

# IDENTIFY HEALTH DRUG SCREEN TEST For Forensic Use Only

The Identify Health Drug Screen Test detects multiple drugs and drug metabolites in human urine at the following cutoff concentrations:

Abbreviation 6AM	<b>Drug</b> 6-Acetylmorphine	Cutoff (ng/n
AMP	Amphetamine	500
AMP1000	Amphetamine	1,000
BAR	Barbiturates	300
BAR200	Barbiturates	200
BUP	Buprenorphine	10
BZO	Benzodiazepines	300
BZO200	Benzodiazepines	200
CLO	Clonazepam	300
COC	Cocaine	150
COC300	Cocaine	300
COT	Cotinine	200
EDDP	Methadone Metabolite	300
ETG	Ethyl Glucuronide	500
FEN	Norfentanyl	20
FEN 25	Norfentanyl	25
FEN	Norfentanyl	50
GAB 2000	Gabapentin	2000
K2 25	Synthetic Marijuana	25
KRA	Mitragynine	100
MDMA	Ecstasy	500
MET	Methamphetamine	500
MET1000	Methamphetamine	1,000
MTD	Methadone	300
OPI	Opiates/Morphine	300
OPI2000	Opiates	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Tricyclic Antidepressants	1,000
THC	Marijuana	50
TRA	Tramadol	100
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#### **WARNINGS AND PRECAUTIONS**

- Treat all urine specimens and materials as if capable of transmitting infection. Wear gloves and proper laboratory attire to avoid skin contact with urine specimens. Proper handling and disposal methods should be established.
- Use a new specimen collection container for each urine sample to avoid crosscontamination of urine samples.
- Collect a fresh urine sample in the container provided or a clean, dry plastic or glass container. Fresh urine does not require any special pretreatment. If the specimen is not tested immediately, it may be refrigerated at 2-8°C up to 2 days.
- Do not use the test kit after the expiration date.

# MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Specimen collection container
- External positive and negative controls

# **PROCEDURE**

# Preparation:

- 1. Allow the test device, controls, and/or specimens to equilibrate to room temperature (15-30°C) prior to testing.
- 2. Do not open the test device pouch until ready to perform the test.

# Dip Card:

- 1. Remove the dip card from the sealed pouch. Write the donor name or ID on the dip card in the provided space, then remove the cap.
- 2. With the arrows pointing toward the urine specimen, immerse the sample tips vertically in the urine specimen for at least 20 seconds. Replace the cap back onto the dip card and place the dip card on a flat surface. Alternatively, the dip card can be left in the urine specimen throughout the testing process.
- 3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
- 4. Read Specimen Validity Test (SVT) results by comparing the color of the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes.

Position of SVT pads may vary based on the drug strip configuration.

#### Cup:

- 1. Remove cup from the sealed pouch and write the donor name or ID in the provided space.
- 2. Collect urine in the cup.
- Peel off label to view results. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
- 4. Read Specimen Validity Test (SVT) results by comparing the color of the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes.



# **RESULT INTERPRETATION**

Read results after 5 minutes. Do not read results past 60 minutes.

A red or pink line must appear next to the "C" (control) on all of the test strips. The appearance of a red or pink line next to the "C" on each test strip indicates that the test has worked properly.

# **Negative Result:**

A red or pink line next to the "T" under the drug name indicates a negative result for that drug. If a test line appears next to the "T" all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.

# **Preliminary Positive Result:**

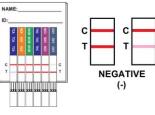
If NO red or pink line appears next to the "T" under the drug name, the sample may **contain** that drug. The manufacturer recommends sending the sample to a laboratory for confirmation testing.

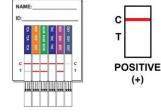
The illustration on the right shows preliminary positive results for AMP and THC. but negative for all other drugs.

#### Invalid Result:

A colored line should always appear next to the letter "C" on every test strip. If no control line appears on any of test strips, the result is invalid.

The illustration at right shows no line next to the letter "C" on the first strip (MTD. TCA) and fourth strip (COC, THC). The test results for those two test strips are invalid.









