



INSTANT TESTING ACKNOWLEDGEMENT

Performance Characteristics



BENEFITS:

- **SAME DAY TEST RESULT**
- **HIGHER DRUG CUT-OFF USED** (THC 50ng/mL instead of 15ng/mL).
- **LOWEST COST (\$ 65.00).**
- **AUTOMATIC LC/MS/MS Confirmation Testing** on all faint and no line readings, included.
- **AUTOMATIC Medical Review Officer(MRO) Services** on all confirmation testing, included.
- **HIRE APPLICANTS FASTER - SAME DAY!**

DOWN SIDE:

- **HIGHER DRUG CUT-OFFS USED** (Less drug users identified)
- **LESS ACCURATE** (+/-50% at the cut-off used)
- **MORE FALSE POSITIVE AND FALSE NEGATIVE SCREENINGS** (Auto-Confirm fixes this issue).

INFORMED CONSENT TO UTILIZE INSTANT/POCT SCREENING DEVICES

COMPANY NAME:

START USE DATE:

Requesting D.E.R. Name:

E-Mail:

The above listed Company D.E.R. is directing FORENSIC Drug Testing Services, Inc. to offer and use Instant/Point Of Collection Test drug screening devices for their employment testing account. The Company has been fully informed of all the pros & cons of using instant testing, and has agreed to read the attached 11 page "Package Insert" before signing this Informed Consent/Directive.

D.E.R. Signature:

Date

FDTSI Acceptance Date Stamp

INSTANT/POCT DRUGS OF ABUSE SCREENING DEVICE PACKAGE INSERT

1. INTENDED USE

Instant/POCT Drugs of Abuse Screening devices are one-step immunochromatographic screens for the rapid, qualitative detection of one or more of the following metabolites in human urine: Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, THC (Cannabinoids) and Tricyclic Antidepressants or their metabolites.

Instant/POCT Drugs of Abuse Screening System is for *in vitro* diagnostic use and is intended for prescription use only. It is not intended for use in point-of-care, medical or employment settings.

Instant/POCT Drugs of Abuse Screening Device detects drug classes at the following cutoff concentrations:

AMP Amphetamine (d-Amphetamine)	500 ng/mL	OPI Opiates (Morphine)	100 ng/mL or 2000 ng/mL
BAR Barbiturates (Butalbital)	200 ng/mL		
BZO Benzodiazepines (Nordiazepam)	150 ng/mL	OXY Oxycodone (Oxycodone)	100 ng/mL
BUP Buprenorphine (Buprenorphine)	10 ng/mL	PCP Phencyclidine (Phencyclidine)	25 ng/mL
COC Cocaine (Benzoylecgonine)	150 ng/mL	PPX Propoxyphene (Norpropoxyphene)	300 ng/mL
MAMP Methamphetamine (d-Methamphetamine)	500 ng/mL	THC Cannabinoids (11-nor-9-carboxy- Δ^9 -THC)	50 ng/mL
MTD Methadone (Methadone)	200 ng/mL	TCA Tricyclic Antidepressants (Desipramine)	300 ng/mL

Configurations of the Instant/POCT Drugs of Abuse Screening Device may consist of any combination of the above listed drug analytes. The screening(AKA: Test) Devices will have an opiate cutoff of either 100 ng/mL or 2000 ng/mL. Refer to specific product labeling for the combination of drug tests included on that test device.

Instant/POCT Drugs of Abuse Screening Devices only PROVIDE A PRELIMINARY ANALYTICAL SCREEN RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY / MASS SPECTROMETRY (GC/MS), HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) OR LIQUID CHROMATOGRAPHY / TANDEM MASS SPECTROMETRY (LC/MS/MS) ARE THE PREFERRED CONFIRMATORY METHODS. CLINICAL CONSIDERATION AND PROFESSIONAL MEDICAL REVIEW OFFICE(MRO) REVIEW SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE OBTAINED

2. SUMMARY AND EXPLANATION OF THE TEST

Instant/POCT Drugs of Abuse Screening Devices utilize a one-step, solid-phase immunoassay technology.

The amphetamines are a group of drugs that are central nervous system stimulants. This group includes amphetamine and methamphetamine. Amphetamine (d-amphetamine) is detected on the Test Device only at the (AMP) position, methamphetamine (MAMP) is detected at the (MAMP) position.

Barbiturates (BAR) are a group of structurally related prescription drugs that are used to reduce restlessness and emotional tension, induce sleep and to treat certain convulsive disorders.

Benzodiazepines (BZO), a group of structurally related central nervous system depressants, are primarily used to reduce anxiety and induce sleep.

Buprenorphine (BUP) is a potent analgesic often used in the treatment of opiate abusers.

Cocaine (COC) is a central nervous system stimulant. Its primary metabolite is benzoylecgonine.

Methadone (MTD) is a synthetic opioid used clinically as a maintenance drug for opiate abusers and for pain management.

Opiates (OPI) are a class of natural and semi-synthetic sedative narcotic drugs that include morphine, codeine and heroin.

Oxycodone (OXY) (Oxycontin[®], Percodan, Percocet) is a semi synthetic narcotic analgesic that is prescribed for moderately severe pain. It is available in both standard and sustained release oral formulations. Oxycodone is metabolized to Oxymorphone and Noroxycodone.

Phencyclidine (PCP) is a hallucinogenic drug.

Propoxyphene (PPX) is a narcotic analgesic. Its primary metabolite is norpropoxyphene.³

Tricyclic Antidepressants (TCA) are a group of structurally related prescription drugs that are used to manage depression.

Marijuana (THC) is a hallucinogenic drug derived from the hemp plant. Marijuana contains a number of active ingredients collectively known as Cannabinoids.

