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ONE STEP™ DRUG SCAN

NAME AND INTENDED USE

The **Health-Chem One Step™ Drug Scan** is an immunochromatographic assay for rapid, qualitative detection of the following 6 drugs and their principal metabolites in urine at or above the specified cut-off concentrations:

DRUG CLASS	SENSITIVITY
MDMA*	500 ng/ml
Opiates/Morphine	300 ng/ml
Marijuana/Tetrahydrocannabinol	50 ng/ml
Amphetamine	500 ng/ml
Cocaine/Benzoyl Ecgonine	300 ng/ml
Phencyclidine (PCP)	25 ng/ml

Note: The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

* MDMA is an abbreviation for the chemical methylenedioxymethamphetamine MDMA. It has many street names, including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuit and Shamrocks, etc.

SUMMARY AND EXPLANATION OF PROCEDURE

The **One Step™ Drug Scan** is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need of instrumentation. The method employs unique mixture of monoclonal and polyclonal antibodies to selectively identify MDMA, Morphine, Marijuana, Amphetamine, Cocaine, Phencyclidine (PCP) and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economical concern in many developed and developing countries throughout the world. Cocaine, marijuana, amphetamines, and morphine are the most frequently abused illicit drugs, according to the U.S. Substance Abuse and Mental Health Services Administration. Phencyclidine (PCP) and opiates are also among a class of heavily abused prescription drugs. The opiates detectable by this test include illicit opiates as well as components of common antidepressants, cough and anti-diarrhea medications.

The sensitivity of the **One Step™ Drug Scan** is set at 500 ng/ml for MDMA and Amphetamine, 300 ng/ml for Cocaine and Morphine, 25 ng/ml for Phencyclidine (PCP), and 50 ng/ml for Marijuana, as required for the screening immunoassays of these drugs in the reference guidelines set by the National Institute on Drug Abuse (NIDA) and the U.S. Department of Health and Human Services.

PRINCIPLE OF THE TEST

The **One Step Drug Scan™** is a competitive binding immunoassay in which drug and drug metabolites in a urine sample compete with chemically labeled drug compounds for limited antibody binding sites. By utilizing antibodies that are specific to different drug classes, the test permits independent, simultaneous detection of six drugs from a single sample. The approximate run time is 5 minutes.

In the assay procedure, urine mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a rose-pink color band in the appropriate Test Zone (marked "T") for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the immobilized antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen-antibody complex, preventing the development of a rose-pink color band.

Regardless of the drug levels in the sample, a rose-pink color band is produced in each Control Zone (marked "C") by a parallel immunochemical reaction. These bands serve as built-in quality control measures by demonstrating antibody recognition, verifying that the reagents are chemically active.

REAGENTS AND MATERIALS SUPPLIED

1. Test Devices.	Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.
2. Test Instructions.	

Optional:

3. Negative Control.	Contains 1 ml of buffered protein solution with sodium azide.
4 MDMA Positive Control.	Contains 1 ml of MDMA 500 ng/ml in a buffered solution with sodium azide.
5. Opiates Positive Control.	Contains 1 ml of MOR 1000 ng/ml in a buffered protein solution with sodium azide
6. Marijuana (THC) Positive Control.	Contains 1 ml of THC 150 ng/ml in a buffered protein solution with sodium azide.
7. Amphetamine Positive Control.	Contains 1 ml of AMP 3000 ng/ml in a buffered protein solution with sodium azide.
8. Cocaine Positive Control.	Contains 1 ml of BEG 1000 ng/ml in a buffered protein solution with sodium azide.
9. Phencyclidine (PCP) Positive Control.	Contains 1 ml of PCP 100 ng/ml in a buffered protein solution with sodium azide.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.
2. Specimen collection containers.

PRECAUTIONS

1. For in vitro diagnostic and professional use only.
2. Do not use the test device beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
4. Visually inspect the foil package to insure it is intact. If the package is not intact, discard the device.

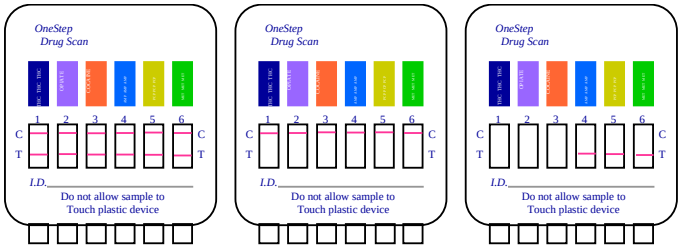
TEST PROCEDURE

1. Bring a urine sample and a foil test pouch to room temperature (15 °-28 °C).
2. Do not break the seal of the pouch until ready to begin testing.
3. Remove a Test Device from the foil pouch.
4. Remove the protective cap and dip the revealed strips into the urine sample. Do not allow the urine level to touch the plastic device.
5. Read the results at 5 minutes.

