Multi Drug Screening Test 10 Drugs IVD CE

PRODUCT CODE
RT011

INTENDED USE:
The One Step Drug of Abuse Test is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs **(THC, COC, OPI, AMP, PCP, MAMP, BZO, BAR, MTD, TCA)** and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/ml)
Amphetamine (AMP 1000)	D-Amphetamine	1,000 ng/mL
Amphetamine (AMP 500)	D-Amphetamine	500 ng/mL
Amphetamine (AMP 300)	D-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	200 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Marijuana (THC 50)	11-nor-Δ9 -THC-9 COOH	50 ng/mL
Marijuana (THC 20)	11-nor-Δ9 -THC-9 COOH	20 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (MAMP 1000)	D-Methamphetamine	1,000 ng/mL
Methamphetamine (MAMP 500)	D-Methamphetamine	500 ng/mL
Methamphetamine (MAMP 300)	D-Methamphetamine	300 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL
Opiate 2000 (OPI 2000)	Morphine	2,000 ng/mL

This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.1 Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained

PRINCIPLE:
The One Step Drug of Abuse Test is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a 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 show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not 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.

MATERIALS SUPPLIED:
1. Test Devices 2. Desiccant 3. Package Insert
4. Color Chart Card for Adulterant Interpretation (when applicable)
5. Disposable specimen droppers (for test cassette only)

ADDITIONAL REQUIREMENTS:
1. Specimen collection container (for strip, cassette, discard)
2. Disposable gloves 3. Timer 4. Dropper (for strip, cassette)

STORAGE AND STABILITY:
Store as packaged in the sealed pouch at 2-30o C (36-86o F). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do Not Freeze. Do not use beyond the expiration date

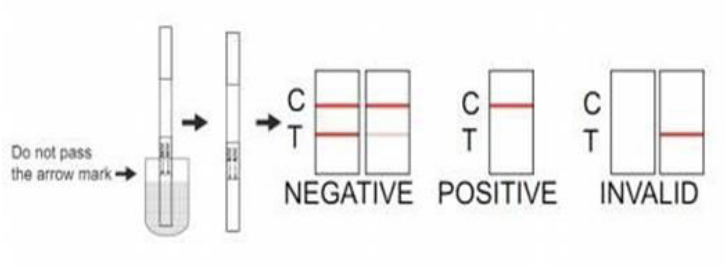
SPECIMEN AND SAMPLE PREPARATION:
Urine Assay: The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be allowed to settle to obtain a clear specimen for testing.
Specimen Storage: Urine specimens may be stored at 2-8°C (36-46°F) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

PRECATIONS:
1. For medical and other professional in vitro diagnostic use only.
2. Do not use after the expiration date.
3. The test device should remain in the sealed pouch until use.
4. The test is for single use.
5. While urine is not classified by OSHA or the CDC as a biological hazard unless visibly contaminated with blood,
6. The use of gloves is recommended to avoid unnecessary contact with the specimen.
7. The used test device and urine specimen should be discarded according to federal, state and local regulations.

PROCEDURE:
Allow the test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

(For Strip)
1. Remove the strip from the foil wrapper or the desiccated container (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label the strip with patient or control identifications.
2. Immerse the strip into the urine with the arrow end pointing toward the urine. Do not cover the urine over the MAX (maximum) line. You may leave the strip in the urine or you may take the strip out after a minimum of 15 seconds in the urine and lay the strip flatly on a non-absorptive clean surface.
3. Read results at 5 minutes.

***Note:** Do Not Interpret Result After 10 Minutes.



(For Cassette)
1. Remove the test device from its foil wrapper by tearing along the slice (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label the device with patient or control identifications.
2. Using the specimen dropper, withdraw the urine sample from the specimen cup and slowly dispense 3 drops (approximately 120Ul) into the circular sample well, being careful not to overfill the absorbent pad.
3. Read results at 5 minutes.