Many factors influence the length of time required for drugs to be metabolized and excreted into the urine. A variety of factors influence the time period during which drug metabolites are detected in urine. These include the rate of urine production, the volume of fluid consumption, the amount of drug taken, the urine pH, and the length of time over which drug was consumed. Drinking large volumes of liquid or using diuretics to increase urine volume will lower the drug concentration in the urine and may decrease the detection period. Lower detection levels may increase the detection time window. Although the detection period for these drugs varies widely depending upon the compound taken, dose and route of administration and individual rates of metabolism, some general times have been established and are listed below.¹⁻⁵

Drug	Detection Period
Amphetamine Acid Conditions Alkaline Condition	1-3 days 3-10 days
Barbiturates Short-Acting Long-Acting	Up to 6 days Up to 16 days
Benzodiazepines	1-12 days
Buprenorphine	up to 3 days
Cocaine metabolite	Up to 5 days 1 to 3 days typical
Methadone	1-3 days
Methamphetamine Acid Conditions Alkaline Conditions	1-3 days 3-10 days

Drug	Detection Period
Opiates Heroin Morphine Codeine	1 day 1-3 days 1-3 days
Oxycodone	1-3 days
PCP Single Use Chronic Use	1-8 days Up to 4 weeks
Propoxyphene	Up to 1 week
THC Single Use Chronic Use	1-7 days Less than 30 days typical
Tricyclic Antidepressants	1-7 days

3. PRINCIPLES OF THE PROCEDURE

Instant/POCT Drugs of Abuse Screening Devices include the one-step, competitive, membrane-based immunochromatographic Test Device only. A single urine sample can be evaluated for the presence of each of the classes of drugs specified in a single sample. The Instant/POCT Drugs of Abuse Screening Device includes antibody-colloidal gold, drug-conjugates and a control line.

ANTIBODY-COLLOIDAL GOLD Mouse monoclonal antibodies were developed that bind specifically to the drug class being tested. The individual monoclonal antibodies were adsorbed to colloidal gold and dried onto the test device.

DRUG-CONJUGATES Drugs from each class to be tested were individually conjugated to bovine serum albumin (BSA) or IgG. Each drug conjugate is immobilized on a test line at a designated position on the membrane strip.

CONTROL LINE Each test strip has anti-mouse antibody immobilized at the Control position of the membrane strip. The anti-mouse antibody will bind excess antibody-colloidal gold, indicating that the reagents are working properly.

When the urine sample is placed in the sample well of a test strip, the dried antibody-colloidal gold on the sample pad dissolves and the urine wicks up the white strips carrying the reddish-purple antibody-colloidal gold with it. The Instant/POCT Drugs of Abuse Screening Device will detect specific classes of drugs in urine because drug(s) in the urine and the drug(s) conjugated to the protein compete to bind to the antibody-colloidal gold. A test line will form when drug in the sample is below the detection threshold (negative result).

Negative Samples

When no drug(s) is present, above the established cut-off, in the urine sample, the reddish purple antibody-colloidal gold solutions migrate along the strip and bind to the respective drug conjugate(s) immobilized on the membrane. Each strip has up to 10 drug test lines. The binding of the antibody-colloidal gold to the drug conjugate generates a line at the corresponding test position on the strip. A "Negative" will show the presence of two viable "lines" (*Control & Result*).

Presumptive Positive Samples

When drug(s) is present, above the established cut-off, in the urine sample the antibody-colloidal gold binds to the drug(s) before it migrates along the strip. When the antibody-colloidal gold binds to the drug(s) in the urine, it cannot bind to the drug conjugate immobilized on the membrane and no line is generated at the drug-specific position in the result window. A "Presumptive Positive" will show the presence of only one Control line, but NO result line. Devices showing a very faint line should be sent out to a DHHS certified lab for further testing.

Control Line Missing (Valid or Invalid results)

Each screening device has an internal procedural control. A line must form at the Control position in the result window to indicate that sufficient sample was applied and that the reagents are migrating properly. If a Control line does not form, the test is invalid, and the sample should be sent out to a DHHS certified lab for further testing.

4. SAMPLE COLLECTION AND PREPARATION

The urine sample should be collected in a clean, dry container. Approximately 75 µL is required for each sample well. Collection of 30 mL of urine is more than sufficient for initial and subsequent testing. No preservatives should be added. Urine may be tested immediately following collection. If it is necessary to store the urine, store under refrigeration at 2 to 8°C (36 to 46° F) for no more than two days. Urine may be frozen at -20°C (-4° F) or colder for storage. Stored urine must be brought to ambient temperature (18 to 25°C/64 to 77°F) and mixed well to assure a homogeneous sample prior to testing.

5. PRECAUTIONS

- Instant/POCT Drugs of Abuse Screening devices is for *in vitro* diagnostic use only.
- Do not use Instant/POCT Drugs of Abuse Screening devices after the expiration date printed on the package label.
- Instant/POCT Drugs of Abuse Screening devices should remain in its original sealed foil pouch until ready to use. If the pouch is damaged, or beyond its printed expiration date the devices should be discarded and not used.
- If the Instant/POCT Drugs of Abuse Screening device has been stored refrigerated, bring to ambient temperature (18-25°C/ 64-77°F) prior to opening foil pouch.
- Do not store the test kit at temperatures above 25°C (77°F). Do not freeze.
- Do not cross-contaminate urine samples. Use a new urine specimen container and a fresh pipette tip for each device used. Avoid polystyrene containers. Do not use preservatives.
- Do not touch test strips in large viewing window of the Test Device.
- Do not use Test Device if strips are damaged or dirty.
- Ensure the test device is labeled with a corresponding Specimen ID Number, that matches the matching CCF.
- Do not write outside of the ID area on the left side of the Test Device top.
- Urine specimens and all materials coming in contact with them should be handled and disposed of as if infectious and/or capable of transmitting infection. Avoid contact with eyes, nose, ears or skin.
- Avoid contaminating the top of the test device with urine sample. Clean any urine off the top of the test device using a dry wipe to prevent contamination.

6. REAGENTS and MATERIALS PROVIDED/STORAGE CONDITIONS

- Each test device has all the reagents necessary to test one urine sample for one or more drugs simultaneously.
- Each test device holds one or more test strips composed of a membrane strip coated with drug conjugate and a pad coated with antibody-colloidal gold in a protein matrix.

Kit Contents

1. Twenty-five (25) test devices in individual foil packages
2. Twenty-five (25) disposable pipette tips
3. One Quick Reference guide

Storage Conditions

The kit, in its original packaging, should be stored at 2-25°C (36-77°F) until the expiration date on the label.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Split Urine specimen collection container & vials.

