

Drugs of Abuse Integrated Strip/Card/Device/Cup(Urine)

Package Insert for testing of any combination of the following drugs:

6-MAM/7-ACL/ACE/AMP/BAR/BUP/BZO/COC/COT/EDDP/ETG/FYL/GAB/HMO/K2/K3/KET/LS
D/MDMA/MET/MOP/MPD/MQL/MTD/OP/XY/PCP/PPX/TCA/THC/TRA/ZOL/TZD/PGB/ ALC

For Employment, Insurance, & Forensic Testing

Master IFU**INTENDED USE**

Drug Tests (Strip/Card/Device/Cup) is a rapid visual immunoassay for the qualitative, presumptive detection of any combination of drugs of abuse in human urine specimens at the cut-off concentrations listed below:

Test	Calibrator	Cut-off (ng/mL)
6-MAM	6-Monoacetyl-morphine	10
7-ACL	7-Aminoclonazepam	300
ACE	Acetaminophen	5000
ALC	Alcohol	0.02%
AMP	d-Amphetamine	1000
AMP	d-Amphetamine	500
AMP	d-Amphetamine	300
BAR	Secobarbital	300
BUP	BUP-3-D-Glucuronide	10
BUP	BUP-3-D-Glucuronide	5
BZO	Oxazepam	300
BZO	Oxazepam	200
BZO	Oxazepam	100
COC	Benzoylcegonine	300
COC	Benzoylcegonine	200
COC	Benzoylcegonine	150
COC	Benzoylcegonine	100
COT	(-) -Cotinine	600
COT	(-) -Cotinine	500
COT	(-) -Cotinine	300
COT	(-) -Cotinine	200
EDDP	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
EDDP	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
ETG	Ethyl Glucuronide	500
FYL	Fentanyl	20
FYL	Fentanyl	10
GAB	Gabapentin	2000
HMO	Hydromorphone	250
K2	JWH-073/JWH-018	50
K2	JWH-073/JWH-018	25
K3	AB- PINACA	25
KET	Ketamine	1,000
LSA	9,10-Didehydro-N,N-diethyl-6-methylergoline-8beta-carboxamide	50
MDMA	3,4-Methylenedioxy-MET	1000
MDMA	3,4-Methylenedioxy-MET	500
MET	Methamphetamine	1000
MET	Methamphetamine	500
MET	Methamphetamine	300
MOP	Morphine	300
MOP	Morphine	200
MOP	Morphine	100
MPD	Methylphenidate	300
MQL	Methaqualone	300
MTD	Methadone	300
OPI	Morphine	2000
OPI	Morphine	1000
OXY	Oxycodone	300
OXY	Oxycodone	100
PCP	Phencyclidine	25
PGB	Pregabalin	500
PGB	Pregabalin	1000
PPX	D-Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor- Δ^9 -THC-9-COOH	200
THC	11-nor- Δ^9 -THC-9-COOH	150
THC	11-nor- Δ^9 -THC-9-COOH	50
THC	11-nor- Δ^9 -THC-9-COOH	25
TML	Tramadol	300
TML	Tramadol	200
TML	Tramadol	100
TZD	Trazodone	25
ZOL	Zolpidem	50
ZOL	Zolpidem	25

The Integrated Split Specimen Cup (Urine) can also come with adulteration strips listed below:

Adulteration (StripA)	Oxidants / Specific Gravity / PH
Adulteration (StripB)	Nitrite / Glutaraldehyde / Creatinine

PRINCIPLE

Drug Tests (Strip/Card/Device/Cup) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will appear in the test line region of the corresponding drug strip. The presence of drug above the cut-off concentration in the urine specimen will saturate all the binding sites of the antibody. Therefore, no colored line will form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as Creatinine, pH, and Specific Gravity and to detect the presence of Glutaraldehyde, Nitrite and Oxidants/Pyridinium Chlorochromate in urine.

Creatinine (CRE): Tests for specimen dilution. Creatinine is a waste product of Creatine, and is an amino-acid contained in muscle tissue and found in urine. A person may attempt to foil a drug test by drinking excessive amounts of water or diuretics such as herbal teas to flush the system. Creatinine and Specific Gravity are two ways to check for dilution and flushing, which are the most common mechanisms used to circumvent drug testing. Low Creatinine and Specific Gravity levels may indicate diluted urine. The absence of Creatinine (<5 mg/dL) is indicative of a specimen not consistent with **human urine**.

