



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	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
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

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:

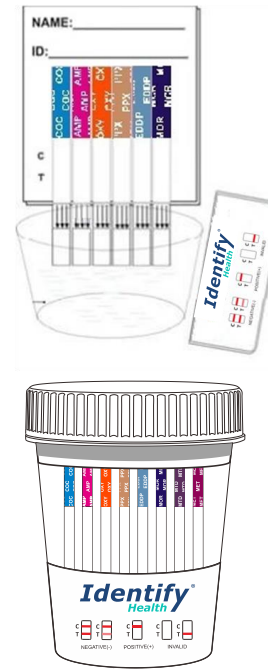
1. Allow the test device, controls, and/or specimens to equilibrate to room temperature (15-30°C) prior to testing.
2. Do not open the test device pouch until ready to perform the test.

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.

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.



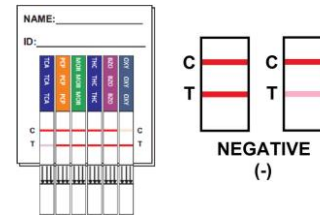
RESULT INTERPRETATION

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:

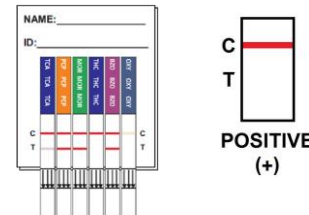
A red or pink line next to the "T" under the drug name indicates a negative result for that drug. If a test line appears next to the "T" all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.



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.

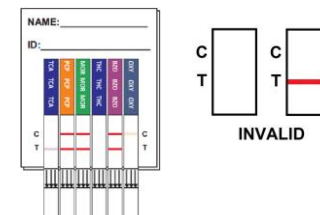
The illustration on the right shows preliminary positive results for AMP and THC, but negative for all other drugs.



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.

Summary of Accuracy Results on the Identify Health Drug Screen Test

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						% Agreement
		Drug-free	-50% -<-25% C/O	-25% C/O - C/O	C/O - +25% C/O	>+25% C/O	>+50% C/O	
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%
GAB/2000	Neg	40	0	0	1	0	0	>99%
	Pos	0	0	0	0	0	47	97.92%
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%
MDMA/500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%