NOTE: The result must be interpreted at five minutes. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS

Important: Control lines are necessary in order to validate test results. If a rose-pink color band is not visible in any one or more Control Zone(s) ("C") the corresponding drug test(s) are invalid. Retest the sample using a new device.



NEGATIVE POSITIVE INVALID

Negative: A *rose-pink* band is visible in each control zone ("C") and in the appropriate test zone ("T"), indicating that the concentration of the corresponding drug of that specific test zone is below the detection limit of the test.
Positive: A *rose-pink* band is visible in each control zone ("C"). No color band appearing in the appropriate test zone ("T") indicates a positive result for the corresponding drug of that specific test zone.
Invalid: If a *rose-pink* color band is not visible in any one or more of the control zones ("C"), the corresponding drug test(s) test are invalid. Another test should be run to re-evaluate the specimen.
Note: There is no meaning attributed to line color intensity or width.

QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.
The use of an external control is recommended to verify proper kit performance.
Quality control samples should be tested according to quality control requirements established by the testing laboratory.

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of MDMA, cocaine, marijuana, amphetamine, phencyclidine (PCP), and opiates in human urine only.
2. Although the test is very accurate, there is the possibility false results will occur due to the presence of interfering substances in the specimen sample.
3. The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels in urine, or the level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens, can cause erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity**. The Health-Chem **One Step™ Drug Scan** detects MDMA, opiates, marijuana, amphetamine, cocaine, Phencyclidine (PCP) and their major metabolites in urine at concentrations equal to or greater than 500 ng/ml for MDMA and amphetamine, 300 ng/ml for cocaine and opiates, 25 ng/ml for phencyclidine (PCP), and 50 ng/ml for marijuana, which is suggested by the National Institute on Drug Abuse (NIDA) for the immunoassay method.

2. **Specificity**. A study was conducted with the **One Step™ Drug Scan** to determine the cross-reactivity of drug-related compounds with the test. Substances listed in **Table I** produced results approximately equivalent to the cutoff levels. A separate study was conducted to determine the cross-reactivity of non-related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross reactivity was detected with the substances listed in **Table II**.

Table I: Concentrations of drug-related compounds showing positive response approximately equivalent to the cut-off set for the test:

The following substances yield positive results for MDMA Methamphetamine:

(+) Methamphetamine	500 ng/ml
(±) Methamphetamine	1.0 µg/ml
(±) 3, 4 Methylenedioxymethamphetamine	100 ng/ml
(±) 3, 4 Methylenedioxyamphetamine	1.0 µg/ml
MethylenedioxyethylMDMA (MDEA)	1000 ng/ml
L-methMDMA	100 ng/ml
d-methMDMA	100 ng/ml
HydroxymethMDMA (HAM)	100 ng/ml
DihydroxumethMDMA (HMMA)	100 ng/ml
N-methyl-1 (1-3-benzoidioxol-5-yl)-2-butanamine (MBDB)	100 ng/ml

The following Opiates-related substances yield a positive result for Opiates:

Morphine	300 ng/ml	Oxycodone	1,000 ng/ml
Morphine-3-b-D-Glucuronide	300 ng/ml	Levorphanol	600 ng/ml
Codeine	300 ng/ml	Naloxone	1,000 ng/ml
Norcodeine	2,000 ng/ml	Thebaine	1,500 ng/ml
Nalorphine	300 ng/ml	Imipramine	50,000 ng/ml
Hydrocodone	500 ng/ml	Atropine	100,000 ng/ml
Hydromorphone	300 ng/ml	Meperidine	100,000 ng/ml
Ranitidine	100,000 ng/ml		

The following Marijuana-related substances yield positive results for Marijuana:

11-Nor-Δ 8-THC-9-COOH	50 ng/ml
11-Nor-Δ 9-THC-9-COOH	50 ng/ml
Δ 8–THC	1 µg/ml
Δ 9-THC	4 µg/ml
Cannabinol	10 µg/ml
11-hydroxy-Δ 9-THC	10 µg/ml

The following Amphetamine-related substances yield positive results for Amphetamine:

d-Amphetamine	1000 ng/ml	Thyramine	100,000 ng/ml
l-Amphetamine	25,000 ng/ml	Pseudoephedrine	100,000 ng/ml
d,l-Amphetamine	1000 ng/ml	Ephedrine	250,000 ng/ml
(±)Phenylpropanolamine	50,000 ng/ml	B –Phenylthylamine	90,000 ng/ml
(±)3,4-Methylenedioxyamphetamine(MDA)	1000 ng/ml		