Nitrite (NIT): Tests for commonly used commercial adulterants. They work by oxidizing the major cannabinoid metabolite THC-COOH. Normal urine should contain no trace of Nitrites. Positive results generally indicate the presence of an adulterant.

Glutaraldehyde (GLUT): Tests for the presence of aldehydes. Adulterants can contain Glutaraldehyde and can cause false negative screening results by disrupting the enzyme used in some immunoassay tests. ³Glutaraldehyde is not normally found in urine; therefore, detection of Glutaraldehyde in a urine specimen is generally indicates adulteration.

pH: Tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate that the specimen has been altered.

Specific Gravity (SG): Tests for specimen dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

Oxidants/Pyridinium Chlorochromate (OXI/PCC): Tests for the presence of oxidizing reagents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is a commonly used adulterant. ³Normal human urine should not contain Oxidants or PCC.

MATERIALS**Materials Provided**

Test strip/card/device/cup

Package insert

Materials Required but Not provided

Timer

Centrifuge

Positive and negative controls

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

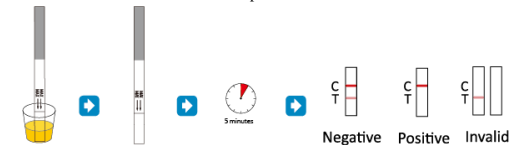
- The kit should be stored at 2-30 °C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

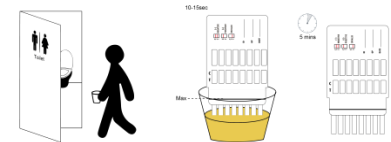
- The Drugs of Abuse Integrated Cup(Urine) is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8 °C for up to 2 days. For long term storage, specimens should be kept below -20 °C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE**For Drug Test Strip:**

- Equilibrate the test strip, urine specimens or external controls to room temperature (15-30 °C) prior to testing.
- Remove the test strip from the sealed pouch and dip the end of the strip into the specimen for at least 15 seconds to 20 seconds or until migration occurs. Immerse the strip just below the top line of the wave line on the test strips.
- Place the test strip on a flat dry surface.
- Read the results at 5 minutes. Do not interpret the result after 10 minutes.

**For Drug Test Card:**

- Equilibrate the test card, or the test strip, urine specimens or external controls to room temperature (15-30 °C) prior to testing.
- Removing the test card from the sealed pouch and dip the card into the specimen for at least 15 seconds to 20 seconds or until migration occurs. Immerse the strip(s) of the test card just below the top line of the wave line on the test strips; do not dip the card above the top line.
- Place the test card or the test strip on a flat dry surface.
- Read the adulteration strips between 3 to 5 minutes (when applicable) by comparing the colors in the adulteration pads to the enclosed color chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimens. We recommended not to interpret the drug test results and suggest you to retest the urine by using another specimen.
- Read the results at 5 minutes. Do not interpret the result after 10 minutes.

**For Drug Test Device:**

Allow the test device, urine specimen, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. The result should be read at 5. Do not interpret the result after 10 minutes.. It is important that the background is clear before the result is read.

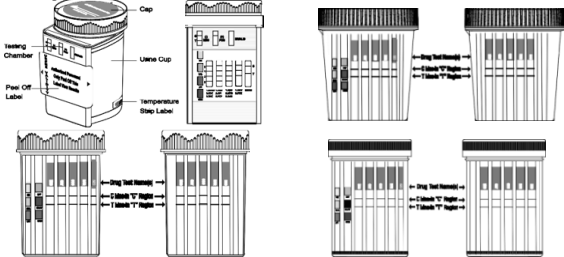
**For Drug Test Cup :**

Bring tests, specimens, and/or controls to room temperature (15-30 °C) before use if stored at refrigerated temperatures. Remove the cup from sealed pouch and use it as soon as possible.

- Donor dates and initials body label.
- Donor provides a urine specimen in the cup and screws cap on to it. Start timer immediately.
- Operator checks the cap for tightness.
- Remove the peel-off label.

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5. Check the temperature strip label at 2-4 minutes after specimen collection for the fresh urine specimen.A green color will appear to indicate the temperature of the urine specimen.The proper range for an unadulterated specimen is 90-100 °F (32-38 °C).
6. Drug test results are indicated by the presence or absence of colored band(s) in the result area of the test strips. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.
7. Positive test results must be confirmed by another test method.Send the cup and urine specimen intact to a toxicology laboratory for confirmation.
8. For the adulteration,compared with the color card, and the results should be read at 2 minutes , do not interpret the result after 5 minutes.



