

TECHNICAL NOTE

MEDTOX CONTROLS: 11-NOR-DELTA 9-THC-9-COOH STABILITY

MEDTOX controls are stable for the length of time stated in this package insert when stored under the recommended conditions. In spite of this fact, under certain conditions, there may be observed a gradual decline in THC-COOH levels, over time, from continuous use of a single bottle of control material. This drop in THC-COOH values may occur from any THC-COOH sample (i.e. calibrators, controls and samples). The apparent loss of THC-COOH 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-COOH:

1. Soft plastic especially low density polyethylene transfer pipettes should be avoided.
2. Best results are obtained using glass pipettes or pouring controls into sample cups. Pipettes with disposable polypropylene plastic tips are also acceptable, but to minimize losses:
 - a. Do not rinse the pipette back and forth into the sample.
 - b. When pipetting, immerse the pipette tip as little as possible into the sample solution.
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. 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, etal. Adsorption losses from urine-based cannabinoid calibrators during routine use. Clin Chem 1993; 39:1705-1712.
2. Roth KDW, Siegel NA, etal. 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

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To place an order or for technical assistance, call 1-800-832-3244



1238 Anthony Road Burlington, N.C. 27215

TOXICOLOGY URINE CONTROLS

MEDTOX 300 Positive
MEDTOX 2000 Positive
MEDTOX Negative

Controls prepared from human based urine available as a negative and Cutoff +50% to monitor 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 by Biochemical Diagnostics, Inc.
180 Heartland Blvd, Edgewood, NY 11717

DESCRIPTION

Each bottle contains stabilized human based urine. Positive control urines have been spiked with authentic reference drug standards and/or appropriate metabolites. Negative control urines are certified negative by EMIT[®], ONLINE[™] and GC/MS for the constituents listed in this insert.

PRECAUTIONS

For in vitro diagnostic use only - Please read the entire package insert before using the MEDTOX Toxicology 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.

Although target values are provided with the MEDTOX Toxicology urine liquid controls, each laboratory should run these controls as unknowns in order to establish "in-house" assay values for them.

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.

STORAGE & STABILITY - (Please refer to the Technical Note on the back page of this package insert for detailed handling instructions)

Unopened:

- The controls are stable for two years or until the expiration date, whichever comes first, when stored at -20°C protected from light.
- The controls are stable for six months or until the expiration date, whichever comes first, when stored at 2-8°C.

After Opening:

- The controls are stable for six months or until the expiration date, whichever comes first, when stored at -20°C. (Controls can be aliquoted and frozen)
- The controls are stable for one month or until the expiration date, whichever comes first, when stored at 2-8°C.

Thaw controls as needed; allow to come to room temperature followed by gentle swirling before using.

APPLICATIONS

The MEDTOX Toxicology urine controls are designed to monitor the performance of MEDTOX drugs of abuse test devices.

The MEDTOX Toxicology urine controls are compatible with all quantitative and qualitative drug detection procedures, which are sufficiently sensitive to detect the control constituents. They should be treated as any "unknown" specimen while following the specific protocol of the assay being used.

MEDTOX TOXICOLOGY URINE CONTROLS

CONSTITUENTS	TARGET VALUES (ng/mL)		
	Negative	300 Positive	2000 Positive
SAMHSA Mandated			
Delta-9-THC-COOH	0	75	75
Benzoylecgonine	0	450	450
PCP	0	37.5	37.5
Morphine (MEDTOX 300 Positive)	0	450	N/A
Morphine (MEDTOX 2000 Positive)	0	N/A	3000
d-Methamphetamine	0	1500	1500
d-Amphetamine	0	1500	1500
Non-Mandated			
Butalbital	0	300	300
Nordiazepam	0	450	450
Methadone	0	450	450
Desipramine	0	450	450
Propoxyphene	0	450	450
Oxycodone	0	150	150

- **MEDTOX Negative Toxicology Urine Control Part Number 101183**
(Use with all MEDTOX drugs of abuse test devices)
- **MEDTOX 300 Positive Toxicology Control Part Number 101830**
(Use for Opiate 300 tests (PROFILE-II ER[®] and all VERDICT[®]-II products))
- **MEDTOX 2000 Positive Toxicology Control Part Number 101829**
Use for Opiate 2000 tests (All PROFILE[®]-II except ER[®])

EMIT[®] is a trademark of SYVA Co. (Dade Behring), Palo Alto, CA

ONLINE[™] is a trademark of Roche Diagnostics Corp., Indianapolis, IN