#### STORAGE

The Identify Health Drug Screen Test should be stored at 2-30°C (36-86°F) in the original sealed pouch. Do not freeze. Do not store and/or expose reagent kits to temperatures greater than 30°C.

### QUALITY CONTROL

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

To ensure proper kit performance, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. External controls are available from commercial sources. Additional testing may be necessary to comply with the requirements of accrediting organizations and/or local, state, and/or federal regulators.

Quality control testing should be performed with each new lot, with each new shipment. and every thirty days to check storage conditions. External controls can be purchased from the following vendor: Medical Distribution Group Inc (888)-600-0431. www.identifydiagnostics.com.

### PERFORMANCE CHARACTERISTICS

# A. ACCURACY

The accuracy of the Identify Health Drug Screen Test was evaluated in comparison to GC/MS and LC/MS. Drug-free urine samples collected from presumed non-user volunteers were tested with Identify Health Drug Screen Test. Of these negative samples, all were correctly identified as negative. 10% of the negative samples were confirmed with GC/MS as drug negative. At least 30 drug positive urine specimens for each drug test were obtained from reference labs. Drug concentrations were confirmed with GC/MS and LC/MS (for TCA, FYL and EtG). A summary of the accuracy results on the Identify Health Drug Screen Test are shown in the following table.

Summa	Summary of Accuracy Results on the Identify Health Drug Screen Test Range of GC/MS Data					Test		
Drug Test/ Cutoff (ng/ml)	Result	Drug-free	-50% - <-25% C/O	-25% C/O - C/O	C/O - +25% C/O	>+25% - +50% C/O	>+50/% C/O	% Agreeme
	Neg	40	2	1	0	0	0	100%
6AM/10	Pos	0	0	0	0	2	14	100%
	Neg	40	3	0	0	0	0	97.7%
AMP/500	Pos	0	0	1	2	2	45	100%
AMD/4000	Neg	40	2	0	0	0	0	97.7%
AMP/1000	Pos	0	0	1	3	2	42	100%
D 4 D /000	Neg	40	1	1	0	0	0	95.2%
BAR/300	Pos	0	0	2	5	2	36	100%
D 4 D (000	Neg	40	1	1	0	0	0	95.45%
BAR/200	Pos	0	0	2	2	3	42	100%
DUD(40	Neg	40	1	1	0	0	0	95.5%
BUP/10	Pos	0	0	2	8	0	32	100%
D70/000	Neg	40	0	1	0	0	0	93.2%
BZO/300	Pos	0	0	3	1	6	34	100%
	Neg	40	0	1	0	0	0	93.2%
BZO/200	Pos	0	0	3	2	2	43	94%
CLO/300	Neg	40	2	0	0	0	0	97.67%
CLO/300	Pos	0	0	1	0	1	26	100%
	Neg	40	0	3	0	0	0	97.7%
COC/150	Pos	0	0	1	4	1	53	100%
	Neg	40	0	3	1	0	0	100%
COC/300	Pos	0	0	0	4	1	46	98.0%
	Neg	40	0	0	0	0	0	>99.0%
COT/200	Pos	0	0	0	0	0	40	>99.0%
	Neg	40	0	1	0	0	0	93.2%
EDDP/300	Pos	0	0	3	5	2	33	100%
	Neg	141	15	8	5	13	65	99.40%
EtG/500	Pos	0	0	1	2	0	0	97.60%
FEN/20	Neg	100	3	2	0	0	0	99.06%
FEIN/20	Pos	0	0	1	3	3	46	100%
	Neg	40	0	0	0	0	0	>99%
FEN/25	Pos	0	0	0	0	0	22	>99%
	Neg	42	0	0	0	0	0	100%
FEN/50	Pos	0	0	0	1	0	17	100%
GAB/2000	Neg	40	0	0	1	0	0	>99%
GAB/2000	Pos	0	0	0	0	0	47	97.92%
	Neg	40	2	1	0	0	0	93.5%
K2/25	Pos	0	0	3	2	3	21	100%
VD 4/400	Neg	40	2	0	0	0	0	97.67%
KRA/100	Pos	0	0	1	1	3	14	>99%
	Neg	40	1	1	0	0	0	95.5%
MDMA/500	Pos	0	0	2	5	1	34	100%