INTERPRETATION OF RESULTS

(See previous illustration)

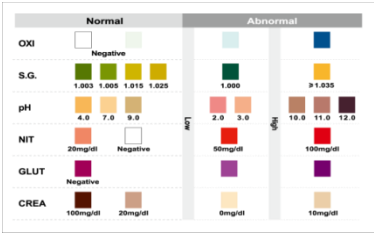
POSITIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T) for the drug in question. A positive result indicates that the drug concentration exceeds the detectable level.

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) for the drug in question. A negative result indicates that the drug concentration is below the detectable level.

INVALID:Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

- NOTE:**
1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

The Result Of Adulteration Strips:



The Urine Adulteration Test Strips (Urine) are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.

Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases show dilute urine.

Nitrite: Nitrite is not a normal component of human urine. However, Nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of >20 mg/dL may produce false positive Glutaraldehyde results.

Glutaraldehyde: Glutaraldehyde is not normally found in urine. However, certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.

Specific Gravity: Elevated levels of protein in urine may cause abnormally high Specific Gravity values.

Oxidants/PCC: Normal human urine should not contain Oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the Oxidants/PCC pad.

QUALITY CONTROL

The Quality Control Of DOA:

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

The Quality Control Of Adulteration Strips:

Control standards are not supplied with this kit. However, it is recommended that positive and negative specimens or controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. Drug Tests (Strip/Card/Device/Cup) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of drugs of abuse.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between drugs of abuse and certain medications.

The Limitations Of Adulteration Strips:

The Urine Adulteration Test Strips (Urine) are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.

- 1.**Creatinine:** Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases show dilute urine.
- 2.**Nitrite:** Nitrite is not a normal component of human urine. However, Nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of >20 mg/dL may produce false positive Glutaraldehyde results.
- 3.**Glutaraldehyde:** Glutaraldehyde is not normally found in urine. However, certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
- 4.**Specific Gravity:** Elevated levels of protein in urine may cause abnormally high Specific Gravity values.
- 5.**Oxidants/PCC:** Normal human urine should not contain Oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the Oxidants/PCC pad.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of Drug Tests (Strip/Card/Device/Cup) was established by running urine samples against GC/MS.

Specimen	ACE	AMP	AMP500	AMP300	BAR	BUP10	BUP5	BZO
Positive	96.1%	95.8%	95.9%	96.1%	97.8%	100%	100%	95.3%
Negative	100%	100%	100%	100%	98.1%	100%	100%	92.9%
Total	98.1%	98.1%	98.1%	98.1%	98%	100%	100%	93.9%

Specimen	BZO200	BZO100	COC	COC200	COC150	COC100	COT	COT300
Positive	97.4%	95.9%	98.2%	95.7%	96%	98.2%	96.5%	97.9%
Negative	98.2%	98%	98.1%	98.1%	94%	98.1%	98%	98.1%
Total	97.9%	97%	98.2%	97.0%	95%	98.2%	97.2%	98%

Specimen	COT200	EDDP	EDDP100	ETG500	FYL20	FYL10	HMO	K2	K2 25
Positive	97.7%	98.6%	95.8%	79.7%	96.8%	94.4%	95.9%	98.9%	97.5%
Negative	97.9%	100%	100%	84.7%	100%	100%	100%	100%	98.4%
Total	98%	99.1%	98.1%	82.2%	98.3%	97.2%	98.0%	99%	98.0%

Specimen	KET	LSD	6-MAM	MDMA	MDMA50	MET	MET500	MET300
Positive	98%	100%	96.8%	98.5%	100%	96.8%	96.9%	96.8%
Negative	98.6%	100%	100%	98.2%	100%	100%	100%	100%
Total	98.3%	100%	98.2%	98.3%	100%	98.3%	98.3%	98.4%

Specimen	MOP	MOP200	MOP100	MPD	MQL	MTD	OPI	OPI1000
Positive	96.8%	96.1%	96.1%	97.7%	98.4%	96.1%	97.6%	96.5%
Negative	97.9%	100%	100%	98.4%	98%	100%	98.4%	96%
Total	97.3%	98.1%	98.1%	98.1%	98.2%	98.1%	98.1%	96.3%