***Note**: Do Not Interpret Result After 10 Minutes.

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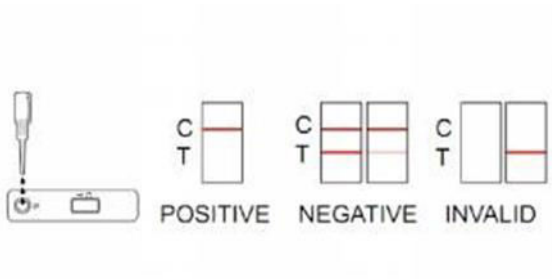
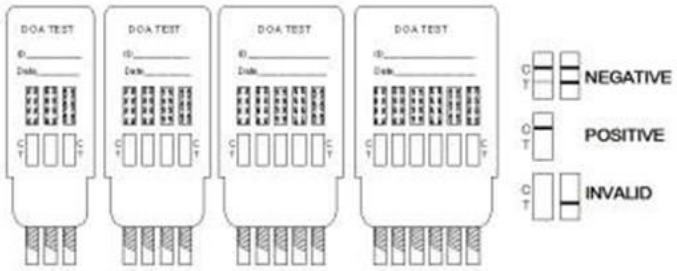


(For Dip card)

4. Remove the test device from the foil pouch.
5. Remove the cap from the test device. Label the device with patient or control identifications.
6. Immerse the absorbent tip into the urine sample for about 10 seconds. Urine sample should not touch the plastic device.
7. Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface
8. Read results at 5 minutes.

***Note**: Do Not Interpret Result After 10 Minutes.



RESULTS:

Negative: Two lines appear, one color line should be in the control region, and another apparent color line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

***Note:** The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint distinguishable color line.

Positive: One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your supplier.

QUALITY CONTROL:

A procedural control is included in the test. A color line appearing in the control region is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATION:

1. The One Step Drug of Abuse Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen and a new test device.
4. A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
5. 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.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements
8. The adulterant tests included with the product are meant to aid in the determination of abnormal specimens, but may not cover all the possible adulterants.
9. Oxidants: Normal human urine should not contain oxidants. The presence of high level of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants pad.
10. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
11. Nitrite (NIT) : 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.
12. Glutaraldehyde(GLU): Is not normally found in a urine specimen. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
13. Creatinine(CRE): Tests for the specimen for dilution and flushing. Normal creatinine levels are between 20 and 350 mg/Dl. Under rare conditions, certain kidney diseases may show dilute urine

PERFORMANCE CHARACTERISTICS:

In the Comparison Study, the One Step Drug of Abuse Tests were compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for each of the drug types of Cocaine, Benzodiazepine, Morphine, Oxycodone, Methadone, EDDP, Amphetamine, Barbiturates, Marijuana, Methamphetamine, MDMA, Opiate 2000, Phencyclidine, Buprenorphine and Tricyclic Antidepressants. Clinical specimens were quantified by GC/MS analysis before testing.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital
BZO	Oxazepam
COC	Benzoylecgonine
THC	11-nor-Δ9 -THC-9 COOH
MTD	Methadone
MAMP	Methadone
PCP	Phencyclidine
TCA	Nortriptyline
OPI	Morphine

The following results are tabulated from these clinical studies

	AMP 1000	AMP 500	AMP 300	MTD	OPI 2000	BAR	TCA	MDMA
Positive Agreement	98%	98%	95%	98%	95%	95%	98%	93%
Negative Agreement	98%	98%	95%	95%	98%	98%	95%	95%
Overall Agreement	98%	98%	95%	96%	96%	96%	96%	94%

	EDDP	THC	PCP	COC	TRA	BUP	BZO300	OXY
Positive Agreement	98%	95%	93%	93%	93%	93%	98%	95%
Negative Agreement	95%	98%	95%	95%	95%	95%	93%	95%
Overall Agreement	96%	96%	94%	94%	94%	94%	95%	95%

