Identify® Diagnostics USA

IDENTIFY DIAGNOSTIC USA DRUG SCREEN TEST

For Forensic Use Only

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

Abbreviation	Drug	Cutoff (ng/ml)
6AM	6-Acetylmorphine	10
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
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

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 cross-contamination 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

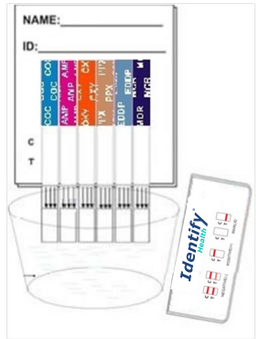
PROCEDURE

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.

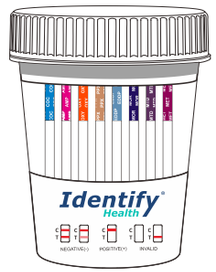
Dip Card:

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.
3. 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.



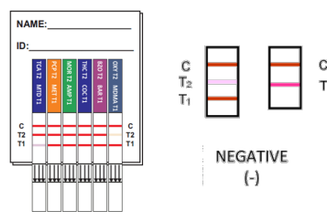
RESULT INTERPRETATION

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:

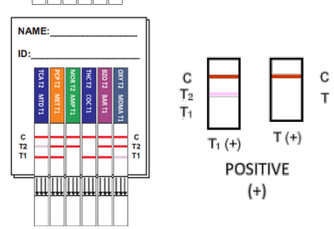
A red or pink line next to the "T1" or "T2" (drug test line) under the drug name indicates a negative result for that drug. If a test line appears next to the "T1" or "T2" for all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.



Preliminary Positive Result:

If NO red or pink line appears next to the "T1" or "T2" under the drug name, the sample may contain that drug. The manufacturer recommends sending the sample to a laboratory for confirmation testing.

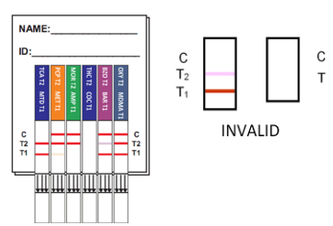
The illustration on the right shows preliminary positive results for AMP and THC, but negative for all other drugs.



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 Diagnostic USA 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: Identify (888)-600-0431, www.identifydiagnostics.com.

PERFORMANCE CHARACTERISTICS

A. ACCURACY

The accuracy of the Identify Diagnostics USA 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 the Identify Diagnostic USA 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 Diagnostic USA Drug Screen Test are shown in the following table.

Summary of Accuracy Results on the Identify Diagnostic USA Drug Screen Test

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						
		Drug-free	-50% - <-25% C/O	-25% C/O - C/O	C/O - +25% C/O	>+25% - +50% C/O	>+50/% C/O	% Agreement
6AM/10	Neg	40	2	1	0	0	0	100%
	Pos	0	0	0	0	2	14	100%
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
AMP/1000	Neg	40	2	0	0	0	0	97.7%
	Pos	0	0	1	3	2	42	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BAR/200	Neg	40	1	1	0	0	0	95.45%
	Pos	0	0	2	2	3	42	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
BZO/200	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	2	2	43	94%
CLO/300	Neg	40	2	0	0	0	0	97.67%
	Pos	0	0	1	0	1	26	100%
COC/150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
COC/300	Neg	40	0	3	1	0	0	100%
	Pos	0	0	0	4	1	46	98.0%
COT/200	Neg	40	0	0	0	0	0	>99.0%
	Pos	0	0	0	0	0	40	>99.0%
EDDP/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
EtG/500	Neg	141	15	8	5	13	65	99.40%
	Pos	0	0	1	2	0	0	97.60%
FEN/20	Neg	100	3	2	0	0	0	99.06%
	Pos	0	0	1	3	3	46	100%
FEN/25	Neg	40	0	0	0	0	0	>99%
	Pos	0	0	0	0	0	22	>99%
FEN/50	Neg	42	0	0	0	0	0	100%
	Pos	0	0	0	1	0	17	100%
K2/25	Neg	40	2	1	0	0	0	93.5%
	Pos	0	0	3	2	3	21	100%
KRA/100	Neg	40	2	0	0	0	0	97.67%
	Pos	0	0	1	1	3	14	>99%

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						
		Drug-free	-50% - <-25% C/O	-25% C/O - C/O	C/O - +25% C/O	>+25% - +50% C/O	>+50/% C/O	% Agreement
MDMA/500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
MET/1000	Neg	40	0	1	0	0	0	95.3%
	Pos	0	0	2	2	3	45	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
PPX/300	Neg	40	0	1	0	0	0	95.3%
	Pos	0	0	2	5	2	33	100%
TCA/1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%
TRA/100	Neg	40	8	4	0	0	0	>99%
	Pos	0	0	0	1	4	62	>99%

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 Diagnostic USA Drug Screen Test.