Specimen	OXY	OXY100	PCP25	PPX	TCA	THC	THC150	THC50	ZOL25
Positive	98%	96.1%	97.8%	97.8%	92.1%	96.1 %	98.4%	96.8%	98.4%
Negative	97%	100%	100%	100%	100%	100 %	98.3%	98.3%	98.2%
Total	97%	98.1%	98.9%	99%	96.8%	98.1 %	98.4%	97.5%	98.3%

Specimen	THC25	TML	TML100	ZOL	GAB	PGB500	PGB1000	K3	TZD
Positive	96.8 %	96.6%	98.4%	96.3%	97.7%	97.2%	97.2%	99.9%	99.9%
Negative	98.3 %	98.2%	100%	98%	98.4%	98.3%	98.2%	99.9%	99.9%
Total	97.5 %	97.4%	99.1%	97.1%	98.1%	97.8%	97.8%	99.9%	99.9%

Specimen	TML200	LSD	ZOL50
Positive	99 %	100%	96.3%
Negative	99 %	100%	98%
Total	99 %	100%	97.1%

*NOTE: BUP was based on LC/MS data instead of GC/MS

B. Sensitivity

The sensitivity of Drug Tests (Strip/Card/Device/Cup)was determined by testing GC/MS confirmed controls at negative, -50% cut-off, -25% cut-off, cut-off, +25% cut-off, +50% cut-off and 3 times cut-off concentrations. The results are summarized below:

Drug Conc.	n	ACE	AMP	AMP500	AMP300	BAR	BUP	BUP5	BZO
(Cut-off)	-	+	-	+	-	+	-	+	-
Negative	50	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0
Cutoff	50	19	31	16	34	14	36	20	30
125% Cutoff	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50
3XCutoff	50	0	50	0	50	0	50	0	50

Drug Conc.	n	BZO200	BZO100	COC	COC200	COC150	COC100	HMO	K2
(Cut-off)	-	+	-	+	-	+	-	+	-
Negative	50	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0
Cutoff	50	11	39	12	39	11	39	18	32
125% Cutoff	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50
3XCutoff	50	0	50	0	50	0	50	0	50

Drug Conc.	n	LSD	6-MAM	COT	COT300	COT200	EDDP	EDDP100	ETG
(Cut-off)	-	+	-	+	-	+	-	+	-
Negative	50	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0
Cutoff	50	22	28	25	25	15	35	17	33
125% Cutoff	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50
3XCutoff	50	0	50	0	50	0	50	0	50

Drug	n	FYL20	FYL10	KET	MDMA	MDMA500	MET	MET500	MET300
(Cut-off)	-	+	-	+	-	+	-	+	-
Negative	50	50	0	50	0	50	0	50	0
50%	50	50	0	50	0	50	0	50	0
75%	50	50	0	50	0	50	0	50	0
Cutoff	50	22	28	25	25	16	34	25	25
125%	50	0	50	0	50	0	50	0	50
150%	50	0	50	0	50	0	50	0	50
3XCutoff	50	0	50	0	50	0	50	0	50

Drug Conc.	n	MOP		MOP200		MOP100		MPD		MQL		MTD		OPI		OPI1000		ZOL
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
50%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
Cutoff	50	18	32	18	32	20	30	22	28	14	36	6	44	23	27	13	37	16
125%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
150%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
3XCutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0

Drug Conc.	n	OXY		OXY100		PCP		PPX		TCA		THC200		THC150		THC50		TZD
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
50%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
Cutoff	50	19	31	19	31	9	41	20	30	9	41	17	33	19	31	17	33	20
125%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
150%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
3×Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0

Drug Conc.	n	THC25	TML	TML100	ZOL	K2 25	GAB	PGB500	PGB1000
(Cut-off)		-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	30	30	0	50
50% Cut-off	50	50	0	50	0	30	30	0	50
75% Cutoff	50	50	0	50	0	24	21	9	6
Cutoff	50	11	39	15	35	11	39	1	3
125% Cutoff	50	0	50	0	50	2	2	28	28
150% Cutoff	50	0	50	0	50	0	0	30	30
3×Cutoff	50	0	50	0	50	0	0	30	30

Drug Conc.	n	K3	TML200	LSD	ZOL50
(Cut-off)		-	+	-	+
Negative	50	50	0	50	0
50% Cut-off	50	50	0	50	0
75% Cutoff	50	50	0	50	0
Cutoff	50	12	38	14	36
125% Cutoff	50	0	50	0	50
150% Cutoff	50	0	50	0	50
3×Cutoff	50	0	50	0	50

C. Specificity
The following tables list the concentrations of compounds (ng/mL) above which the Drug Tests (Strip/Card/Device/Cup)identified positive results at 5 minutes.

