RAPID TOX®

Rapid TOX is a cost effective cassette test that detects up to ten drugs of abuse in urine either by pipetting or dipping.

Drug name	Cut-off ng/ml	Detection Times (approximate)
AMP amphetamines	1000	2-4 days
BAR barbiturates	300	2-4 days
BZO benzodiazepines	300	Up to 2 weeks
BUP buprenorphine	12.5	2-3 days
COC cocaine	150 300	1-3 days
MDMA ecstasy	1000	2-4days
METH methamphetamines	1000	1-2days
MTD methadone	300	1-4days
OPI opiates	300 2000	1-3 days
OXY oxycodone	100	1-3 days
PCP phencyclidine	25	3-8days
PPX propoxyphene	300	1-3days
TCA tricyclic antidepressants	1000	5-7days
THC thc/marijuana	50	Infrequent use: 2-5 days Moderate use: 10-15 days Chronic use: 1 month

Prior to using Rapid TOX read complete test procedure, including quality control, found in this Quick Reference Guide and manufacturer's Product Instructions.

The Rapid TOX test is designed for use with human urine specimens only.

Pipette Procedure

STORAGE AND PIPETTE PROCEDURE

Store at room temperature 59° - 89° F (15° - 30° C)

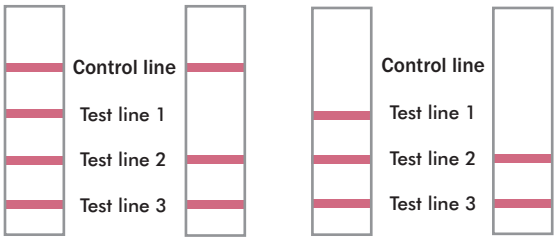
Verify foil pouch is intact and expiration date is valid.
(embossed at the top of the pouch)

- Open pouch just prior to collection.
- Lay cassette on a flat surface.
- Using the pipette provided, apply 3 drops of urine (120µl) into the sample well(s).
- Wait approximately 3-5 minutes for the control line(s) to be visible before reading test.

INTERPRETATION OF RESULTS

Line intensities may vary. Any line, without regard to intensity, color or size, is a line.

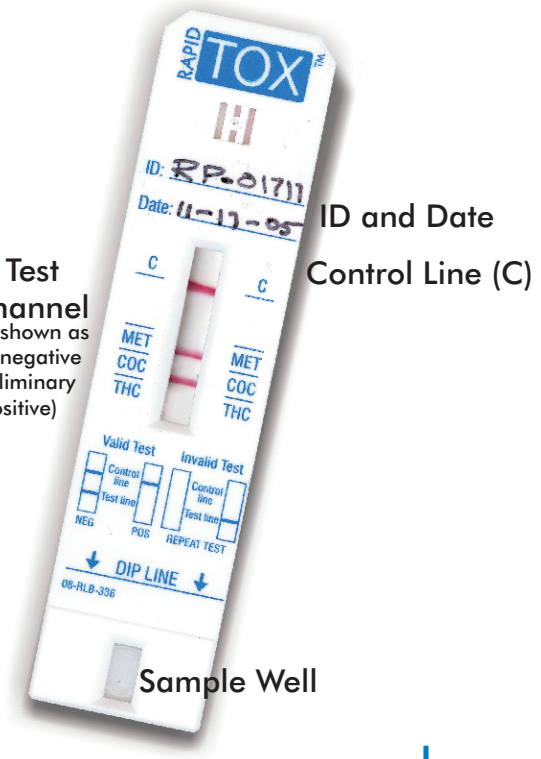
The results may be interpreted once the control line(s) have formed and the background has cleared.



control line = test valid
no control line = test invalid
test line = test negative
no test line = test preliminary positive

Results are stable for up to 6 hours.

This test provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result.



ID and Date

Control Line (C)

Test Channel
THC shown as non-negative (preliminary positive)

Sample Well

(800) 227-1243 ■ (518) 758-8158

www.abmc.com

ADDITIONAL INFORMATION-PIPETTE PROCEDURE

The ABMC Rapid TOX test may be used by sites holding a Certificate of Waiver. Certificate of Waiver sites must follow the complete manufacturer's instructions for performing the test. The Rapid TOX test is only waived for urine specimens. The Rapid TOX test should be stored at room temperature (59° to 86°F or 15° to 30°C).

SPECIMEN COLLECTION AND HANDLING

1. Use fresh urine specimens.
2. Urine specimens do not require any special handling or pre-treatment.
3. It is best to test urine specimens immediately after collection. If necessary, urine specimens may be refrigerated at 2° to 8°C for 2 days.
4. Handle and dispose of urine specimens according to established protocols.
5. Avoid contact with skin.
6. Avoid cross-contamination of urine specimens by using a new container for each urine specimen.

PIPETTE PROCEDURE

1. Verify the foil pouch is intact.
2. Verify the product is within the expiration date indicated on the pouch.
3. When an acceptable sample is obtained, the test device maybe removed from the foil pouch.
4. Lay test device flat. An absorbent pad may be placed under the test device.
5. Using the pipette provided, apply 3 drops of urine (approximately 120µL) to the sample well(s) at the bottom of each device.
6. Allow test to proceed undisturbed until the reddish-purple control line appears and the test background clears. The control line [C] is the uppermost line in the test channel. Once the control line is visible, the test is ready to be interpreted; typically this occurs in 3-5 minutes.
7. Read results as explained under Interpretation of Results.
8. Color blindness will not affect reading of the results of the test (The results are determined by the absence or presence of the test and control lines).
9. There are no additional safety considerations for untrained users.
10. The Rapid TOX may be disposed of in a regular trash receptacle without any special handling.

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use.
For professional use.
Follow proper handling and disposal procedures.

While the Centers for Disease Control (CDC) has stated that “Universal precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine, and vomitus unless they contain visible blood.”, the use of gloves is recommended for handling of all samples and is good hygienic practice. The Rapid TOX test devices may be disposed of in a regular trash receptacle without any special handling.

Do not use if foil pouch seal is not intact (seal broken, tears, holes, etc.).

Do not use if beyond the expiration date printed or embossed on the pouch.
The expiration date is formatted as YYYY/MM, e.g. 2011/01 means the kits should not be used after the end of January, 2011.

QUALITY CONTROL

A procedural control (the control line [C]) is built into each test strip indicating that the reagents on the device are present and functioning properly. It is also good laboratory practice to use positive and negative controls to ensure proper test performance. Control samples are commercially available. Positive and negative controls should be used :

1. Prior to using a new lot, each new shipment, and every thirty days to check storage, or
2. If the product has been stored outside the recommended storage conditions, or
3. In accordance with your laboratory defined policies.

If the test does not perform as expected with quality control solutions, or if repeated invalid results are obtained, call ABMC Technical Service at (800) 227-1243 or (518) 758-8158 extension #3.