QUICK REFERENCE GUIDE

RAPID TOX®

Dip Procedure

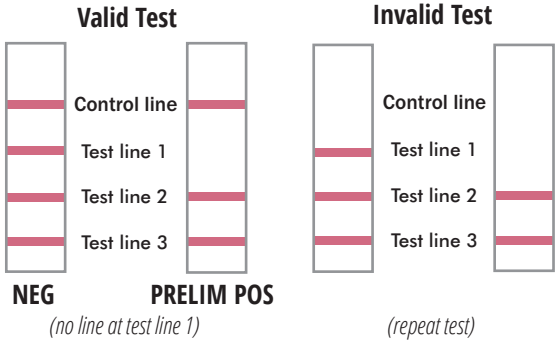
STORAGE AND DIP PROCEDURE

Store at room temperature 59°-89° F (15°-30° C)
Verify foil pouch is intact and expiration date is valid.
(expiration date is embossed at the top of the pouch)

- Open pouch just prior to collection.
- Dip the Rapid TOX cassette into sample to the indicated Dip Line for 3-5 seconds.
- Remove test cassette from sample and lay it on a flat surface.
- Wait approximately 3-5 minutes for the control line(s) to be visible before reading test.

INTERPRETATION OF RESULTS

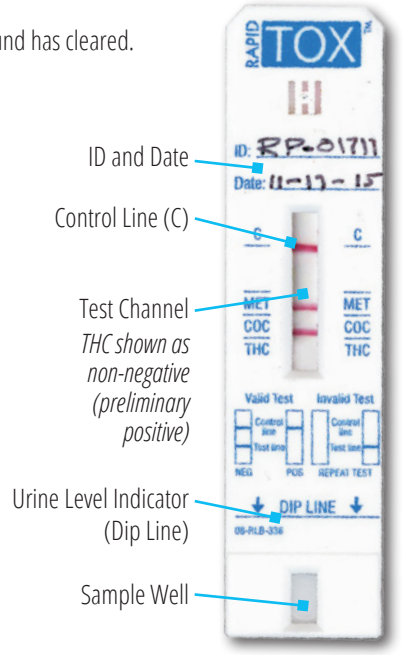
Line intensities may vary. Any line, without regard to intensity, color or size, is a line.
The results may be interpreted once the control line(s) have formed and the background has cleared.



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.



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ADDITIONAL INFORMATION — DIP 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 pretreatment.
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.

DIP PROCEDURE

1. Instruct donor to provide adequate sample volume. The Rapid TOX dip procedure can be done with as little as 3mL in a collection cup. If an adequate sample is not provided, use the pipette procedure.
2. Verify the foil pouch is intact. Verify the product is within the expiration date indicated on the pouch. When an acceptable sample is obtained, the test device may be removed from the foil pouch.
3. Insert the bottom of the test cassette into the urine sample up to the Dip Line for 3-5 seconds. Do not allow urine to touch the cassette above the Dip Line.
4. Remove the test device from the sample and lay flat across the top of the cup or on a flat surface.
5. 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.
6. Read results as explained under Interpretation of Results.
7. 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).
8. There are no additional safety considerations for untrained users.
9. 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. 2017/08 means the kits should not be used after the end of August, 2017.

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.

DRUG DETECTION TIMES

Rapid TOX is a cost effective cassette test that detects up to ten drugs of abuse in urine either by pipetting or dipping. Pipetting procedures are on separate Quick Reference Guide.

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	2-4 days
METH methamphetamines	1000	1-2 days
MTD methadone	300	1-4 days
OPI opiates	300 2000	1-3 days
OXY oxycodone	100	1-3 days
PCP phencyclidine	25	3-8 days
PPX propoxyphene	300	1-3 days
TCA tricyclic antidepressants	1000	5-7 days
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.

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 ext 3.