7. TEST PROCEDURE

1. Open one pouch for each sample to be tested and mark/affix the Test Device with the Donor's Specimen ID number. Make sure you only mark/affix along the left edge of the test device (labeled "ID").
(You may notice a reddish-purple color in the sample well. This is normal, do not discard the test).
2. Dispense 75µL of urine into sample well (indicated by ▽ on the test device).
3. Let the device draw-up the urine sample for no less than 3-5 minutes, then interpret the presence or absence of drug lines.

8. READING AND INTERPRETATION OF THE TEST RESULTS

Valid: ALL control lines must be present for the test to be valid.

NEG: A NEGATIVE test result for a specific drug indicates that the sample does not contain the drug/drug metabolite above the cutoff level.

POS: A presumptive POSITIVE test result for a specific drug indicates that the sample may contain drug/drug metabolite near or above the cutoff level. It does not indicate the level of intoxication or the specific concentration of drug in the urine sample. Positive samples should be sent to a DHHS certified laboratory for more definitive testing.

Invalid: ALL control lines must be present for the test to be valid. The absence of a control line indicates the test is invalid. The urine sample should be properly packaged and sent to a DHHS laboratory for additional testing.

9. QUALITY CONTROL

The purpose of quality control is to ensure accuracy and reliability of results and to ensure each device used is operating according to the manufactures specifications.

10. LIMITATIONS OF THE PROCEDURE

1. The Instant/POCT Drugs of Abuse Screening device is only for use with unadulterated preservative free, human urine samples. Urine samples that are either extremely acidic (below pH 4.0) or basic (above pH 9.0) may produce erroneous results. If adulteration is suspected, ship the sample to a DHHS laboratory for further testing.
2. A presumptive positive result for any drug does not indicate the level of intoxication, administration route or concentration of that drug in the urine specimen. False positives and false negatives may occur due to prescription drug use, diet and many other factors.
3. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
4. The Instant/POCT Drugs of Abuse Screening device is not intended for use in point-of-care or employment settings.
5. There is a possibility that other substances and/or factors, e.g. technical or procedural errors, may interfere with the test and cause false positive or false negative test results.
6. Gas Chromatography/Mass Spectroscopy is the recommended confirmatory method for most drugs. HPLC or LC/MS/MS is the preferred confirmatory method for Tricyclic Antidepressants and Benzodiazepines. Any of the drugs being tested for Drugs of Abuse may give a preliminary positive result if ingested at prescribed therapeutic doses.
7. The Instant/POCT Drugs of Abuse Screening device cannot distinguish between abused drugs and certain prescribed medications. A positive test may be obtained from certain foods or food supplements, thus confirmation via a DHHS laboratory & MRO is mandated.

11. PERFORMANCE CHARACTERISTICS

Sensitivity

The Instant/POCT Drugs of Abuse Screening device detects one or more of the following drugs at the cutoff levels listed below.

AMP	Amphetamine	500 ng/mL
BAR	Barbiturates (Butalbital)	200 ng/mL
BZO	Benzodiazepines (Nordiazepine)	150 ng/mL
BUP	Buprenorphine	10 ng/mL
COC	Benzoyllecgonine	150 ng/mL
MAMP	Methamphetamine	500 ng/mL
MTD	Methadone	200 ng/mL
OPI	Morphine	100 ng/mL
OPI2	Morphine	2000 ng/mL
OXY	Oxycodone	100 ng/mL
PCP	Phencyclidine	25 ng/mL
PPX	Propoxyphene (Norpropoxyphene)	300 ng/mL
THC	11-nor-9-carboxy- Δ^9 -THC	50 ng/mL
TCA	Tricyclic Antidepressants (Desipramine)	300 ng/mL

Accuracy

Accuracy and Comparison to GC/MS or LC/MS/MS

The accuracy of the Instant/POCT Drugs of Abuse Screening device was evaluated by assaying a panel of blind coded clinical urine samples containing varying concentrations of drugs and comparing to GC/MS or LC/MS/MS results. The samples were obtained from DHHS Laboratories and grouped in the following manner: Negative samples that screened negative by KIMS (Kinetic Interaction of Microparticles in Solution), and not confirmed by GC/MS; Below Cutoff Negative samples that fell between limit of detection or quantitation and 50% of cutoff; Near Cutoff Negative samples that fell between 50% of the cutoff concentration and the cutoff concentration; Near Cutoff Positive samples that fell between the cutoff concentration and 150% of the cutoff concentration; and High Positive samples that were greater than 150% of cutoff concentration. Drug concentrations were assayed by GC/MS or LC/MS/MS for BZO and TCA. Concentrations used to assign the cutoff ranges for each drug were determined by summing the GC/MS and LC/MS/MS levels measured for all test-specific analytes found in the sample. The testing was performed by in-house operators.

Instant/POCT Drugs of Abuse Screening device results vs. stratified GC/MS or LC/MS/MS Values

DRUG	P-V Test System	No Drug	Low negative by GC/MS or LC/MS/MS (Less than -50%)	Near Cutoff Negative (between -50% and cutoff)	Near Cutoff Positive (Between cutoff and +50%)	High Positive (greater than +50%)	% Agreement.
AMP (500)	Positive	0	0	4	5	41	96%
	Negative	40	5	0	2	0	92%
BAR (200)	Positive	0	0	3	4	36	100%
	Negative	40	3	2	0	0	94%
BZO (150)	Positive	0	0	1	4	41	100%
	Negative	40	3	3	0	0	98%
BUP (10)	Positive	0	0	0	4	36	100%
	Negative	40	0	4	0	0	100%
COC (150)	Positive	0	0	2	4	52	97%
	Negative	56	1	5	1	1	97%
mAMP (500)	Positive	0	0	1	3	40	98%
	Negative	40	4	3	1	0	98%
MTD (200)	Positive	0	0	2	3	40	98%
	Negative	40	4	2	1	0	96%
OPI (100)	Positive	0	0	3	5	44	100%
	Negative	46	2	2	0	0	94%
OPI (2000)	Positive	0	0	1	4	36	100%
	Negative	40	4	3	0	0	98%
OXY (100)	Positive	0	0	0	3	36	98%
	Negative	40	3	4	1	0	100%
PCP (25)	Positive	0	0	3	10	30	100%
	Negative	40	1	1	0	0	93%
PPX (300)	Positive	0	0	4	4	40	100%
	Negative	45	1	2	0	0	92%
TCA (300)	Positive	0	0	3	4	36	100%
	Negative	40	2	1	0	0	93%
THC (50)	Positive	0	0	2	7	33	100%
	Negative	40	4	2	0	0	96%
All Drugs	Positive	0	0	29	64	541	99%
	Negative	587	37	34	6	1	96%