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	MAMP 1000	MAMP 500	MAMP 300	THC20	BZO200	COC150	MOP300	PPX
Positive Agreement	93%	95%	98%	98%	95%	98%	98%	95%
Negative Agreement	95%	98%	95%	95%	98%	98%	95%	98%
Overall Agreement	94%	96%	96%	96%	96%	98%	96%	96%

Analyte	THC		BZO300		PPX		OXY		MTD		EDDP	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	20	0	20	0	20	0	20	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19	3	17	1	19	2	18	2	18	2	18
Near Cut-off Positive Samples [between cutoff and 150% of cut-off]	18	2	19	1	18	2	18	2	19	1	19	1
Positive Samples [>150% of cut-off]	20	0	20	0	20	0	20	0	20	0	20	0
Agreement with GC/MS	95%	98%	98%	93%	95%	98%	95%	95%	98%	95%	98%	95%

Analyte	BAR		COC		OPI2000		MDMA		mAMP		BUP	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	20	0	20	0	20	0	20	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19	2	18	1	19	2	18	2	18	2	18
Near Cut-off Positive Samples [between cutoff and 150% of cut-off]	18	2	17	3	18	2	17	3	17	3	17	3
Positive Samples [>150% of cut-off]	20	0	20	0	20	0	20	0	20	0	20	0
Agreement with GC/MS	95%	98%	93%	95%	95%	98%	93%	95%	93%	95%	93%	95%

Analyte	mAMP500		AMP300		MOP300		THC20		COC150		TRA	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	20	0	20	0	20	0	20	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19	2	18	2	18	1	19	1	19	2	18
Near Cut-off Positive Samples [between cutoff and 150% of cut-off]	18	2	18	2	19	1	18	2	19	1	17	3
Positive Samples [>150% of cut-off]	20	0	20	0	20	0	20	0	20	0	20	0
Agreement with GC/MS	95%	98%	95%	95%	98%	95%	95%	98%	98%	98%	93%	95%

Analyte	TCA		AMP1000		PCP		AMP500		BZO200		mAMP300	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	20	0	20	0	20	0	20	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	2	18	1	19	2	18	1	19	1	19	2	18
Near Cut-off Positive Samples [between cutoff and 150% of cut-off]	19	1	19	1	17	3	19	1	18	2	19	1
Positive Samples [>150% of cut-off]	20	0	20	0	20	0	20	0	20	0	20	0
Agreement with GC/MS	98%	95%	98%	98%	93%	95%	98%	98%	95%	98%	98%	95%

REPRODUCIBILITY:

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

Amphetamine (AMP1000)

Amphetamine (AMP) conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
500	40	40 negative	>99%
1500	40	40 positive	>99%
2000	40	40 positive	>99%

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Amphetamine (AMP500)

Amphetamine (AMP) conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
250	40	40 negative	>99%
750	40	40 positive	>99%
1000	40	40 positive	>99%

Amphetamine (AMP300)

Amphetamine (AMP) conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Barbiturates (BAR)

Secobarbital conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Benzodiazepines (BZO300)

Oxazepam conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Benzodiazepines (BZO200)

Oxazepam conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
100	40	40 negative	>99%
300	40	40 positive	>99%
400	40	40 positive	>99%

Cocaine (COC300)

Benzoylecgonine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Cocaine (COC150)

Benzoylecgonine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
75	40	40 negative	>99%
225	40	40 positive	>99%
300	40	40 positive	>99%

Marijuana (THC50)

11-nor-Δ^9-THC-9-COOH conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
10	40	40 negative	>99%
30	40	40 positive	>99%
40	40	40 positive	>99%

Marijuana (THC20)

11-nor-Δ^9-THC-9-COOH conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
10	40	40 negative	>99%
30	40	40 positive	>99%
40	40	40 positive	>99%

Methadone (MTD)

Methadone conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Methamphetamine (MAMP1000)

Methamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
500	40	40 negative	>99%
1500	40	40 positive	>99%
2000	40	40 positive	>99%

Methamphetamine (MAMP500)

Methamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
250	40	40 negative	>99%
750	40	40 positive	>99%
1000	40	40 positive	>99%

Methamphetamine (MAMP300)

Methamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Opiate 2000 (OPI 2000)

Morphine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
1000	40	40 negative	>99%
3000	40	40 positive	>99%
4000	40	40 positive	>99%

Phencyclidine (PCP)

Phencyclidine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
12.5	40	40 negative	>99%
37.5	40	40 positive	>99%
50	40	40 positive	>99%

Tricyc antidepressants (TCA)

Nortiptyline conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
500	40	40 negative	>99%
1500	40	40 positive	>99%
2000	40	40 positive	>99%

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ANALYTICAL SENSITIVITY

A drug-free urine pool was spiked with drugs to the concentrations at ±50% cut-off and ± 25% cut-off. The results are summarized below.

Drug concentration Cut-off Range	n	AMP1000		BAR		BZO		COC300		THC50	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	27	3	28	2	30	0	20	10
Cut-off	30	17	13	15	15	16	14	9	21	13	17
+25% Cut-off	30	6	24	4	26	3	27	7	23	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	MTD		AMP500		mAMP1000		MDMA		MOP300	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	27	3	24	6	28	2	28	2
Cut-off	30	16	14	16	14	14	16	19	11	20	10
+25% Cut-off	30	3	27	3	27	7	23	2	28	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	OXY		PCP		TRA		TCA		EDDP	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	23	7	27	3	26	4	20	10	27	3
Cut-off	30	10	20	19	11	16	14	14	16	16	14
+25% Cut-off	30	1	29	1	29	3	27	4	26	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	OPI2000		BUP		AMP500		mAMP500		mAMP300	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	28	2	26	4	27	3	27	3
Cut-off	30	14	16	16	14	19	11	20	10	14	16
+25% Cut-off	30	4	26	5	25	3	27	6	24	29	1
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	AMP 300		COC150		THC 20		BZO200	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	26	4	25	5	26	4	25	5
Cut-off	30	14	16	13	17	18	12	14	16
+25% Cut-off	30	5	25	2	28	4	26	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30

ANALYTICAL SPECIFICITY:

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the One Step Drug of Abuse Test at a read time of 5 minutes.

Drug	Concentration (ng/ml)
AMPHETAMINE (AMP1000)	
d-amphetamine	1,000
D,l-amphetamine	1,000
l-amphetamine	20,000
Phentermine	1,250
(+/-)-Methylenedioxyamphetamine (MDA)	1,500
(+/-)-4-Hydroxyamphetamine HCL	600
AMPHETAMINE (AMP500)	
d-amphetamine	500
D,l-amphetamine	750
l-amphetamine	16,000
Phentermine	650

Drug	Concentration (ng/ml)
(+/-)-Methylenedioxyamphetamine (MDA)	800
AMPHETAMINE (AMP300)	
d-amphetamine	300
D,l-amphetamine	500
l-amphetamine	10,000
Phentermine	400
(+/-)-Methylenedioxyamphetamine (MDA)	500
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	750
Aprobarbital	250
Butabarbital	6,000
Butalbital	2,500
Butethal	2,500
Cyclopentobarbital	500
Pentobarbital	2,500
Phenobarbital	25,000
BENZODIAZEPINES (BZO300)	
a-Hydroxyalprazolam	1,260
Alprazalam	200
Bromazepam	1,560
Chlordiazepoxide	1,565
Chlordiazepoxide HCl	780
Clobazam	100
Clonazepam	785
Clorazepate Dipotassium	195
Delorazepam	1,560
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	385
(±) Lorazepam	1,560
RS-Lorazepam glucuronide	160
Midazolam	12,500
Nitrazepam	95
Norchlordiazepoxide	200
Nordiazepam	390
Oxazepam	300
Temazepam	100
Triazolam	2,500
BENZODIAZEPINES (BZO200)	
a-Hydroxyalprazolam	840
Alprazalam	150
Bromazepam	1,040
Chlordiazepoxide	1,040
Chlordiazepoxide HCl	520
Clobazam	70
Clonazepam	560
Clorazepate Dipotassium	160
Delorazepam	1,040