6-MAM 10 related compounds

6-Monoacetylmorphine	10
Acetylcodeine	>10,000
Buprenorphine	>10,000
Codeine	>10,000
Diacetylmorphine	1,000
Dihydrocodeine	>10,000
Ethylmorphine	>10,000
Hydrocodone	>10,000
Hydromorphone	5,000
Morphine	10,000
Morphine-3-glucuronide	>10,000
Nalorphine	5,000
Thebaine	>20,000
<u>7-ACL 300 related compounds</u>	
7-amine-clonazepam	300
Oxazepam	>10,000
Alprazolam	>10,000
Bromazepam	>10,000
Chlordiazepoxide	>10,000
Clobazam	>10,000
Clonazepam	10000
Clorazepate dipotassium	>10,000
Desalkylflurazepam	>10,000
Diazepam	>10,000
Estazolam	>10,000
Flunitrazepam	>50,000
(±) Lorazepam	10000
Midazolam	>100,000
Nitrazepam	>10,000
Norchlordiazepoxide	>100,000
Nordiazepam	>100,000

Temazepam	>10,000
<u>Acetaminophen 5000 related compounds</u>	
Acetaminophen	5,000
Acetophenetidine	7,500
<u>Amphetamine 1000 related compounds</u>	
d-Amphetamine	1,000
l-Amphetamine	>100,000
d-methamphetamine	>100,000
l-methamphetamine	>100,000
3,4-Methylenedioxymphetamine	1,250
3,4-Methylenedioxy-methamphetamine	>100,000
3,4-Methylenedioxyethylamphetamine	>100,000
Paramethoxyamphetamine	625
Phentermine	1,250
Tyramine	>100,000
<u>Amphetamine 500 related compounds</u>	
d-Amphetamine	500
l-Amphetamine	50,000
3,4-Methylenedioxymphetamine	625
Phentermine	1,250
Paramethoxyamphetamine	625
Tyramine	>100,000
<u>Amphetamine 300 related compounds</u>	
d-Amphetamine	300
l-Amphetamine	50,000
Mephentermine hemisulfate salt	>100,000
3,4-Methylenedioxymphetamine (MDA)	625
Phentermine	625
Paramethoxyamphetamine (PMA)	625
Paramethoxymethamphetamine (PMMA)	>100,000
Tyramine	>100,000
<u>Barbiturates 300 related compounds</u>	
Secobarbital	300
Allobarbital	1,250
Alphenal	625
Amobarbital	625
Aprobarbital	188
Butabarbital	94
Butalbital	2,500
Butethal	200
Cyclopentobarbital	400
Pentobarbital	1,000
Phenobarbital	300
<u>Benzodiazepines 500 related compounds</u>	
Oxazepam	500
<u>Benzodiazepines 300 related compounds</u>	
Oxazepam	300
Alprazolam	125
Bromazepam	625
Chlordiazepoxide	2500
Clobazam	63
Clonazepam	2500
Clorazepate	3330
Desalkflurazepam	250
Diazepam	250
Estazolam	5000
Fentanyl	>100,000
Flunitrazepam	375
Flurazepam	>100,000
Lorazepam	1250
Lormetazepam	1250
Medazepam	>100,000
Midazolam	>100,000

Nitrazepam	25000
Norchlordiazepoxide	250
Nordiazepam	500
Prazepam	>100,000
Temazepam	63
Triazolam	5000
<u>Benzodiazepines 200 related compounds</u>	
Oxazepam	200
Alprazolam	83
Bromazepam	417
Chlordiazepoxide	1,667
Clobazam	42
Clonazepam	1,667
Clorazepate	2,220
Desalkflurazepam	167
Diazepam	167
Estazolam	3,333
Fentanyl	>100,000
Flunitrazepam	250
Flurazepam	>100,000
Lorazepam	833
Lormetazepam	833
Medazepam	>100,000
Midazolam	>100,000
Nitrazepam	16,667
Norchlordiazepoxide	167
Nordiazepam	333
Prazepam	>100,000
Temazepam	42
Triazolam	3,333
<u>Benzodiazepines 100 related compounds</u>	
Oxazepam	100
Alprazolam	42
Bromazepam	208
Chlordiazepoxide	833
Clobazam	21
Clonazepam	833
Clorazepate	1,110
Desalkflurazepam	83
Diazepam	83
Estazolam	1,667
Fentanyl	>100,000
Flunitrazepam	125
Flurazepam	>100,000
Lorazepam	417
Lormetazepam	417
Medazepam	>100,000
Midazolam	>100,000
Nitrazepam	8,333
Norchlordiazepoxide	83
Nordiazepam	167
Prazepam	>100,000
Temazepam	21
Triazolam	1,667
<u>Buprenorphine 10 related compounds</u>	
Buprenorphine	10
Buprenorphine–3–β–D–Glucuronide	10
Norbuprenorphine	50
Norbuprenorphine–3–β–D–Glucuronide	100
<u>Buprenorphine 5 related compounds</u>	
Buprenorphine	5
Buprenorphine–3–β–D–Glucuronide	5
Norbuprenorphine	25