For samples giving preliminary positive results below the cutoff and negative results above the cutoff, the assayed values are detailed in the table below:

ACCURACY/SUMMARY OF DISCORDANT RESULTS

Cutoff Value (ng/mL)	P-V Test System	GC/MS or LC/MS/MS Value
500	AMP positive	Amphetamine at 277 ng/mL
	AMP positive	Amphetamine at 352 ng/mL
	AMP positive	Amphetamine at 368 ng/mL
	AMP positive	Amphetamine at 463 ng/mL
	AMP negative	Amphetamine at 504 ng/mL
	AMP negative	Amphetamine at 667 ng/mL
200	BAR positive	Butalbital at 126 ng/mL
	BAR positive	Butalbital at 159 ng/mL
	BAR positive	Butalbital at 184 ng/mL
150	BZO positive	Alprazolam at 146 ng/mL
150	COC positive	Benzoyllecgonine at 114 ng/mL
	COC positive	Benzoyllecgonine at 121 ng/mL
	COC negative	Benzoyllecgonine at 180 ng/mL
	COC negative	Benzoyllecgonine at 278 ng/mL
500	mAMP positive	Methamphetamine at 483 ng/mL
	mAMP negative	Methamphetamine at 554 ng/mL
200	MTD positive	Methadone at 148 ng/mL
	MTD positive	Methadone at 176 ng/mL
	MTD negative	Methadone at 250 ng/mL
100	OPI positive	Morphine at 51 ng/mL
	OPI positive	Morphine at 79 ng/mL
	OPI positive	Morphine at 92 ng/mL
2000	OPI positive	Morphine at 1375 ng/mL
25	PCP positive	Phencyclidine at 19 ng/mL
	PCP positive	Phencyclidine at 21 ng/mL
	PCP positive	Phencyclidine at 24 ng/mL
100	OXY negative	Oxycodone at 71 ng/mL, Oxymorphone at 31 ng/mL
300	PPX positive	Norpropoxyphene at 172 ng/mL
	PPX positive	Norpropoxyphene at 194 ng/mL
	PPX positive	Norpropoxyphene at 228 ng/mL
	PPX positive	Norpropoxyphene at 271 ng/mL
300	TCA positive	Nortriptyline at 194 ng/mL
	TCA positive	Nortriptyline at 217 ng/mL
	TCA positive	Desipramine at 287 ng/mL
50	THC positive	11-nor-9-carboxy- Δ^9 -THC at 35 ng/mL
	THC positive	11-nor-9-carboxy- Δ^9 -THC at 39 ng/mL

Sensitivity/Precision/ Distribution of Random Error

Performance of the Instant/POCT Drugs of Abuse Screening device around the specific cutoff for each drug was evaluated by testing standard drug solutions diluted in drug-free urine in triplicate on 5 different intervals by 3 in-house operators using different readers (45 determinations for each level). Drug free urine was also tested on each interval.

Sample Concentration (ng/mL)	% of Cutoff	Number of Observations	# Neg	# Pos	Sample Concentration (ng/mL)	% of Cutoff	Number of Observations	# Neg	# Pos
AMP (500)					BAR (200)				
0	NEG	45	45	0	0	NEG	45	45	0
100	20%	45	45	0	100	50%	45	45	0
250	50%	45	41	4	150	75%	45	32	13
375	75%	45	37	8	250	125%	45	0	45
625	125%	45	8	37	300	150%	45	0	45
750	150%	45	0	45					
BZO (150)					 BUP (10)				
0	NEG	45	45	0	0	NEG	45	45	0
75	50%	45	45	0	5	50%	45	45	0
112.5	75%	45	33	12	7.5	75%	45	30	15
187.5	125%	45	8	37	12.5	125%	45	0	45
225	150%	45	0	45	15	150%	45	0	45
COC (150)					mAMP (500)				
0	NEG	45	45	0	0	NEG	45	45	0
75	50%	45	45	0	100	20%	45	45	0
112.5	75%	45	24	21	250	50%	45	27	18
187.5	125%	45	0	45	375	75%	45	13	32
225	150%	45	0	45	625	125%	45	1	44
					750	150%	45	2	43
MTD (200)					OPI (100)				
0	NEG	45	45	0	0	NEG	45	45	0
50	25%	45	45	0	25	25%	45	45	0
100	50%	45	34	11	50	50%	45	37	8
150	75%	45	8	37	75	75%	45	4	41
250	125%	45	0	45	125	125%	45	0	45
300	150%	45	0	45	150	150%	45	0	45
OPI (2000)					OXY (100)				
0	NEG	45	45	0	0	NEG	45	45	0
1000	50%	45	45	0	25	25%	45	45	0
1500	75%	45	31	14	50	50%	45	44	1
2500	125%	45	0	45	75	75%	45	19	26
3000	150%	45	0	45	125	125%	45	0	45
					150	150%	45	0	45
PCP (25)					PPX (300)				
0	NEG	45	45	0	0	NEG	45	45	0
6.25	25%	45	45	0	150	50%	45	45	0
12.5	50%	45	31	14	225	75%	45	31	14
18.75	75%	45	1	44	375	125%	45	2	43
31.25	125%	45	0	45	450	150%	45	0	45
37.5	150%	45	0	45					
TCA (300)					THC (50)				
0	NEG	45	45	0	0	NEG	45	45	0
150	50%	45	45	0	25	50%	45	45	0
225	75%	45	9	36	37.5	75%	45	39	6
375	125%	45	0	45	62.5	125%	45	0	45
450	150%	45	0	45	75	150%	45	0	45

Non Cross-reactive Endogenous Compounds

The Instant/POCT Drugs of Abuse Screening device was evaluated for cross reactivity with fifteen endogenous compounds. The compounds were dissolved in appropriate solvents at a concentration of at least 1.0 mg/mL. Each compound was further diluted to 100 µg/mL except for albumin (20 mg/mL) and bilirubin (200 µg/mL). None of these compounds showed cross-reactivity at the referenced concentrations to any of the Instant/POCT Drugs of Abuse Screening device.