C. ANALYTICAL SPECIFICITY

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

Compound	Conc. (%)	Compound	Conc. (%)
6-AM			
6-Acetylmorphine	10 (100%)	Morphine	>100,000 (<0.1%)
Diacetylmorphine (heroin)	300 (3%)	Codeine	>100,000 (<0.1%)
Oxycodone	>100,000 (<0.1%)	Oxymorphone	>100,000 (<0.1%)
AMP			
D-Amphetamine	1,000 (100%)	MDA	15,000 (6.7%)
L-Amphetamine	100,000 (1%)	Phentermine	100,000 (1.0%)
AMP 500			
D-Amphetamine	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	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	60 (333%)		
BUP			
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%)
Desalkylflurazepam	1,200 (25%)	Nordazepam	390 (76.9%)
Diazepam	1,000 (30%)	Temazepam	150 (200%)
Flunitrazepam	250 (120%)	Triazolam	2,500 (12%)
Clonazepam	1500 (20%)		

Compound	Conc. (%)	Compound	Conc. (%)
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%)
Desalkylflurazepam	800 (25%)	Nordazepam	260 (76.9%)
Diazepam	650 (30.7%)	Temazepam	100 (200%)
Flunitrazepam	160 (125%)	Triazolam	1,650 (12.1%)
CLO			
7-Amino Clonazepam	300 (100%)	Clonazepam	75,000 (0.4%)
Meclonazepam	>100,000 (<0.3%)	Oxazepam	>100,000 (<0.3%)
Alprazolam	>100,000 (<0.3%)	Bromazepam	>100,000 (<0.3)
Clobazam	>100,000 (<0.3%)	Clorazepate dipotassium	>100,000 (<0.3%)
Desalkylflurazepam	100,000 (0.30%)	Diazepam	>100,000 (<0.3%)
Flunitrazepam	>100,000 (<0.3%)	α-Hydroxyalprazolam	>100,000 (<0.3%)
Lorazepam	>100,000 (<0.3)	Lorazepam glucuronide	>100,000 (<0.3%)
Nitrazepam	>100,000 (<0.3%)	Norchlordiazepoxide	>100,000 (<0.3%)
Nordiazepam	>100,000 (<0.3%)	Temazepam	>100,000 (<0.3%)
Triazolam	>100,000 (<0.3%)		
COC			
Benzoylecgonine	300 (100%)	Cocaine	10,000 (3%)
Cocaethylene	100,000 (0.3%)	Ecgonine	100,000 (0.3%)
COC 150			
Benzoylecgonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
COT			
(-)-Cotinine	200 (100%)	(R,S)-Norcotine	100,000 (0.2%)
Trans-3´-hydroxycotinine	5,000 (4%)	S(-)-Nicotine	>100,000 (<0.2%)
EDDP			
EDDP	300 (100%)		
EtG			
Ethyl glucuronide	500 (100%)		
FEN20			
Norfentanyl(calibrator)	20 (100%)	Fentanyl(parent drug)	1,000 (2%)
Alfentanil	>100,000(>0.02%)	Sufentanil	>10,000(>0.2%)
Carfentanil	>10,000(>0.2%)		
FEN 25			
Norfentanyl	25 (100%)	Fentanyl	325 (7.69%)
FEN 50			
Norfentanyl	50 (100%)	Fentanyl	350(14.3%)
K2 25			
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	100 (100%)	Olanzapine	50,000 (0.02%)
7-Hydroxymitragynine	125 (80%)		
MDMA			
(+/-)-MDMA	500 (100%)	(+/-)-MDEA	500 (100%)
(+/-)-MDA	3,900 (12.8%)		
MET			
D-Methamphetamine	1,000 (100%)	MDEA	60,000 (1.7%)
D-Amphetamine	100,000 (1%)	MDMA	8,000 (12.5%)
L-Amphetamine	100,000 (1%)	Mephentermine	100,000 (1%)
1R,2S(-)-Ephedrine	>100,000 (<0.5%)		
MET 500			
D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%)	MDMA	3,500 (14.3%)
L-Amphetamine	50,000 (1%)	Mephentermine	75,000 (0.7%)
1R,2S(-)-Ephedrine	100,000 (0.5%)		
MTD			
Methadone	300 (100%)		
OPI 300			
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine	100 (300%)	Morphine 3-glucuronide	400 (75%)
Ethylmorphine	100 (300%)	Norcodeine	6,000 (1.9%)
Heroin	8,000 (37.5%)	Oxycodone	75,000 (0.4%)
Hydrocodone	1,250 (24%)	Thebaine	90,000 (0.3%)
Hydromorphone	2,500 (12%)		
OPI 2000			
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)
Ethylmorphine	1,500 (133.3%)	Oxycodone	70,000 (2.9%)
Heroin	11,000 (18.2%)	Thebaine	95,000 (2.1%)
Hydrocodone	5,000 (40%)		

Compound	Conc. (%)	Compound	Conc. (%)
OXY			
Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)
Ethylmorphine	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)
PCP			
Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)
PPX			
Propoxyphene	300 (100%)	Norpropoxyphene	300 (100%)
TCA			
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-Δ9-THC-9-COOH	50 (100%)	(-)-Δ8-THC	20,000 (0.3%)
(+/-)-11-Hydroxy-Δ9-THC	5,000 (1%)	(-)-Δ9-THC	20,000 (0.3%)
TRA			
Tramadol	100 (100%)	N-Desmethyl-cis-tramadol	700 (14.28%)
O-Desmethyl-cis-tramadol	9,000 (1.11%)		

D. INTERFERENCE

The following compounds were evaluated for potential positive or negative interference with the Identify Diagnostics USA 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 Diagnostic USA 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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