

Multi-Drug Screen Test

For Forensic Use Only

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

Abbreviation	Drug	Cutoff (ng/ml)
AMP	Amphetamine	500
AMP1000	Amphetamine	1,000
BAR	Barbiturates	300
BAR200	Barbiturates	200
BUP	Buprenorphine	10
BUP5	Buprenorphine	5
BZO	Benzodiazepines	300
BZO200	Benzodiazepines	200
COC	Cocaine	150
COC300	Cocaine	300
COT	Cotinine	200
EDDP	Methadone Metabolite	300
ETG	Ethyl Glucuronide	500
FEN	Norfentanyl	100
K2	Synthetic Marijuana	50
MDMA	Ecstasy	500
MET	Methamphetamine	500
MET1000	Methamphetamine	1,000
MTD	Methadone	300
MOR	Morphine	300
OPI	Opiates	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Tricyclic Antidepressants	1,000
THC	Marijuana	50
TRA	Tramadol	100

This test does not distinguish between drugs of abuse and certain medications. It may yield preliminary positive results when prescription tricyclic antidepressants, barbiturates, benzodiazepines, methadone, buprenorphine or opiates are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

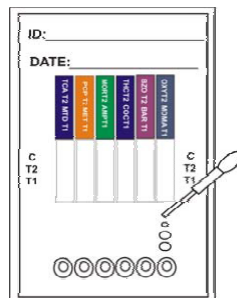
PROCEDURE

Preparation:

1. Allow the test device, and/or controls 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.

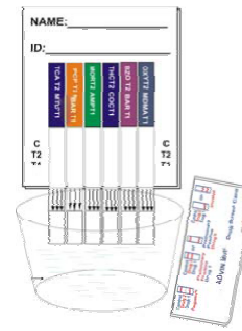
Cassette:

1. Remove the cassette from the sealed pouch and write the donor name or ID on the device in the provided space.
2. Add 3 drops of specimen with the provided dropper to each sample well.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read urine adulteration test results by visually comparing the color of the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes.



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.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read urine adulteration test 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. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read urine adulteration test results by comparing the color of the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes.



Strip:

1. Remove strip from the sealed pouch or bottle.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 20 seconds. Do not immerse the strip past the maximum line (MAX). Place the test strip on a non-absorbent flat surface.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.

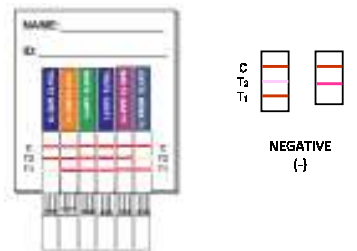
RESULT INTERPRETATION

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:

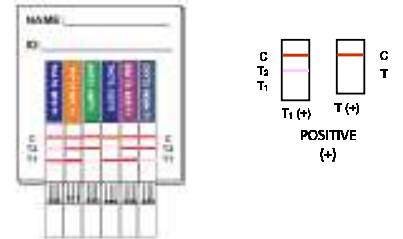
A red or pink line next to the "T1" or "T2" (drug test line) under the drug name indicates a negative result for that drug. If a test line appears next to the "T1" or "T2" for all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.



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. Send the sample to a laboratory for confirmation testing.

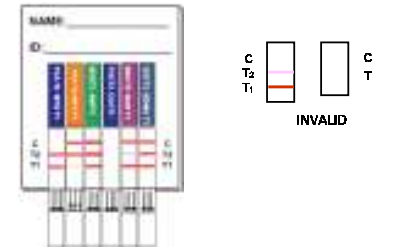
The illustration on the right shows preliminary positive results for AMP and THC, but negative for all other drugs.



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.



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: Biomedical Diagnostics, 1-631-595-9200, www.biochemicaldiagnostics.com.

PERFORMANCE CHARACTERISTICS

A. ACCURACY

The accuracy of the Multi-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 Multi-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). A summary of the accuracy results on cassette, dip card, cup and strip formats are shown in the following tables.