Norbuprenorphine–3–β-D-Glucuronide	50	Norfentanyl	>10,000	Δ8-Tetrahydrocannabinol	10,000
<u>Cocaine 300 related compounds</u>		<u>GAB related compounds</u>		Δ9-Tetrahydrocannabinol	31,250
Benzoylcegonine	300	Gabapentin	2000	Cannabinol	50,000
Cocaine	1,000	Pregbalin	> 100,000	<u>Marijuana 50 related compounds</u>	313
Ecgonine	100,000	<u>HMO 250 related compounds</u>		11-nor-Δ9-THC-9-COOH	625
Ecgonine Methyl Ester	>100,000	hydromorphone	250	11-nor-Δ8-THC-9-COOH	4,000
<u>Cocaine 200 related compounds</u>		Acetylcodeine	4000	11-hydroxy-Δ9-Tetrahydrocannabinol	
Benzoylcegonine	200	Buprenorphine	>10,000	Δ8-Tetrahydrocannabinol	500
Cocaine	125	Codeine	3000	Δ9-Tetrahydrocannabinol	12,500
Ecgonine	5,000	Diacetyl Morphin	3000	Cannabinol	12,500
Ecgonine Methyl Ester	>100,000	Dihydrocodeine	4000	Cannabidiol	3,125
<u>Cocaine 150 related compounds</u>		Ethylmorphine	4000	<u>Marijuana 25 related compounds</u>	25,000
Benzoylcegonine	150	Hydrocodone	300	11-nor-Δ9-THC-9-COOH	12,500
Cocaine	125	Morphine	2500	11-nor-Δ8-THC-9-COOH	1,875
Ecgonine	10000	6-Monoacetylmorphine	3000	Δ8-Tetrahydrocannabinol	625
Ecgonine Methyl Ester	>10000	Morphine-3-glucuronid	2500	Δ9-Tetrahydrocannabinol	2,000
<u>Cocaine 100 related compounds</u>		Nalorphine	12500	<u>MDMA 500 related compounds</u>	
Benzoylcegonine	100	Thebaine	> 20000	3,4-Methylenedioxy-methamphetamine	500
<u>Cotinine 600 related compounds</u>		Methadone	> 100000	d-Amphetamine	>100,000
(-)-Cotinine	600	Oxazepam	> 100000	l-Amphetamine	>100,000
<u>Cotinine 500 related compounds</u>		Oxycodone	100000	d-methamphetamine	>100,000
(-)-Cotinine	500	EDDP	>1000000	l-methamphetamine	>100,000
Buprenorphine	>100,000	<u>K2 50 related compounds</u>		3,4-Methylenedioxyamphetamine	2,500
<u>Cotinine 300 related compounds</u>		JWH-018-5-Pentanoic acid	50	3,4-Methylenedioxyethylamphetamine	156
(-)-Cotinine	300	<u>K3 related compounds</u>		Paramethoxyamphetamine	50,000
(-)-Nicotine	9,375	AB- PINACA	25	Paramethoxymethamphetamine	>100,000
<u>Cotinine 200 related compounds</u>		AB-PINACA 5-Pentanoic	25	<u>MDMA 1000 related compounds</u>	
(-)-Cotinine	200	AB-PINACA 5-hydroxypentyl	25	3,4-Methylenedioxy-methamphetamine	1,000
(-)-Nicotine	6,250	AB- FUBINACA	40	<u>Methadone 300 related compounds</u>	
<u>EDDP 100 related compounds</u>		AB-PINACA 4-hydroxypentyl	>10,000	Methadone	300