- | | | |
|----------------|-----------------------|---------------------|
| Acetaldehyde | Creatinine | Hemoglobin, Human |
| Acetone | Epinephrine | Sodium Chloride |
| Albumin, Human | β-Estradiol | Tetrahydrocortisone |
| Bilirubin | Estril | d,1-Thyroxine |
| Cholesterol | Glucose Std. Solution | Uric Acid |

Unrelated Compounds, Prescription and Over-the-Counter Medications

The following compounds were tested for reactivity to the Instant/POCT Drugs of Abuse Screening device. Listed compounds were dissolved in appropriate solvents and then added to drug-free urine for testing. Unless otherwise noted by a drug name abbreviation such as "AMP" or "BAR" etc., all of the listed compounds were negative in each of the tests at 100 µg/mL or the highest level tested. If a drug name is followed by an abbreviation such as "AMP" or "BAR" etc., check the "Related Compounds and Cross Reactants" listing for the drug in question under the appropriate heading (AMP, BAR, etc.) to find its level of cross-reactivity to that test.

Acetaminophen	Ephedrine-MAMP	Ofloxacin
Acetylsalicylic Acid	Erythromycin	Olanzapine
Allobarbitol-BAR	Ethanol	Orphenadrine
Alprazolam-BZO	Ethylmorphine-OPI, OXY	Oxaprosin
Alprazolam, 1-Hydroxy-BZO	Fenfluramine-MAMP, AMP	Oxazepam glucuronide-BZO
7-Aminoclonazepam	Fenopropfen	Oxazepam-BZO
7-Aminoflunitrazepam	Fentanyl (Synthetic opiate)	Oxycodone-OXY
Amitriptyline-TCA	Flunitrazepam-BZO	Oxymetazoline
Amobarbital-BAR	Fluoxetine (Prozac)	Oxymorphone-OXY
Amoxapine	Flurazepam	Penicillin G
Amoxicillin	Fluvoxamine	Pentazocine
d-Amphetamine-AMP	Furoxamide	Pentobarbital-BAR
l- Amphetamine-AMP	Glutethimide	Perphenazine-TCA
Ampicillin	Haloperidol	Phencyclidine-PCP
Apomorphine	Hexobarbital	Phendimetrazine
l-Ascorbic Acid	Hydralazine	Phenethylamine
Atomoxetine	Hydrochlorothiazide	Pheniramine
Atropine Sulfate	Hydrocodone-OPI, OXY	Phenmetrazine
Barbital-BAR	Hydrocortisone	Phenobarbital-BAR
Barbituric Acid	Hydromorphone-OPI, OXY	Phenothiazine
Benzocaine (ethyl-4-aminobenzoate)	Hydroxybutpropion	Phentermine-AMP
Benzic Acid	l-11-Hydroxy- Δ^9 -THC	Phenylbutazone
Benzoyllecgonine-COC	4-Hydroxyphencyclidine-PCP	Phenylephrine-MAMP
Benzphetamine	Hydroxyzine	Phenylpropranolamine
Benztropine	Ibuprofen	Piroxicam
Brompheniramine	Imipramine-TCA	Prednisone
Buprenorphine-BUP	Ketamine	Procainamide
Bupropion	Ketoprofen	Procaine-MAMP
Butabarbital-BAR	Levorphanol-OPI	Prochlorperazine-TCA
Butalbital-BAR	Lidocaine	Promazine-TCA
Caffeine	Lithium carbonate	Promethazine
Cannabidiol	Loperamide	Propoxyphene-PPX
Cannabinol	Lorazepam glucuronide-BZO	Propranolol
Carbamazepine	Lorazepam-BZO	Protriptyline-TCA
Carbamazepine- 10,11 epoxide	Loxapine	d-Pseudoephedrine
Carisoprodol (Meproamate)	Lysergic Acid	Pyrilamine
Cephalexin	Lysergic Acid Diethylamide (LSD)	Quetiapine (Seroquel)-TCA
Chlordiazepoxide	Maprotiline-TCA	Quinidine
Chlorothiazide	MDA-AMP	Ranitidine
Chlorpheniramine	MDE (MDEA)-MAMP	Riboflavin
Chlorpromazine	MDMA-MAMP	Salicylic Acid
Clobazam-BZO	Meperidine	Secobarbital-BAR
Clomipramine	Mephobarbital	Sertraline (Zoloft)
Clonazepam-BZO	Mepivacaine	Sildenafil (Viagra)
Clorazepate-BZO	Mesoridazine	Sulfamethazine
Clozapine-TCA	Methadone-MTD	Sulindac
Cocaine-COC	d-Methamphetamine-MAMP	Talbutal-BAR
Codeine-OPI, OXY	l-Methamphetamine-MAMP	Temazepam glucuronide-BZO
Cotinine	Methaqualone	Temazepam-BZO
Cyclobenzaprine-TCA	Methcathinone	Tetracycline
Cyclopentobarbital-BAR	Methocarbamol	Δ^8 -Tetrahydrocannabinol
Desalkylflurazepam-BZO	Methylphenidate	Δ^9 -Tetrahydrocannabinol-THC
Desipramine-TCA	Metoprolol	Tetrahydrozoline
Desmethylchlordiazepoxide-BZO	Midazolam-BZO	Thebaine-OPI
Desmethylflunitrazepam-BZO	Mirtazapine	Theophylline
Desmethylenlafaxine	6-Monoacetylmorphine-OPI	Thiopental
Dextromethorphan	Morphine-OPI, OXY	Thioridazine
Diacetylmorphine-OPI	Morphine 3- β -D-Glucuronide-OPI	Thiothixene
Diazepam-BZO	Morphine 6- β -D-Glucuronide-OPI, OXY	Tolmetin (Tolectin)
Diclofenac	Nalorphine-OPI	Trazodone
Diethylpropion	Naloxone-OXY	Triamterene
Digoxin	Naltrexone-OXY	Triazolam, 1-hydroxy-BZO
Dihydrocodeine-OPI, OXY	Naproxen	Triazolam-BZO
Diphenhydramine	Nicotine	Trifluoperazine
Diphenylhydantoin (Phenytoin)-BAR	Nitrazepam-BZO	Trimethoprim
Domperidone	11-Nor-9-carboxy- Δ^9 -THC -THC	Trimipramine-TCA
Dopamine	Norclomipramine	Tripelennamine
Doxepin-TCA	Norcodeine-OPI, OXY	Tryptophan
Doxylamine	Nordiazepam-BZO	Tyramine
Ecgonine	Nordoxepin-TCA	Valproic Acid
Ecgonine Methyl Ester	Norlysergic Acid	Venlafaxine
EDDP-(Primary metabolite of methadone)	Normeperidine	Verapamil
Efavirenz (Sustiva)	Norpropoxyphene-PPX	
EMDP-(Secondary metabolite of methadone)	l-Norpseudoephedrine	
	Nortriptyline-TCA	