The following Cocaine-related substances yield positive results for Cocaine:

Benzoylecgonine	300 ng/ml
Cocaine	300 ng/ml
Isoxsurpine	1,500 ng/ml

The following Phencyclidine-related substances yield positive results for Phencyclidine (PCP):

N-Acetylprocainamide	10,000 ng/ml
Codeine	5,000 ng/ml
p-Hydroxymethamphetamine	50,000 ng/ml
Thebaine	10,000 ng/ml
1-(1-phenylcyclohexyl)-morphine	600 ng/ml
N,N-Diethyl-1-phenyl-Cyclohexylamine	2.0 ng/ml
1-[1-(2-Thienyl)cyclohexyl]-morphine	60,000 ng/ml

Table II: Compounds tested and found not to cross-react with the test at indicated concentrations in urine:

The following compounds do not cross-react with MDMA Methamphetamine (10mg/ml):

Acetaminophen	Dextromethorphan	Meperidine	L-Phenylephrine
Acetylsalicylic acid	Diazepam	Methylphenidate	Quinine
Amikacin	Diethylpropion	Methaqualone	Ranitidine
Amitryptyline	Diphenylhydantoin	Morp. Glucuronide	Sodium Salicylate
Ampicillin	Doxylamine	Morphine Sulfate	Tryptophan
Arterenol	Ecgonine HC1	Oxazepam	Tetracycline
Aspartame	Ecgonine Methyl Ester	Oxycodone	Tetrahydrozoline
Atropine Sulfate	Glucose	Pendimetrazine	Theophylline
Benzoic Acid	Histamine	Penicillin G	Thioridazine
Benzoylecgonine HC1	Hydrocodone	Pentobarbital	Trifluoperazine
Caffeine	Hydromorphone	d-Propoxyphene	
		Hydrochlorothiazide	
Chlorpheniramine	Indomathacin	Propanol	
Chlorpropmazine HC1	Ketoprofen	Phencyclidine	
Cimetidine	Levorphanol	Phenobarbital	
Codeine	Δ–9-THC	Phentermine	
Deoxyephedrine	11-nor- Δ-9-carboxy-THC-9-COOH	Phenylpropanolamine	

The following compounds do not cross-react with Opiates (10mg/ml):

Acetaminophen	Ecgonine HCl	Propanol
Acetylsalicylic Acid	Ecgonine Methyl Ester	Phencyclidine
Amikacin	Glucose	Phenobarbital
Amitriptyline	Histamine	Phentermine
Ampicillin	Indomathacin	Phenylpropanolamine
Arterenol	Ketoprofen	L-Phenylephrine
Aspartame	Levorphanol	Quinine
Atropine Sulfate	Δ - 9 THC	Rantidine
Benzoic Acid	11-nor-Δ-9-carboxy-THC-9-COOH	Sodium Salicylate
Benzoylecgonine HCl	Meperidine	Tryptophan
Caffeine	Methylphenidate	Tetracycline
Chlorpheniramine	Methadone	Tetrahydrozoline
Chlorpropmazine HCl	Methaqualone	Theophylline
Cimetidine	Morp. Glucuronide	Thioridazine
Codeine	Morphine Sulfate	Trifluoperazine
Deoxyephedrine	Oxazepam	
Dextromethorphan	Oxycodone	
Diazepam	Pendimetrazine	
Diethylpropion	Penicillin G	
Diphenylhydantoin	Pentobarbital	
Doxylamine	d-Propoxyphene Hydrochlorothiazide	

The following compounds do not cross-react with Marijuana (10mg/ml):

Acetaminophen	Digoxin	Naloxone
4-Acetamidophenol	Ecgonine Hydrochloride	Neomycin
Acetylsalicyclic acid	Ecgonine Methyl Ester	Niacinamide
Amikacin	Ephedrine	Oxazepam
Ampicillin	Epinephrine	Perphenazine
d,l-Amphetamine	Gentisic acid	Penicillin G
Amitriptyline	Glucose	Phencyclidine
Arterenol	Guaiacol	Phenobarbital
Aspartame	Histamine	Phenylethylamine-a
Atropine sulfate	Hydrochlorothiazide	Phenylpropanolamine
Benzoic Acid	Hydrocodone	Promethazine
Benzoylecgonine	Hydromorphone	Pseudophedrine
Caffeine	Homatropine	Rantidine
Camphor	Imipramine	Salycyclic acid
Chloroquine	Isoproterenol	Secobarbital
Chlorpheniramine	Ketamine	Tetracycline
Chlorpromazine HCl	Lidocaine	Tetrahydrozoline
Cocaine Hydrochloride	d-Methamphetamine	Theophylline
Cocaine	Meperidine	Thiridazine
Cimetidine	Methadone	Triflouperazine
Cortisone	Methaqualone	Tryptophan
Deoxyepinophrine	Methylpehnidate	
Dextromethorphan	Morphine glucuronide	
Diazepam	Morphine sulfate	
Digitoxin	Morphine	

