

DRUGCHECK® LIQUID TOXICOLOGY CONTROL URINE

Controls prepared from human based urine available as a negative and at various constituent target levels to monitor the performance of hand-held drug detection devices.

Target levels available: Negative and Positive Control (Cutoff +50% and 2X Cutoff)

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

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 DrugCheck® 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.

Although target values are provided with the DrugCheck® liquid controls, each laboratory should run these controls as unknowns in order to establish “in-house” assay values for them. Biochemical Diagnostics will (upon request), supply assay values derived from our contract assay laboratories and customer base on a particular lot of control material.

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

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 three 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.

EMIT® is a trademark of SYVA Co. (Dade Behring), Palo Alto, CA
ONLINE™ is a trademark of Roche Diagnostics Corp., Indianapolis, IN

APPLICATIONS

The DrugCheck® controls are designed to monitor the performance of on-site drugs of abuse detection methods.

The DrugCheck® 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.

DRUGCHECK TOXICOLOGY CONTROLS					
CONSTITUENTS	TARGET VALUES (ng/mL)				
SAMHSA MANDATED	Negative	Drug Check	Cutoff +50% Positive	2X Cutoff Positive	Drug Check-H
Delta-9-THC-COOH	0	Negative	75	100	Positive
Benzoyllecgonine	0	Negative	450	600	Positive
PCP	0	Negative	37.5	50	Positive
Morphine	0	Negative	3000	4000	Positive
d-Methamphetamine	0	Negative	1500	2000	Positive
d-Amphetamine	0	Negative	1500	2000	Positive
Non-Mandated					
Secobarbital	0	Negative	450	600	Positive
Oxazepam	0	Negative	450	600	Positive
Methadone	0	Negative	450	600	Positive
Methaqualone	0	Negative	450	600	Positive
Propoxyphene	0	Negative	450	600	Positive
Nortriptyline	0	Negative	1500	2000	Positive
MDMA	0	Negative	750	1000	Positive
Oxycodone	0	Negative	150	200	Positive

CATALOG #	DESCRIPTION
18001123	-50 DOA Control, 20 mL
18001124	+50 DOA Control, 20 mL
18001129	DrugCheck Negative Control 20 mL
18001264	DrugCheck Positive Control with MDMA & OXY at 2X cutoff and BUP at 30 ng/mL, 20 mL

Distributed by:

Express Diagnostics Int'l, Inc.
1550 Industrial Drive
Blue Earth, MN 56013

TECHNICAL NOTE

Re: DrugCheck® CONTROLS, THC STABILITY

DrugCheck® 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 DrugCheck® controls) which may contain THC:

- Preferably, use glass pipettes or pour controls into sample cup. As an alternate, pipettors with disposable plastic tips may be used. Soft plastic transfer pipettes should be avoided.
- Do not rinse the pipette back and forth into the sample.
- 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.
- When pipetting, immerse the pipette tip as little as possible into the sample solution.
- 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:

- Blanc JA, Manneh VA, et al. Adsorption losses from urine-based cannabinoid calibrators during routine use. Clin Chem 1993; 39:1705-1712
- 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

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