Related Compounds and Cross Reactants

The following metabolites and reacting compounds were evaluated for the specified test on the Instant/POCT Drugs of Abuse Screening device. Reference standards for the various metabolites and compounds were prepared in negative urine samples. Results are expressed as the minimum concentration expected to produce a positive result in the indicated assay. Compounds that reacted with the test are listed first, and related compounds that did not react with the highest concentration tested are listed second as Negative at 100,000 ng/mL. "% Cross-Reactive" values were calculated from the cut-off level for the calibrator used for each test (approximate 50% positive rate) divided by the lowest reported level found to react in the same test (greater than 66% positive rate).

Amphetamines (AMP) (d-Amphetamine) 500 ng/mL

	Result	% Cross-Reactive
I-Amphetamine	Positive at 50,000 ng/mL	1%
Fenfluramine	Positive at 10,000 ng/mL	5%
MDA	Positive at 250 ng/mL	200%
Phentermine	Positive at 7,500 ng/mL	7%
Ephedrine	Negative at 100,000 ng/mL	None Detected
MDE (MDEA)	Negative at 100,000 ng/mL	None Detected
MDMA	Negative at 100,000 ng/mL	None Detected
l-Methamphetamine	Negative at 100,000 ng/mL	None Detected
d-Methamphetamine	Negative at 100,000 ng/mL	None Detected
Phenethylamine	Negative at 100,000 ng/mL	None Detected
Pseudoephedrine	Negative at 100,000 ng/mL	None Detected
Tyramine	Negative at 100,000 ng/mL	None Detected

Barbiturate (BAR) (Butalbital) 200 ng/mL

	Result	% Cross-Reactive
Allobarbitol	Positive at 250 ng/mL	80%
Amobarbitol	Positive at 800 ng/mL	25%
Barbitol	Positive at 2,500 ng/mL	8%
Butabarbitol	Positive at 400 ng/mL	50%
Cyclopentobarbitol	Positive at 250 ng/mL	80%
Diphenylhydantoin (Phenytoin)	Positive at 2,000 ng/mL	10%
Pentobarbitol	Positive at 300 ng/mL	67%
Phenobarbitol	Positive at 1,250 ng/mL	16%
Secobarbitol	Positive at 50 ng/mL	400%
Talbutal	Positive at 50 ng/mL	400%
Barbituric Acid	Negative at 100,000 ng/mL	None Detected
Glutethimide	Negative at 100,000 ng/mL	None Detected
Hexobarbitol	Negative at 100,000 ng/mL	None Detected
Mephobarbitol	Negative at 100,000 ng/mL	None Detected
Thiopental	Negative at 100,000 ng/mL	None Detected

Benzodiazepine (BZO) (Nordiazepam) 150ng/mL

	Result	% Cross-Reactive
Alprazolam	Positive at 100 ng/mL	150%
Alprazolam, 1-OH	Positive at 25,000 ng/mL	<1%
Clobazam	Positive at 75 ng/mL	200%
Clonazepam	Positive at 900 ng/mL	17%
Clorazepate	Positive at 200 ng/mL	75%
Desalkylflurazepam	Positive at 600 ng/mL	25%
Desmethylchloridiazepoxide	Positive at 1,000 ng/mL	15%
Desmethylflunitrazepam	Positive at 75 ng/mL	200%
Diazepam	Positive at 75 ng/mL	200%
Flunitrazepam	Positive at 50 ng/mL	300%
Lorazepam	Positive at 1,200 ng/mL	13%
Lorazepam glucuronide	Positive at 1,000 ng/mL	15%
Midazolam	Positive at 5,000 ng/mL	3%
Nitrazepam	Positive at 50 ng/mL	300%
Oxazepam	Positive at 200 ng/mL	75%
Oxazepam glucuronide	Positive at 2,500 ng/mL	6%
Temazepam	Positive at 90 ng/mL	167%
Temazepam glucuronide	Positive at 750 ng/mL	20%
Triazolam	Positive at 750 ng/mL	20%
Triazolam, 1-OH	Positive at 10,000 ng/mL	2%
7-Aminoclonazepam	Negative at 100,000 ng/mL	None Detected
7-Aminoflunitrazepam	Negative at 100,000 ng/mL	None Detected
Chlordiazepoxide	Negative at 100,000 ng/mL	None Detected
Flurazepam	Negative at 100,000 ng/mL	None Detected