The following compounds do not cross-react with Amphetamine (10mg/ml):

Acetaminophen	Doxylamine	Pendimetrazine
Acetylsaclicylic Acid	Ecgonine HCl	Penicillin G
Amikacin	Ecgonine Methyl Ester	Pentobarbital
Amitriptyline	Glucose	d-Propoxyphene Hydrochlorothiazide
Ampicillin	Histamine	Propanol
Arterenol	Hydrocodone	Phencyclidine
Aspartame	Hydromorphone	Phenobarbital
Atropine Sulfate	Indomathacin	Phentermine
Benzoic Acid	Ketoprofen	Phenylpropanolamine
Benzoylecgonine HCl	Levorphanol	L-Phenylephrine
Caffeine	Δ -9-THC	Quinine
Chlorpheniramine	11-nor-Δ-9-carboxy-THC-9-COOH	Ranitidine
Chlorpropmazine HCl	Meperidine	Sodium Salicylate
Cimetidine	Methylphenidate	Tryptophan
Codeine	Methadone	Tetracycline
Deoxyephedrine	Methaqalone	Tetrahydrozoline
Dextromethorphan	Morp. Glucuronide	Theophylline
Diazepam	Morphine Sulfate	Thioridazine
Diethylpropion	Oxazepam	Trifluoperazine
Diphenylhydantoin	Oxycodone	

The following compounds do not cross-react with Cocaine (10mg/ml):

Acetaminophen	Dephenylhydantoin	Propanol
Actylsalicylic Acid	Doxylamine	Phencyclidine
Amikacin	Ecgonine HCl	Phenobarbital
Amitriptyline	Ecgonine Methyl Este	Phentermine
Ampicillin	Glucose	Phenylpropanolamine
Arterenol	Histamine	L-Phenylephrine
Aspartame	Hydrocodone	Quinine
Atropine Sulfate	Hydromorphone	Ranitidine
Benzoic Acid	Indomathacin	Sodium Salicylate
Benzoylecgonine HCl	Ketoprofen	Tryptophan
Caffeine	Levorphanol	Tetrahydrozoline
Chlorpheniramine	Δ -9-THC	Theophylline
Chlorpropmazine HCl	11-nor-Δ -9-carboxy-THC-9-COOH	Thioridazine
Cimetidine	Meperidine	Trifluoperazine
Codeine	Methylphenidate	Oxycodone
Deoxyephedrine	Methadone	Pendimetrazine
Dextromethorphan	Methaqualone	Penicillin G
Diazepam	Morp. Glucuronide	Pentobarbital
Diethylpropion	Morphine Sulfate	d-Propoxyphene
	Oxazepam	Hydrochlorothiazide

The following compounds do not cross-react with Phencyclidine (μg/ml):