METIESS	Neg	40	1	0	0	0	0	93.2%
MET/500	Pos	0	0	3	1	3	51	100%
	Neg	40	0	1	0	0	0	95.3%
MET/1000	Pos	0	0	2	2	3	45	100%
	Neg	40	0	2	0	0	0	95.5%
MTD/300	Pos	0	0	2	4	0	37	100%
OPI/300	Neg	40	0	1	0	0	0	93.2%
OPI/300	Pos	0	0	3	4	0	53	100%
	Neg	40	1	0	0	0	0	93.2%
OPI/2000	Pos	0	0	2	4	3	40	100%
210442	Neg	40	1	0	0	0	0	93.2%
OXY/100	Pos	0	0	3	7	1	33	100%
	Neg	40	0	3	0	0	0	97.7%
PCP/25	Pos	0	0	1	3	8	33	100%
	Neg	40	0	1	0	0	0	95.3%
PPX/300	Pos	0	0	2	5	2	33	100%
TO 1 /1 000	Neg	40	0	2	0	0	0	95.5%
TCA/1000	Pos	0	0	2	5	7	28	100%
TUO/50	Neg	40	1	2	0	0	0	97.7%
THC/50	Pos	0	0	1	4	7	44	100%
TD 4 /4 00	Neg	40	8	4	0	0	0	>99%
TRA/100	Pos	Λ	Λ	Λ	1	1	62	<b>\90%</b>

# B. ANALYTICAL SENSITIVITY/PRECISION

Drug-free urine and urine with drug concentrations at +/-50% cutoff and +/-25% cutoff were tested by 9 operators at 3 physician office laboratories (POL) over 20 non-consecutive days or by in-house personnel at the manufacturing site. Results showed over 99% agreement at +/-50% cutoff levels with the Identify Health Drug Screen Test.

#### C. ANALYTICAL SPECIFICITY

The following compounds are detected positive in urine by the Identify Health Drug Screen Test. Concentrations are given in ng/ml; percent cross-reactivity is shown in parentheses

parenti	ieses.			
Compound 6-AM		Conc. (%)	Compound	Conc. (%)
6-Acetylmorphi	ine	10 (100%)	Morphine	>100,000 (<0.19
Diacetylmorphi	ne (heroin)	300 (3%)	Codeine	>100,000 (<0.19
Oxycodone		>100,000 (<0.1%)	Oxymorphone	>100,000 (<0.1%
AMP				
D-Amphetamin	е	1,000 (100%)	MDA	15,000 (6.7%)
L-Amphetamine	е	100,000 (1%)	Phentermine	100,000 (1.0%)
AMP 500				
D-Amphetamin	е	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	е	50,000 (1%)	Phentermine	45,000 (1.1%)
BAR				
Secobarbital		300 (100%)	Butalbital	300 (100%)
Amobarbital		2,500 (12%)	Cyclopentobarbital	500 (60%)
Aprobarbital		500 (60%)	Phenobarbital	300 (100%)
Butabarbital		100 (300%)	Pentobarbital	250 (120%)
BAR 200				
Secobarbital		200 (100%)	Butalbital	200 (100%)
Amobarbital		1,660 (12%)	Cyclopentobarbital	330 (66.7%)
Aprobarbital		330 (66.7%)	Phenobarbital	200 (100%)
Butabarbital BUP		60 (333%)		
Buprenorphine		10 (100%)	Norbuprenorphine	7.5 (133%)
Buprenorphine	-3-β-D-glucuronide	3.5 (286%)	Norbuprenorphine glucuronide	35 (28%)
BZO				
Oxazepam		300 (100%)	α-Hydroxyalprazolam	1,900 (15.8%)
Alprazolam		200 (150%)	Lorazepam	3,900 (7.7%)
Bromazepam		1,000 (30%)	Lorazepam-glucuronide	5,000 (6%)
Clobazam		200 (150%)	Nitrazepam	250 (120%)
Clorazepate		750 (40%)	Norchlordiazepoxide	500 (60%)
Desalkylfluraze	epam	1,200 (25%)	Nordazepam	390 (76.9%)
Diazepam		1,000 (30%)	Temazepam	150 (200%)
Flunitrazepam		250 (120%)	Triazolam	2,500 (12%)
BZO 200				
Oxazepam		200 (100%)	α-Hydroxyalprazolam	1,300 (15.3%)
Alprazolam		130 (153%)	Lorazepam	2,600 (7.7%)
Bromazepam		650 (30.7%)	Lorazepam-glucuronide	3,500 (5.7%)
Clobazam		130 (153.8%)	Nitrazepam	160 (125%)
Clorazepate		500 (40%)	Norchlordiazepoxide	330 (60.6%)
Desalkylfluraze	epam	800 (25%)	Nordazepam	260 (76.9%)
Diazepam		650 (30.7%)	Temazepam	100 (200%)
Flunitrazepam		160 (125%)	Triazolam	1,650 (12.1%)

