INTENDED USE

The DOA Urine Toxicology 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 DOA Urine Toxicology control urines 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.
This product is intended to be used by health care professionals as an integral part of good laboratory practices.

SUMMARY AND EXPLANATION

The DEA exempt DOA Urine Toxicology 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 manufactures 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. Negative control urines are certified negative by EMIT®, ONLINE™ and GC/MS for the constituents listed on our target sheets.

DOA URINE TOXICOLOGY™ Liquid Control Urine

Target Values (ng/mL)

SAMHSA MANDATED	Negative	Low Positve DOAC-050MO	Positve DOAC-2XMO	19001066 2X
Delta-9-THC-COOH	0	75	100	100
Benzoylecgonine	0	450	600	600
Phencyclidine (PCP)	0	37.5	50	50
Morphine (Low Opiate)	0	450	600	600
d-Amphetamine	0	1500	2000	2000
d-Methamphetamine	0	1500	2000	2000
NON-MANDATED	0			
Secobarbital	0	450	600	600
Oxazepam	0	450	600	600
Methadone	0	450	600	600
Methaqualone	0	450	600	600
Propoxyphene	0	450	600	600
Nortriptyline	0	1500	2000	2000
MDMA*	0	750	1000	1000
Oxycodone	0	150	200	200
Buprenorphine	-	-	-	20
*3,4 Methylenedioxymethyl-amphetamine				

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

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

CATALOG # DESCRIPTION

DOAC-050MO	DOA Urine Toxicology Control, Low Positive, 5 mL (Cutoff +50% with MDMA and Oxycodone)
DOAC-2XMO	DOA Urine Toxicology Control, Positive, 5 mL (2X Cutoff with MDMA and Oxycodone)
DOAC-000-1	DOA Urine Toxicology Control, Negative, 5 mL
19001066	Stat-Skreen with MDMA, OXY & BUP, 2X Cutoff 5 mL (Low Opiate Controls)

For additional information on our other products please contact us or refer to our website: www.novacentury.com

PRECAUTIONS

For in vitro diagnostic use only

Please read the entire package insert before using the DOA Urine Toxicology control urines. 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.

STORAGE & STABILITY - Please refer to Technical Note 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, however, no stability claims can be made for Oxazepam as it may deteriorate over time when stored refrigerated.

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 to come to room temperature followed by gentle swirling before use.

PROCEDURE

A. Allow controls to come to room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE.
B. Pipette an appropriate aliquot of DOA Urine Toxicology control urine as required by the drugs of abuse test device or screening method.

DN: DOAC-050MO,DOAC-2XMO,DOAC-000-1,19001066
Effective Date: Apr 15 2011 rev. 2

TECHNICAL NOTE

DOA URINE TOXICOLOGY CONTROLS, THC STABILITY

DOA Urine Toxicology 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, theremay 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 DOA Urine Toxicology controls) which may contain THC:

1. Preferably, 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, Manneh 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-delta 9-THC-9-carboxylic acid. J Anal Tox 1996; 20:291-300

DOA URINE TOXICOLOGY CONTROLS, OXAZEPAM STABILITY

Oxazepam has known stability problems in urine stored refrigerated, and to a lesser degree, frozen. Our experience indicates that Oxazepam will not deteriorate more than 10% of target level for at least one year when stored frozen at -20°C. Further deteriorations may occur beyond this period although Oxazepam ordinarily tests positive throughout the control's shelf life.

LIMITATIONS OF PROCEDURE

This 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 DOA Urine Toxicology liquid 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.*

EXPECTED RESULTS

The positive DOA Urine Toxicology control must test positive on the drugs of abuse test device or screening method. The negative control must test negative. Biochemical Diagnostics will (upon request), supply assay values derived from our contract assay laboratories and customer base on a particular lot of control material.

Distributed by Nova Century Scientific, Inc.

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DOA URINE

TOXICOLOGY

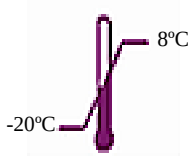
LIQUID

CONTROLS

Controls prepared from human based urine available as a negative and positive for constituent target levels to monitor the performance of on-site drug detection devices.

Target levels available: Negative, Low Positive (Cutoff +50%), & 2 High Positive (2X Cutoff)

Please read the entire package insert before using the DOA Urine Toxicology control urines.



Temperature Limit


Consult Instructions for Use

For In Vitro Diagnostic Use