4-Acetamidophenol	100	Imipromine	190
Acetophenetidin	100	(-) Isoproterenol	120
Acetylsalicylic acid	300	Iproniazid	120
Alphenol	100	Isoxsuprine	130
Alprozolam	25	Ketamine	130
Amitryptyline	100	Ketoprofen	140
Amobarbital	100	Labetalol	100
Amoxicillin	130	Levorphanol	100
l-Amphetamine	100	Lidocaine	100
Apomorphine	100	Loperamide	150
Aprobarbital	100	Lormetazepam	100
ASP-PHE Methyl Ester	100	(+) Lorazepam	100
Atropine	100	(-) Lorazepam	100
Barbital	100	Maprotiline	140
Benzilic Acid	300	Medazepam	100
Benzoic Acid	280	Meperidine	100
Benzoylecgonine	100	Meprobamate	100
Benzphetamine	100	Methadone	100
Bromazepam	100	Methaqualone	100
Butabarbital	100	(s) 6-Methoxy-a-Methyl-2-Naphthaleneacetic acid	250
Cannabidiol	100	Methylphenidate	100
Chloral Hydrate	100	Methyprylon	100
Chlorothiazide	320	Morphine-3−β-D-glucuronide	100
Chlordiazepoxide	100	(±) 3,4-Methylenedioxy Methamphetamine	100
Chlorpromazine	100	(±) 3,4-Methylenedioxy Amphetamine	100
Chloroquine	330	Methoxyphenamine	150
Cholesterol	160	Nalidixic acid	130
Clobazam	100	Nalorphine	100
Clomipramine	230	Naloxone	100
Clonazepam	100	Naltrexone	100
Clorazepate	75	Niacinamide	170
Clonidine	100	Nifedipine	140
Cocaine	100	Nitrazepam	100
Codeine	100	Norcodeine	100
Cortisone	120	Norethindrone	100
(-) Cotinine	100	d-Norpropoxyphene	100
Creatinine	190	Noscapine	100
Deoxycorticosterone	170	Nylidrin	190
Desmethyldiazepam	100	d,l-Octopamine	190
Dextromethorphan	100	Oxalic acid	400
Diazepam	500	Oxolinic Acid	110
Diclofenac	100	Oxazepam	100
Diflunisal	100	Oxycodone	100
Digoxin	150	Oxymetazoline	100
4-(Dimethylamino)antipyrine	100	Papaverine	120
(+) Ephedrine	130	Penicillin-G	120
(±) Ephedrine	160	Promethazine	220
(-) ψ-Ephedrine	290	Propiomazine	220
(-) Ephedrine	130	d-Propoxyphene	100
Erythromycin	150	d-Pseudoephedrine	100
β-Estradiol	110	Quinidine	100
Estrone-3-sulfate	100	Quinine	100
Fenoprofen	100	Ranitidine	200
Flunitrazepam	100	Salicylic acid	100
Flurazepam	100	Secobarbital	100
Furosemide	150	Sulfamethazine	150
Gentisic acid	120	Sulindac	120
Guaiacol Glyceryl Ester Carbonate	220	Temazepam	100
Glucuronic acid	200	Tetracycline	200
Glutethimide	100	D^9 – Tetrahydrocannabinol	100
5-Hydroxytryptamin	100	Tetrahydrocortisone	100
Hyppuric acid	200	Tetrahydrozoline	100
Hydralazine	100	Thebaine	100
Hydrochlorothiazide	100	Thiamine	120
Hydrocodone	100	(±) Thiopental	100
Hydrocotisone	130	Thioridazine	110
Hydromorphone	100	d,1-Thyroxine	120
Hydroxyhippuric acid	140	Tolbutamide	100
Hydroxytyramine	160	Triamterene	120
Ibuprofen	100	Triazolam	12.5
Pentazocaine	100	Trifluoperazine	220
Pentobarbital	100	Trimethoprim	130
Penoprofen	200	Trimipramine	190
Perphenazine	140	Tryptamine	150
Phendimetrazine	100	d,1-Tryptophan	170
Phenelzine	350	Tyramine	120
Phenobarbital	100	d,1-Tyrosine	250
Phentermine	100	Uric acid	230
l-Phenylephrine	100	Verapamil	150
(±)-Phenylpropanolamine	100	Zomepirac	130
β-Phenylethylamine	180		
Prednisolone	150		
Prednisone	120		
Promazine	120		

3. **Accuracy**: Positive specimens above the cut-off concentration for each of the six (6) specific drugs were evaluated using the **One Step™ Drug Scan**, gas chromatography/mass spectrophotometry (GC/MS), and a commercially available enzyme immunoassay (EIA) for drug abuse. Drug-free specimens were also evaluated. The results are presented in Table III below:

Table III:

Drug/Metabolite	Syva EMIT EIA II (+/-)	GC/MS (+/-)	One Step Drug (+/-)
MDMA			
> 500 ng/ml	63/0	63/0	63/0
< 500 ng/ml	1/99	0/99	1/99
MOR (Opiates/Morphine)			
> 300 ng/ml	148/0	148/0	148/0
< 300 ng/ml	0/150	0/150	0/150
THC (Marijuana/Tetrahydrocannabinol)			
> 50 ng/ml	149/0	149/0	149/0
< 50 ng/ml	1/153	1/153	0/154
AMP (Amphetamine)			
> 500 ng/ml	153/0	140/13	153/0
< 500 ng/ml	0/155	0/155	0/155
COC (Cocaine/Benzoylecgonine)			
> 300 ng/ml	153/0	150/3	153/0
< 300 ng/ml	0/151	0/151	0/151
PCP (Phencyclidine)			
> 25 ng/ml	97/0	97/0	97/0
< 25 ng/ml	0/130	0/130	0/130

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