

TECHNICAL NOTE

MEDTOX CONTROLS: THC STABILITY

MEDTOX controls are stable for the length of time under the storage conditions stated in the package insert. In spite of this fact, under certain conditions, there may be observed a gradual decline in THC levels, over time, from continuous use of a single bottle of control material. This drop in THC values may occur from any THC sample (i.e. calibrators, controls and samples). The apparent loss of THC most often occurs from handling and not from product instability.

It is well known that THC-COOH binds to surfaces, especially certain plastics^{1,2}. In order to minimize this adsorption loss we recommend the following when handling any sample (including MEDTOX Cup Controls) which may contain THC:

1. It is preferable to pour controls directly into sample cups for testing. After testing, pour the control back into the original glass bottle.
2. Do not use a plastic funnel or plastic transfer cup to pour the control back into the original glass bottle.
3. As an alternative, a glass pipette may be used. Plastic transfer pipettes should be avoided.
4. When pipetting, immerse the pipette tip as little as possible into the sample solution.
5. Do not rinse the pipette back and forth into the sample.

References:

1. Blanc JA, Menneh VA, et al. Adsorption losses from urine-based cannabinoid calibrators during routine use. Clin Chem 1993; 39:1705-1712.
2. Roth KDW, Siegel NA, et al. Investigation of the effects of solution composition and container material type on the loss of 11-nor-Delta9-THC-9-Carboxylic Acid. J Anal Tox 1996; 20:291-300

To place an order or for technical assistance, call 1-800-334-1116

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TOXICOLOGY URINE CONTROLS Package Insert

MEDTOX Cup 2X Positive

MEDTOX Cup 2X High Positive

MEDTOX Cup Negative

Controls prepared from human based urine available as negative or positive (above cutoff) levels designed to monitor and validate the performance of MEDTOX Cup format drugs of abuse test devices.

For in vitro diagnostic use only - PLEASE READ ENTIRE INSERT CAREFULLY BEFORE USING THESE CONTROLS.

Manufactured for MEDTOX Diagnostics, Inc. by
Biochemical Diagnostics, Inc.
180 Heartland Blvd, Edgewood, NY 11717

INTENDED USE: The MEDTOX Toxicology Urine Control is intended for use as quality control urine to monitor the precision of laboratory urine toxicology testing procedures for the analytes listed in the package insert.

SUMMARY AND EXPLANATION: The DEA exempt MEDTOX product line of controls is manufactured using a human based matrix that has been stabilized to insure that the product will be viable until the date of expiration. Positive controls are spiked with reference drug standards and/or appropriate metabolites that have been obtained from ISO certified manufacturers. Standards are certified by the manufacturers to be at least 98% minimum purity. Specific gravity, pH, and creatinine fall within the limits of normal human urine.

DESCRIPTION: Each bottle contains stabilized human based urine. Positive control urines have been spiked with authentic reference drug standards and/or appropriate metabolites. MEDTOX positive and negative urine controls are certified by combination of immunoassay, GC/MS and/or LC/MS/MS for the constituents listed in the insert.

STORAGE & STABILITY: Please refer to LIMITATIONS for detailed instructions.

Unopened:

- A. The controls are stable until the expiration date when stored at -10 to -20°C and protected from light.
- B. The controls are stable until the expiration date when stored at 2-8°C.

After Opening:

- A. The controls are stable for six months or until the expiration date, whichever comes first, when stored at -10 to -20°C (refrozen in original bottle).
- B. The controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at 2-8°C.
- C. Thaw controls as needed; allow controls to come to room temperature followed by gentle swirling before use.

PROCEDURE: Allow controls to come to room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE. For use in MEDTOX Cup test devices:

- A. Pour the entire contents of one 25 mL bottle of MEDTOX urine control into a new test cup. Read and interpret test results the same as for a donor sample.
- B. After use, return the entire contents of urine control in the cup to the original bottle and store according to After Opening conditions above.
- C. Take reasonable care to minimize contact with airborne or surface contaminants. Return to storage as soon as possible.
- D. One control bottle may be used up to a total of three (3) times.

Users should follow government regulations for the running of QC material.

EXPECTED RESULTS: The positive MEDTOX control must test positive on the MEDTOX drugs of abuse test device. The negative control must test negative. MEDTOX Diagnostics will (upon request), supply assay values derived from certified laboratories on a particular lot of control material.

PRECAUTIONS: For *In Vitro* Diagnostic Use Only. Please read the entire package insert before using the MEDTOX urine controls. Please use the same safety precautions you would use for processing any “unknown” urine sample containing potentially infectious biological material. Protect product from exposure to direct sunlight. Contains sodium azide: To prevent formation of explosive metal azides dispose of waste by flushing with copious amounts of water or according to local governing regulations. *Do not use beyond the expiration date.*

LIMITATIONS OF PROCEDURE: The control is meant to be used to validate the performance of immunoassay drug screening methods. Consult test manufacturers instructions when using this product; changes in reagents, sample requirement, or methodology may effect test results. Although target values are provided with the MEDTOX urine controls, each laboratory should run these controls as unknowns in order to establish “in-house” assay values for them. *This product is not meant to be used as a standard or calibrator.*

APPLICATIONS: The MEDTOX Toxicology Urine Controls are designed to monitor and validate the performance of drugs of abuse detection methods at levels established by SAMHSA, CAP/AACC and many state programs. The MEDTOX controls are compatible with all quantitative and qualitative drug detection procedures which are sufficiently sensitive to detect the control constituents. Controls should be treated as any “unknown” specimen while following the specific protocol of the assay being used. This product is intended to be used by health care professionals as an integral part of good laboratory practices.

**MEDTOX
TOXICOLOGY URINE CONTROL**

TARGET VALUES (ng/mL)

Drug Constituents	MEDTOX Cup Negative	MEDTOX Cup 2X Positive	MEDTOX Cup 2X High Positive
Delta-9-THC-COOH	0	80	100
Benzoylcegonine (COC)	0	200	600
Phencyclidine (PCP)	0	50	50
Morphine (OPI)	0	200	4000
d-Methamphetamine	0	2000	2000
d-Amphetamine	0	600	2000
Butalbital (BAR)	0	400	400
Nordiazepam (BZO)	0	400	600
Methadone	0	400	600
Desipramine (TCA)	0	0	600
Propoxyphene	0	600	600
Oxycodone	0	200	200
Buprenorphine	0	20	0

CATALOG

PART NUMBER	DESCRIPTION	SIZE
102352	MEDTOX Cup Negative	25 mL
102351	MEDTOX Cup 2X Positive	25 mL
102350	MEDTOX Cup 2X High Positive	25 mL