EDDP	100	UR-144 5-Pentanoic	5000	(-)-alpha-methadol	2,000
Meperidine	>100,000	UR-144	>10,000	<u>Methamphetamine 300 related compounds</u>	
Methadone	>100,000	UR-144 5-hydroxypentyl	>10,000	d-Methamphetamine	300
Norfentanyl	>100,000	UR-144 4-hydroxypentyl	>10,000	Chloroquine	7,500
Phencyclidine	>100,000	APINACA	>10,000	Fenfluramine	12,500
Promazine	50,000	APINACA 5-hydroxypentyl	>10,000	l-Methamphetamine	10,000
Promethazine	25,000	ADB-PINACA N-(5-hydroxypentyl)	50	Mephentermine hemisulfate salt	31,250
Prothipendyl	50,000	ADB-PINACA Pentanoic Acid	25	MDEA	50,000
Prozine	12,500	5-fluoro AB-PINACA N-(4-hydroxypentyl)	50	MDMA	313
<u>EDDP 300 related compounds</u>		5-fluoro AB-PINACA	50	PMMA	625
EDDP	300	<u>Ketamine 1000 related compounds</u>		(-)-Ephedrine	2,000
Meperidine	>100,000	Ketamine	1,000	<u>Methaqualone 300 related compounds</u>	
Methadone	>100,000	Norketamine	1,000	Methaqualone	300
Norfentanyl	>100,000	Dextromethorphan	500	Amitriptyline	50,000
Phencyclidine	>100,000	Dextrophan tartrate	500	Carbamazepine	20,000
Promazine	80,000	D-Norpropoxyphene	31,250	Nortriptyline	50,000
Promethazine	75,000	EDDP	800	Phenytion	40,000
Prothipendyl	80,000	Meperidine	12,500	Theophylline	40,000
Prozine	37,500	Mephentermine hemisulfate salt	50,000	<u>Morphine 300 related compounds</u>	
<u>ETG 500 related compounds</u>		Methadone	12,500	Morphine	300
Ethyl Glucuronide	500	D-Methamphetamine	12,500	Acetylcodeine	150
Ethanol	>100,000	3,4-Methylenedioxyethylamphetamine	25,000	Buprenorphine	> 10000
D-Glucuronic Acid	>100,000	Nordoxepin hydrochloride	25,000	Codeine	250
Morphine-3-b-D-glucuronide	>100,000	Phencyclidine	5,000	Diacetyl Morphin	250
<u>ETG 1000 related compounds</u>		Promazine	8,000	Dihydrocodeine	586
Ethyl Glucuronide	1000	Promethazine	25,000	Ethylmorphine	200
<u>Fentanyl 10 related compounds</u>		<u>LSD 50 related compounds</u>		Hydrocodone	12,500
Fentanyl and Fentanyl metabolites	10	Lysergic acid diethylamide	50	Hydromorphone	12,500
Fentanyl	100	<u>Marijuana 200 related compounds</u>		6-Monoacetylmorphine	250
Norfentanyl	>10,000	11-nor-Δ9-THC-9-COOH		Morphine-3-glucuronid	2,500
<u>Fentanyl 20 related compounds</u>		<u>Marijuana 150 related compounds</u>	1,000	Nalorphine	25,000
Fentanyl and Fentanyl metabolites	20	11-nor-Δ9-THC-9-COOH	25,000	Thebaine	25,000
Fentanyl	200	11-nor-Δ8-THC-9-COOH	12,500	<u>Morphine 200 related compounds</u>	