Desalkylflurazepam	260
Diazepam	150
Estazolam	1,500
Flunitrazepam	260
(±) Lorazepam	1,040
RS-Lorazepam glucuronide	100
Midazolam	12,500
Nitrazepam	70
Norchlordiazepoxide	150
Nordiazepam	260

Drug	**Concentration (ng/ml)**
Oxazepam	200
Temazepam	70
Triazolam	1,500
Flunitrazepam	150
(±) Lorazepam	7,000
RS-Lorazepam glucuronide	100
Midazolam	3,500
Nitrazepam	500
Norchlordiazepoxide	150
Nordazepam	700
Temazepam	35,000
Triazolam	1,500
COCAINE (COC300)	
Benzoylecogonine	300
Cocaethylene	300
Cocaine	300
Metoclopromide	80,000
Procaine	75,000
Riboflavin	25,000
Norcocaine	50,000
COCAINE (COC150)	
Benzoylecogonine	150
Cocaethylene	2,500
Cocaine	1000
MARIJUANA (THC50)	
11-Nor-Δ^9-Tetrahydrocannabinol	50
11-Hydroxy-Δ^9-Tetrahydrocannabinol	5,000
11-Nor-Δ^8-Tetrahydrocannabinol	50
11-Nor-Δ^9-Tetrahydrocannabinol-9 Carboxylic Glucuron-id	2,500
Δ^8-Tetrahydrocannabinol	20,000
Δ^9 -Tetrahydrocannabinol	50,000
MARIJUANA (THC20)	
11-Nor-Δ^9-COOH	20
Cannabinol	10,000
11-Nor-Δ^8-COOH	20
11-Nor-Δ^9-Tetrahydrocannabinol-9 Carboxylic Glucuronid	2,500
Δ^8-THC	10,000
Δ^9 -THC	10,000
METHAMPHETAMINE (MAMP 1000)	
+methamphetamine	1,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
+/-methamphetamine	1,000
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2,500
Chloroquine	50,000
Ephedrine	100,000
Fenfluramine	50,000
p-Hydroxymethamphetamine	10,000
METHAMPHETAMINE (MAMP 500)	
+methamphetamine	500
D,l-amphetamine	750
l-amphetamine	16,000
Phentermine	650
(+/-)-Methylenedioxyamphetamine (MDA)	800

METHAMPHETAMINE (MAMP 300)	
+methamphetamine	300
D,l-amphetamine	450

Drug	**Concentration (ng/ml)**
l-amphetamine	9,600
Phentermine	400
(+/-)-Methylenedioxyamphetamine (MDA)	480
METHYLENEDIOXYMETHAMPHETAMINE （MDMA）	
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine HCI (MDA)	3,000
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300
Labetalol	50,000
MORPHINE (OPI 300,MOP,MOR)	
Morphine	300
6-acetylmorphine	500
Codeine	100
Eserine (Physosotigmine)	15,000
Ethylmorphine	100
Heroin	500
Hydromorphone	2,000
Hydrocodone	1,250
Morphine-3-glucuronide	75
Oxycodone	75,000
Thebaine	13,000
OPIATES (OPI 2000)	
Morphine	2,000
6-acetylmorphine	2,500
Codeine	1,000
Ethyl Morphine	250
Heroin	5,000
Hydromorphine	2,500
Hydrocodone	5,000
Morphine-3-glucuronide	75
Oxycodone	75,000
Thebaine	13,000
Levorphanol	25,000
Eserine	50,000
OXYCODONE (OXY)	
Oxycodone	100
Codeine	50,000
Dihydrocodeine	12,500
Ethyl Morphine	75,000
Hydrocodone	1,580
Hydromorphone	100,000
Oxymorphone	750
Thebaine	50,000
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxy PCP	90
PCP Morpholine Anolog	625
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	50,000
Desipramine	5,000
Doxepine	10,000
Imipramine	10,000
Maprotiline	100,000
Nordoxepin	10,000
Promazine	50,000
Promethazine	2,500
Trimipramine	50,000
Cyclobenzaprine Hydrochloride	5,000
Norclomipramine	50,000
Buprenorphine (BUP)	