Buprenorphine (BUP) (Buprenorphine) 10ng/mL

	Result	% Cross-Reactive
Buprenorphine-glucuronide	Positive at 20 ng/mL	50%
Norbuprenorphine	Positive at 250 ng/mL	4%
Norbuprenorphine-glucuronide	Positive at 500 ng/mL	2%
Codeine	Negative at 100,000 ng/mL	None Detected
Diacetylmorphine	Negative at 100,000 ng/mL	None Detected
Hydrocodone	Negative at 100,000 ng/mL	None Detected
Hydromorphone	Negative at 100,000 ng/mL	None Detected
Levorphanol	Negative at 100,000 ng/mL	None Detected
6-Monoacetylmorphine	Negative at 100,000 ng/mL	None Detected
Morphine	Negative at 100,000 ng/mL	None Detected
Naloxone	Negative at 100,000 ng/mL	None Detected
Naltrexone	Negative at 100,000 ng/mL	None Detected
Oxycodone	Negative at 100,000 ng/mL	None Detected
Oxymorphone	Negative at 100,000 ng/mL	None Detected
Thebaine	Negative at 100,000 ng/mL	None Detected

Cocaine (COC) (Benzoylcegonine) 150 ng/mL

	Result	% Cross-Reactive
Cocaine	Positive at 250 ng/mL	60%
Ecgonine	Negative at 100,000 ng/mL	None Detected
Ecgonine Methyl Ester	Negative at 100,000 ng/mL	None Detected

Methamphetamine (mAMP) (d-Methamphetamine) 500 ng/mL

	Result	% Cross-Reactive
Ephedrine	Positive at 2,500 ng/mL	20%
Fenfluramine	Positive at 50,000 ng/mL	1%
MDE (MDEA)	Positive at 7,500 ng/mL	7%
MDMA	Positive at 1,150 ng/mL	43%
l-Methamphetamine	Positive at 7,500 ng/mL	7%
Phenylephrine	Positive at 25,000 ng/mL	2%
Procaine	Positive at 7,500 ng/mL	7%

d-Amphetamine	Negative at 100,000 ng/mL	None Detected
l-Amphetamine	Negative at 100,000 ng/mL	None Detected
MDA	Negative at 100,000 ng/mL	None Detected
Phenethylamine	Negative at 100,000 ng/mL	None Detected
Phentermine	Negative at 100,000 ng/mL	None Detected
Phenmetrazine	Negative at 100,000 ng/mL	None Detected
Pseudoephedrine	Negative at 100,000 ng/mL	None Detected
Tyramine	Negative at 100,000 ng/mL	None Detected

Methadone (MTD) (Methadone) 200 ng/mL

	Result	% Cross-Reactive
Buprenorphine (MTD Replacement)	Negative at 100,000 ng/mL	None Detected
EDDP (Primary metabolite)	Negative at 100,000 ng/mL	None Detected
EMDP (Secondary metabolite)	Negative at 100,000 ng/mL	None Detected

Opiates-(OPI) (Morphine) 100ng/mL

	Result	% Cross-Reactive
Codeine	Positive at 50 ng/mL	200%
Diacetylmorphine	Positive at 50 ng/mL	200%
Dihydrocodeine	Positive at 75 ng/mL	133%
Ethylmorphine	Positive at 50 ng/mL	200%
Hydrocodone	Positive at 400 ng/mL	25%
Hydromorphone	Positive at 800 ng/mL	13%
Levorphanol	Positive at 2,500 ng/mL	4%
6-Monoacetylmorphine	Positive at 350 ng/mL	29%
Morphine 3-β-D-Glucuronide	Positive at 75 ng/mL	133%
Morphine 6-β-D-Glucuronide	Positive at 500 ng/mL	20%
Nalorphine	Positive at 50,000 ng/mL	<1%
Norcodeine	Positive at 10,000 ng/mL	1%
Thebaine	Positive at 25,000 ng/mL	<1%

Apomorphine	Negative at 100,000 ng/mL	None Detected
Naloxone	Negative at 100,000 ng/mL	None Detected
Naltrexone	Negative at 100,000 ng/mL	None Detected
Oxycodone	Negative at 100,000 ng/mL	None Detected
Oxymorphone	Negative at 100,000 ng/mL	None Detected

Opiates-(OPI2) (Morphine) 2000ng/mL

	Result	% Cross-Reactive
Codeine	Positive at 900 ng/mL	222%
Diacetylmorphine	Positive at 2,500 ng/mL	80%
Dihydrocodeine	Positive at 3,800 ng/mL	53%
Ethylmorphine	Positive at 600 ng/mL	333%
Hydrocodone	Positive at 1,400 ng/mL	143%
Hydromorphone	Positive at 1,900 ng/mL	105%
Levorphanol	Positive at 5,000 ng/mL	40%
6-Monoacetylmorphine	Positive at 3,800 ng/mL	53%
Morphine 3-β-D-Glucuronide	Positive at 5,000 ng/mL	40%
Morphine 6-β-D-Glucuronide	Positive at 6,000 ng/mL	33%
Norcodeine	Positive at 40,000 ng/mL	5%
Thebaine	Positive at 2,500 ng/mL	80%

Apomorphine	Negative at 100,000 ng/mL	None Detected
Nalorphine	Negative at 100,000 ng/mL	None Detected
Naloxone	Negative at 100,000 ng/mL	None Detected
Naltrexone	Negative at 100,000 ng/mL	None Detected
Oxycodone	Negative at 100,000 ng/mL	None Detected
Oxymorphone	Negative at 100,000 ng/mL	None Detected

Oxycodone (OXY) (Oxycodone) 100 ng/mL

	Result	% Cross-Reactive
Codeine	Positive at 5000 ng/mL	2%
Dihydrocodeine	Positive at 25,000 ng/mL	<1%
Ethylmorphine	Positive at 7,500 ng/mL	1%
Hydrocodone	Positive at 50,000 ng/mL	<1%
Hydromorphone	Positive at 50,000 ng/mL	<1%
Morphine	Positive at 25,000 ng/mL	<1%
Morphine 6-β-D-Glucuronide	Positive at 100,000 ng/mL	<1%
Naloxone	Positive at 25,000 ng/mL	<1%
Naltrexone	Positive at 50,000 ng/mL	<1%
Norcodeine	Positive at 100,000 ng/mL	<1%
Oxymorphone	Positive at 250 ng/mL	40%

