50% Cutoff	170	148	0	170	100
-25% Cutoff	20	223	1	19	95
+25% Cutoff	20	373	20	0	100
+50% Cutoff	40	454	40	0	100
+75% Cutoff	20	529	20	0	100

EDDP

% of Cutoff	Number of samples	EDDP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	72	0	20	100
-50% Cutoff	170	156	0	170	100
-25% Cutoff	20	221	1	19	95
+25% Cutoff	20	378	19	1	95
+50% Cutoff	40	448	40	0	100
+75% Cutoff	20	522	20	0	100

COC

% of Cutoff	Number of samples	Cocaine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	76	0	20	100
-50% Cutoff	170	152	0	170	100
-25% Cutoff	20	223	1	19	95
+25% Cutoff	20	377	19	1	95
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	528	20	0	100

MDMA

% of Cutoff	Number of samples	Ecstacy Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	122	0	20	100
-50% Cutoff	170	256	0	170	100
-25% Cutoff	20	381	1	19	95
+25% Cutoff	20	631	20	0	100
+50% Cutoff	40	758	40	0	100
+75% Cutoff	20	869	20	0	100

MET

% of Cutoff	Number of samples	Methamphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	252	0	20	100
-50% Cutoff	170	498	0	170	100
-25% Cutoff	20	752	1	19	95
+25% Cutoff	20	1254	20	0	100
+50% Cutoff	40	1508	40	0	100
+75% Cutoff	20	1748	20	0	100

MOR

% of Cutoff	Number of samples	Morphine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%	20	0	0	20	100
-75% Cutoff	20	506	0	20	100
-50% Cutoff	170	993	0	170	100
-25% Cutoff	20	1507	1	19	95
+25% Cutoff	20	2511	19	1	95
+50% Cutoff	40	3012	40	0	100
+75% Cutoff	20	3510	20	0	100

MTD

% Cutoff	No of samples	Methadone Concentration by GC/MS(ng/mL)	Lay person results		Correct Results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	76	0	20	100
-50% Cutoff	170	152	0	170	100
-25% Cutoff	20	226	1	19	95
+25% Cutoff	20	374	20	0	100
+50% Cutoff	40	451	40	0	100
+75% Cutoff	20	523	20	0	100

OXY

% of Cutoff	Number of samples	Oxycodone Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	20	0	100
-75% Cutoff	20	24	20	0	100
-50% Cutoff	170	51	0	170	100
-25% Cutoff	20	73	1	19	95
+25% Cutoff	20	128	19	1	95
+50% Cutoff	40	153	40	0	100
+75% Cutoff	20	172	20	0	100

PCP

% of Cutoff	Number of samples	Phencyclidine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%	20	0	0	20	100

-75% Cutoff	20	7	0	20	100
-50% Cutoff	170	12	0	170	100
-25% Cutoff	20	20	2	18	90
+25% Cutoff	20	30	20	0	100
+50% Cutoff	40	38	40	0	100
+75% Cutoff	20	45	20	0	100

PPX

% of Cutoff	Number of samples	Propoxyphene Concentration by LC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	79	0	20	100
-50% Cutoff	170	147	0	170	100
-25% Cutoff	20	221	1	19	95
+25% Cutoff	20	377	20	0	100
+50% Cutoff	40	456	40	0	100
+75% Cutoff	20	528	20	0	100

TCA

% of Cutoff	Number of samples	Nortriptyline Concentration by LC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	255	0	20	100
-50% Cutoff	170	496	0	170	100
-25% Cutoff	20	746	0	20	100
+25% Cutoff	20	1259	19	1	95
+50% Cutoff	40	1508	40	0	100
+75% Cutoff	20	1757	20	0	100

THC

% of Cutoff	Number of samples	Marijuana Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	14	0	20	100
-50% Cutoff	170	26	0	170	100
-25% Cutoff	20	36	1	19	95
+25% Cutoff	20	64	19	1	95
+50% Cutoff	40	76	40	0	100
+75% Cutoff	20	89	20	0	100

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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer	②	Do not reuse

Manufacture for:
American Screening, LLC
9742 St. Vincent Ave Ste 100, Shreveport, LA 71106

Customer Service Phone: 866-526-2873

Number: 1110025910
REV 1.0/Effective date: 2018-11-28