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 Toxicology Urine Controls) which may contain THC:

1. It is preferable to use glass pipettes or pour controls into sample cups. As an alternate, pipettors with disposable plastic tips may be used. Soft plastic transfer pipettes should be avoided.
2. Do not rinse the pipette back and forth into the sample.
3. Sample volume to surface area ratio should be as high as possible (i.e. when transferring, sample containers should be filled as much as possible with sample). Avoid rough surface plastic containers.
4. When pipetting, immerse the pipette tip as little as possible into the sample solution.
5. Do not return any unused material back into the original sample.

These same guidelines should also be followed when aliquoting a control (or sample) for future use.

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; 20:29l-300

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

P/N 102370 Rev. 04/14

MEDTOX® DIAGNOSTICS, INC.

1238 Anthony Road, Burlington, NC 27215
Phone (336) 226-6311 • Fax (336) 229-4471

TOXICOLOGY URINE CONTROLS

Package Insert

MEDTOX 300 2X Positive

MEDTOX 2000 2X Positive

MEDTOX Negative

Controls prepared from human based urine available as negative or positive (above cutoff) levels designed to monitor and validate the performance of MEDTOX 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. (Controls can be aliquoted and frozen.)
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. Transfer an appropriate aliquot of MEDTOX urine control as required by the drugs of abuse test device or screening method.
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 Negative	MEDTOX 300 2X Positive	MEDTOX 2000 2X Positive
Delta-9-THC-COOH	0	100	100
Benzoylecgonine (COC)	0	600	600
Phencyclidine (PCP)	0	50	50
Morphine (OPI)	0	600	4000
d-Methamphetamine	0	2000	2000
d-Amphetamine	0	2000	2000
Butalbital (BAR)	0	400	400
Nordiazepam (BZO)	0	600	600
Methadone	0	600	600
Desipramine (TCA)	0	600	600
Propoxyphene	0	600	600
Oxycodone	0	200	200

CATALOG

PART NUMBER	DESCRIPTION	SIZE
101183	MEDTOX Negative	5 mL
102368	MEDTOX 300 2X Positive (use for Opiate 300 tests)	5 mL
102366	MEDTOX 2000 2X Positive (use for Opiate 2000 tests)	5 mL