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Drug	Concentration (ng/ml)
Buprenorphine	10
Norbuprenorphine	20
Methadone (MTD)	
Methadone	300
Doxylamine	50,000
Propoxyphene (PPX)	
Norpropoxyphene	300
Propoxyphene,d-	300
EDDP(Methadone Metabolites)	
EDDP	300
Disopyramide	50,000
Tramadol	100,000
Venlafaxine hydrochloride	100,000
TRAMADOL (TRA)	
Tramadol	200
N-desmethyl-tramadol	500
O-desmethyl-tramadol	20,000

EFFECT OF URINARY SPECIFIC GRAVITY:
Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.030) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Drug of Abuse Test was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

EFFECT OF URINARY PH:
The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the One Step Drug of Abuse Test. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

CROSS REACTIVITY:
A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Cocaine, Barbiturates, Benzodiazepines, Amphetamine , Methamphetamine, Marijuana, Methadone, MDMA(Ecstasy), Opiate , Oxycodone, Phencyclidine, EDDP(Methadone Metabolites), Buprenorphine, Tramadol, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the One Step Drug of Abuse Test at concentrations of 100 ㎍/mL.

NON-CROSS REACTIVITY COMPOUNDS:
Acetophenetidin, l-Cotinine , Ketoprofen , d-Pseudoephedrine, N-Acetyl procainamide , Creatinine, Labetalol ,Quinidine, Acetylscylic acid, Deoxycorticosterone , Loperamide, Quinine, Aminopyrine, Dextromethorphan, Meprobamate, Salicylic acid , Amoxicillin-Diclofenac , Methoxyphenamine , Serotonin, Ampicillin, Diflunisal Methylphenidate, Sulfamethazine, l-Ascorbic acid, Digoxin ,Nalidixic acid, Sulindac Apomorphine, Diphenhydramine, Naproxen, Tetracycline Aspartame, Ethyl-p-aminobenzoate , Niacinamide, Tetra hydrocortisone, Atropine ,Estradiol ,Nifedipine, 3-Acetate, Benzylic acid, Estrone-3-sulfate, Norethindrone , Tetra hydrocortisone, Benzoic acid, Erythromycin , Noscapine, Tetrahydrozoline, Bilirubin, Fenoprofen, d,l-Octopamine, Thiamine, d,l-Brompheniramine, Furosemide, Oxalic acid, Thioridazine, Caffei Gentisic acid, Oxolinic acid, d,l-Tyrosine, Cannabidiol , Hemoglobin , Oxymetazoline , Tolbutamide ,Chloralhydrate , Hydralazine Papaverine, Triamterene, Chloramphenicol ,Hydrochlorothiazide , Penicillin-G, Trifluoperazine, Chlorothiazide, Hydrocortisone, Perphenazine, Trimethoprim , d,l-Chlorpheniramine, o-Hydroxyhippuric acid, Phenelzine, d,l-Tryptophan , Chlorpromazine, 3-Hydroxytyramine, Prednisone, Uric acid Cholesterol, d,l-Isoproterenol, d,l-Propanolol, Verapamil Clonidine, Isoxsuprine, Cortisone, Zomepirac

SYMBOLS OB LABEL

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

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