Compound CLO	Conc. (%)	Compound	Conc. (%)
7-Amino Clonazepam Meclonazepam Alprazolam Clobazam Desalkylflurazepam Flunitrazepam Lorazepam Nitrazepam Nordiazepam Triazolam	300 (100%) >100,000 (<0.3%) >100,000 (<0.3%) >100,000 (<0.3%) 100,000 (<0.3%) >100,000 (<0.3%) >100,000 (<0.3%) >100,000 (<0.3) >100,000 (<0.3%) >100,000 (<0.3%) >100,000 (<0.3%)	Clonazepam Oxazepam Bromazepam Clorazepate dipotassium Diazepam α-Hydroxyalprazolam Lorazepam glucuronide Norchlordiazepoxide Temazepam	75,000 (0.4%) >100,000 (<0.3%) >100,000 (<0.3) >100,000 (<0.3) >100,000 (<0.3%) >100,000 (<0.3%) >100,000 (<0.3%) >100,000 (<0.3%) >100,000 (<0.3%) >100,000 (<0.3%) >100,000 (<0.3%)
COC Benzoylecgonine Cocaethylene COC 150	300 (100%) 100,000 (0.3%)	Cocaine Ecgonine	10,000 (3%) 100,000 (0.3%)
Benzoylecgonine Cocaethylene COT	150 (100%) 50,000 (0.3%)	Cocaine Ecgonine	5,000 (3%) 50,000 (0.3%)
(-)-Cotinine Trans-3'-hydroxycotinine EDDP	200 (100%) 5,000 (4%)	(R,S)-Norcotine S(-)-Nicotine	100,000 (0.2%) >100,000 (<0.2%)
EDDP EtG	300 (100%)		
Ethyl glucuronide FEN20	500 (100%)		
Norfentanyl(calibrator) Alfentanil Carfentanil FEN 25	20 (100%) >100,000(>0.02%) >10,000(>0.2%)	Fentanyl(parent drug) Sufentanil	1,000 (2%) >10,000(>0.2%)
Norfentanyl FEN 50	25 (100%)	Fentanyl	325 (7.69%)
Norfentanyl GAB 2000	50 (100%)	Fentanyl	350(14.3%)
Gabapentin Vigabatrin K2 25	2000 (100%) >100,000 (<2%)	Pregabalin	100,000 (2%)
JWH-018 5- Pentanoic acid metabolite	25 (100%)	JWH-018 4N-(4-Hydroxypentyl) metabolite	2000 (1%)
JWH-073 N- Butanoic acid metabolite	40 (62%)	JWH-018 5-Hydroxypentyl metabolite	1250 (2%)
KRA 100 Mitragynine 7-Hydroxymitragynine	100 (100%) 125 (80%)	Olanzapine	50,000 (0.02%)
MDMA (+/-)-MDMA (+/-)-MDA MET	500 (100%) 3,900 (12.8%)	(+/-)-MDEA	500 (100%)
D-Methamphetamine D-Amphetamine L-Amphetamine 1R,2S(-)-Ephedrine MET 500	1,000 (100%) 100,000 (1%) 100,000 (1%) >100,000 (<0.5%)	MDEA MDMA Mephentermine	60,000 (1.7%) 8,000 (12.5%) 100,000 (1%)
D-Methamphetamine D-Amphetamine L-Amphetamine 1R,2S(-)-Ephedrine MTD	500 (100%) 50,000 (1%) 50,000 (1%) 100,000 (0.5%)	MDEA MDMA Mephentermine	30,000 (1.7%) 3,500 (14.3%) 75,000 (0.7%)
Methadone OPI 300	300 (100%)		
Morphine Codeine Ethylmorphine Heroin Hydrocodone Hydromorphone	300 (100%) 100 (300%) 100 (300%) 8,000 (37.5%) 1,250 (24%) 2,500 (12%)	Levorphanol Morphine 3-glucuronide Norcodeine Oxycodone Thebaine	50,000 (0.6%) 400 (75%) 6,000 (1.9%) 75,000 (0.4%) 90,000 (0.3%)
OPI 2000 Morphine Codeine Ethylmorphine Heroin Hydrocodone OXY	2,000 (100%) 1,800 (111.1%) 1,500 (133.3%) 11,000 (18.2%) 5,000 (40%)	Hydromorphone Morphine-3-glucuronide Oxycodone Thebaine	5,000 (40%) 2,600 (76.9%) 70,000 (2.9%) 95,000 (2.1%)
Oxycodone Codeine Ethylmorphine	100 (100%) 50,000 (0.2%) 50,000 (0.2%)	Hydrocodone Hydromorphone Oxymorphone	5,000 (2%) 25,000 (0.4%) 12,500 (0.8%)
PCP Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)
PPX Propoxyphene	300 (100%)	Norpropoxyphene	300 (100%)
1 21	- ()	1 -1 - 21	- (