Apomorphine	Negative at 100,000 ng/mL	None Detected
Diacetylmorphine	Negative at 100,000 ng/mL	None Detected
Levorphanol	Negative at 100,000 ng/mL	None Detected
6-Monoacetylmorphine	Negative at 100,000 ng/mL	None Detected
Morphine 3-β-D-Glucuronide	Negative at 100,000 ng/mL	None Detected
Nalorphine	Negative at 100,000 ng/mL	None Detected
Thebaine	Negative at 100,000 ng/mL	None Detected

Phencyclidine (PCP) (Phencyclidine) 25 ng/mL 4-Hydroxyphencyclidine	Result Positive at 7,500 ng/mL	% Cross-Reactive <1%
Propoxyphene (PPX) (Norpropoxyphene) 300 ng/mL Propoxyphene	Result Positive at 50 ng/mL	% Cross-Reactive 600%
Cannabinoids (THC) (11-Nor-9-carboxy- Δ^9 -THC) 50 ng/mL Δ^9 -Tetrahydrocannabinol	Result Positive at 100,000 ng/mL	% Cross-Reactive <1%
Cannabidiol	Negative at 100,000 ng/mL	None Detected
Cannabinol	Negative at 100,000 ng/mL	None Detected
l-11-Hydroxy- Δ^9 -THC	Negative at 100,000 ng/mL	None Detected
Δ^8 -Tetrahydrocannabinol	Negative at 100,000 ng/mL	None Detected
Tricyclic Antidepressant (TCA) (Desipramine) 300 ng/mL	Result	% Cross-Reactive
Amitriptyline	Positive at 500 ng/mL	60%
Clozapine	Positive at 7,500 ng/mL	4%
Cyclobenzaprine	Positive at 20,000 ng/mL	2%
Doxepin	Positive at 1,300 ng/mL	23%
Imipramine	Positive at 250 ng/mL	120%
Maprotiline	Positive at 300 ng/mL	100%
Nordoxepin	Positive at 700 ng/mL	43%
Nortriptyline	Positive at 500 ng/mL	60%
Perphenazine	Positive at 75,000 ng/mL	<1%
Prochlorperazine	Positive at 50,000 ng/mL	<1%
Promazine	Positive at 900 ng/mL	33%
Protriptyline	Positive at 50,000 ng/mL	<1%
Quetiapine (Seroquel)	Positive at 10,000 ng/mL	3%
Trimipramine	Positive at 5,000 ng/mL	6%
Carbamazepine	Negative at 100,000 ng/mL	None Detected
Carbamazepine-10, 11 epoxide	Negative at 100,000 ng/mL	None Detected
Chlorpromazine	Negative at 100,000 ng/mL	None Detected
Clomipramine	Negative at 100,000 ng/mL	None Detected
Loxapine	Negative at 100,000 ng/mL	None Detected
Mirtazapine	Negative at 100,000 ng/mL	None Detected
Norclomipramine	Negative at 100,000 ng/mL	None Detected
Olanzapine	Negative at 100,000 ng/mL	None Detected
Phenothiazine	Negative at 100,000 ng/mL	None Detected
Thiothixene	Negative at 100,000 ng/mL	None Detected

Interference

pH and Specific Gravity:

The Instant/POCT Drugs of Abuse Screening device was assayed with three negative clinical samples with pH values of 4.0, 7.0 and 9.0 \pm 0.1. Each sample was assayed in triplicate. The pH samples were fortified with drug concentrations that were the maximum level to give a strong negative (95% or greater negative) result (10-50% of cut-off, see Sensitivity data), and the minimum level above the cut-off to give a strong positive (95% or greater positive) result (125-150% of cut-off, see Sensitivity data). All three pH samples gave negative results when fortified to the maximum strong negative level for each drug, and all gave positive results when fortified to the minimum strong positive level for each drug.

The Instant/POCT Drugs of Abuse Screening device was assayed with three samples with specific gravity values of 1.003, 1.015 and 1.030 \pm 0.001. Each sample was assayed in triplicate. The specific gravity samples were fortified with drug concentrations as described above for pH to give strong negative and strong positive results. All three specific gravity samples gave negative results when fortified to the maximum strong negative level for each drug, and all gave positive results when fortified to the minimum strong positive level for each drug.

Common Drugs:

Following the study of M.L. Smith, et al.⁶ drug free urine samples were spiked with drug concentrations that were the maximum level to give a strong negative (95% or greater negative) result (10-50% of cut-off, see Sensitivity data), and the minimum level above the cut-off to give a strong positive (95% or greater positive) result (125-150% of cut-off, see Sensitivity data). 100,000 ng/mL of the common drugs were then added to the preparation and assayed by the Instant/POCT Drugs of Abuse Screening device. If a common compound name is followed by the abbreviation "COC", "BAR" or "OPI", or "OXY" it has cross-reactivity to the specified drug test (see "Related Compounds and Cross Reactants") and therefore was not assayed for interference for that drug test. Samples were evaluated in triplicate by in-house operators. None of the common drugs listed in the following table affected the expected results.

Common Drugs Evaluated with the Instant/POCT Drugs of Abuse Screening device

Acetylsalicylic Acid	Chlorpheniramine	Morphine - OPI, OXY
Acetaminophen	Cocaine - COC	Phenobarbital - BAR
Brompheniramine maleate	Dextromethorphan	Phenytoin (Diphenylhydantoin)- BAR
Caffeine	Doxylamine	d-Pseudoephedrine
Carbamazepine	Ibuprofen	Salicylic Acid

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13. LIMITED EXPRESS WARRANTIES

The manufacturer makes no express warranty other than the diagnostic test kit will measure certain drugs and/or drug metabolites when used in accordance with the manufacturer's printed instructions. The use of the kit for any other purpose is outside the intended use of this product. The manufacturer gives no express warranty as to what the legal or clinical significance is of the levels of drug(s)/drug metabolites detected by the Instant/POCT Drugs of Abuse Screening device. The manufacturer disclaims any and all implied warranties of merchantability, fitness for use or implied utility for any other purposes. Any and all damages for failure of the kit to perform to its instructions are limited to the replacement value of the kit.