Morphine	200	Oxymorphone	>100,000
Acetylcodeine	100	Rifampicine	>100,000
Buprenorphine	2,000	Thebaine	50,000
Codeine	170	<u>Oxycodone 300 related compounds</u>	
Diacetyl Morphin	168	Oxycodone	300
Dihydrocodeine	395	Hydrocodone	75,000
Ethylmorphine	135	Hydromorphone	>100,000
Hydrocodone	8,350	Naloxone	>100,000
Hydromorphone	8,350	Oxymorphone	750
6-Monoacetylmorphine	170	<u>Oxycodone 100 related compounds</u>	
Morphine-3-glucuronid	1,670	Oxycodone	100
Nalorphine	16,666	Hydrocodone	6,250
Thebaine	16,666	Hydromorphone	50,000
<u>Morphine 100 related compounds</u>		Naloxone	50,000
Morphine	100	Oxymorphone	100
Codeine	100	Naltrexone	50,000
Diacetylmorphine (Heroin)	100	<u>PGB 1000 related compounds</u>	
Ethylmorphine	100	Pregabalin	1000
Hydromorphone	500	Gabapentin	> 20,000
Hydrocodone	500	<u>PGB 500 related compounds</u>	
6-Monoacetylmorphine	100	Pregabalin	500
Morphine-3-β-d-glucuronide	2,000	Gabapentin	> 20,000
Oxycodone	20,000	<u>Phencyclidine 25 related compounds</u>	
Oxymorphone	20,000	Phencyclidine	25
Promethazine	>100,000	Hydrocodone	>100,000
Rifampicine	8,400	Hydromorphone	>100,000
Thebaine	8,400	4-hydroxyphencyclidine	75
Trimipramine	20,000	<u>Propoxyphene 300 related compounds</u>	
<u>MPD 300 related compounds</u>		D-Propoxyphene	300
Methylphenidate	300	D-Norpropoxyphene	5,000
<u>Opiates 2000 related compounds</u>		<u>Tramadol 300 related compounds</u>	
Morphine	2,000	Tramadol	300
Acetylcodeine	1,563	<u>Tramadol 200 related compounds</u>	
Buprenorphine	25,000	Tramadol	200
Codeine	2000	(±)Chlorpheniramine	>1,000,000
Diacetylmorphine (Heroin)	5,000	Dimenhydrinate	>100,000
Dihydrocodeine	1,563	Diphenhydramine	>100,000
Ethylmorphine	250	Phencyclidine	>10,000
Hydromorphone	25,000	(+)-Chlorpheniramine	>100,000
Hydrocodone	50,000	<u>Tramadol 100 related compounds</u>	
Merperidine	>100,000	Tramadol	100
6-Monoacetylmorphine (6-MAM)	4,000	(+/-)-Chlorpheniramine	50,000
Morphine-3-β-d-glucuronide	12,500	Dimenhydrinate	50,000
Nalorphine Hydrochloride	>100,000	Diphenhydramine	50,000
Oxycodone	>100,000	Phencyclidine	50,000
Oxymorphone	>100,000	(+)-Chlorpheniramine	>100,000
Rifampicine	>100,000	<u>Tricyclic Antidepressants related compounds</u>	
Thebaine	50,000	Nortriptyline HCl	1,000
<u>Opiates 1000 related compounds</u>		Amitriptyline	1,500
Morphine	1,000	Clomipramine	>100,000
Acetylcodeine	1,000	Cyclobenzaprine	12,500
Buprenorphine	> 10000	Desipramine	188
Codeine	1000	Doxepin	2,000
Diacetylmorphine (Heroin)	3,000	Imipramine	2,500
Dihydrocodeine	1,000	Maprotiline	750
Ethylmorphine	200	Nortriptyline	3,125
Hydromorphone	25,000	Nordoxepin	500
Hydrocodone	50,000	Opipramol	1,563
Merperidine	>100,000	Promazine	1,000
6-Monoacetylmorphine (6-MAM)	3,000	Promethazine	6,250
Morphine-3-β-d-glucuronide	10000	Prothipendyl	25,000
Nalorphine Hydrochloride	>100,000	Protryptiline	6,250
Oxycodone	>100,000	Prozine	1,250

Trimipramine	>100,000
<u>TZD related compounds</u>	
Trazodone	25
<u>Zolpidem 50 related compounds</u>	
Zolpidem Phenyl-4-carboxylic	50
Zolpidem	>10,000
<u>Zolpidem 25 related compounds</u>	
Zolpidem Phenyl-4-carboxylic	25
Zolpidem	>10,000









A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Drug Tests (Strip/Card/Device/Cup) when tested at concentrations up to 100 µg/mL.

(-)-Ephedrine (Except MET)	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine (Except MET)	Dextromethorphan	Pheniramine
4-Dimethylaminoantipyrene	Dextrophan tartrate	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline (Except TCA)	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Ibuprofen	Vitamin C (Ascorbic Acid)
Bilirubin	Imipramine (Except TCA)	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Caffeine	Lidocaine	Ibuprofen
Chloroquine	Methadone (Except MTD)	

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GLOSSARY OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	<i>In vitro</i> diagnostic medical device		Use by
	Manufacturer		Do not reuse

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

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