Compound TCA	Conc. (%)	Compound	Conc. (%)
	4 000 (4000()	Davanina	4 000 (4000()
Nortriptyline	1,000 (100%)	Doxepine	1,000 (100%)
Amitriptyline	4,000 (25%)	Imipramine	1,000 (100%)
Clomipramine	2,000 (50%)	Promethazine	1,000 (100%)
Desipramine	500 (200%)	Trimipramine	5,000 (20%)
THC	, ,	·	
11-nor-∆9-THC-9-COOH	50 (100%)	(-)-∆8-THC	20,000 (0.3%)
(+/-)-11-Hydroxy-∆9-THC	5,000 (1%)	(-)-∆9-THC	20,000 (0.3%)
TRÁ	, , ,	**	, , ,
Tramadol	100 (100%)	N-Desmethyl-cis-tramadol	700 (14.28%)
O-Deemethyl-cie-tramadol	9 000 (1 11%)		

#### D. INTERFERENCE

The following compounds were evaluated for potential positive or negative interference with the Identify Health Drug Screen Test. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the Identify Health Drug Screen Test cup and dip. An unaltered sample was used as control. No interference was found for following compounds at a concentration of 100 µg/mL.

Acetaminophen	4-Dimethylaminoantipyrine	Niacinamide
Acetone	Diphenhydramine	(+/-)-Norephedrine
Albumin	Dopamine	Oxalic acid
Ampicillin	(+/-)-Isoproterenol	Penicillin-G
Ascorbic acid	(+)-Naproxen	Pheniramine
Aspartame	Erythromycin	Phenothiazine
Aspirin	Ethanol (except EtG)	L-Phenylephrine
Atropine	Furosemide	B-Phenylethylamine
Benzocaine	Glucose	Procaine
Bilirubin	Guaiacol glyceryl ether	Quinidine
Caffeine	Hemoglobin	Ranitidine
Chloroquine	Ibuprofen	Riboflavin
(+)-Chlorpheniramine	(+/-)-Isoproterenol	Sodium chloride
(+/-)-Chlorpheniramine	Levorphanol	Sulindac
Creatine	Lidocaine	Theophylline
Dexbrompheniramine	(1R,2S)-(-)-n-Methylephedrine	Tyramine
Dextromethorphan		

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Gabapentin in Cooperation with ARK Diagnostics, Inc