

FIRST SIGN®

Drug of Abuse Urine Controls

Intended Use

First Sign® Drug of Abuse Urine Controls are developed to evaluate and verify the functionality of First Sign® Drug of Abuse Test. First Sign® Drug of Abuse Urine Controls should be treated as unknown samples when being used. They are intended to be used by laboratory professionals only as part of their quality control system. First Sign® Drug of Abuse Urine Controls are designed to be used with Hemosure First Sign® Drug of Abuse Test products only.

Summary and Explanation

First Sign® Drug of Abuse Urine Controls are manufactured by using stabilized human based urine matrix. The controls are good until the printed expiration date on each bottle. Positive controls are spiked with drug standards and/or relevant drug metabolites from ISO certified manufacturers. Specific gravity, pH, and creatinine all fall inside the range limits of normal human urine.

Description

Each bottle contains stabilized human based urine. Positive control urine samples have been spiked with certified drug standards and/or relevant drug metabolites. Negative control urine samples are certified negative by means of immunoassay and GC/MS for the constituents (urine products) charted below.

List of First Sign® Drug of Abuse Urine Controls

Drug	Calibrator	Drug	Calibrator
Amphetamine (AMP)	d-Amphetamine	Methylenedioxymethamphetamine (MDMA)	3,4 Methylenedioxy-N-methylamphetamine
Barbiturates (BAR)	Secobarbital	Methadone (MTD)	(±) Methadone
Buprenorphine (BUP)	Buprenorphine	Opiate (OPI)	Morphine
Benzodiazepines (BZO)	Oxazepam	Oxycodone (OXY)	Oxycodone
Cocaine (COC)	Benzoylcegonine	Phencyclidine (PCP)	Phencyclidine
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	Tricyclic Antidepressants (TCA)	Nortriptyline
Methamphetamine (mAMP)	d-Methamphetamine	Marijuana (THC)	Δ-9-THC-COOH

First Sign® Drug of Abuse Urine Controls Part Numbers and Description

Part Number	Description
D0115-TC01	First Sign® DOA Control Set, 1 Positive & 1 Negative (5mL each)
D0115-TC02	First Sign® DOA Control Set, 1 Positive & 1 Negative (20mL each)

Storage & Stability

See "Limitations of Procedure" for detailed explanation.

Unopened Bottles:

- I. The controls are stable until the expiration date printed on the bottle label when stored at -20°C to -10°C and are not exposed to the light.
- II. Oxazepam controls' stability cannot be assured due to its deterioration over time even when stored in refrigeration; all other controls are stable until the expiration date when stored at 2°C to 8°C.

After Opened Bottles:

(Controls can be aliquoted and frozen)

- I. The controls are stable for 6 months after they are opened or until the expiration date, whichever one comes first, when they are stored at -20°C to -10°C.
- II. The controls are stable for 31 days after they are opened or until the expiration date, whichever one comes first, when the bottles are tightly capped and are stored at 2°C and 8°C.

Note: Controls need to be thawed; allow controls to come to room temperature followed by light swirling before use.

Procedure

Allow controls to come to room temperature followed by light swirling before use. **Do not shake.** Pipette a proper amount of First Sign® Drug of Abuse Urine Controls as required by the First Sign® Drug of Abuse Test device.

Limitations of Procedure

The controls are intended for validating the performance of First Sign® Drug of Abuse Test's immunoassay drug screening methods. Refer to test manufacturer's instructions when using this product; changes in reagents, sample requirements, or methodology may change the test results. The product is not intended to be used as a standard or calibrator.

Expected Results

Positive controls must test positive on First Sign® Drug of Abuse Test device, and the negative controls must test negative.

Precautions

- For in vitro diagnostic use only.
- Do not use beyond the expiration date.
- Thoroughly read the entire package insert before using First Sign® Drug of Abuse Urine Controls.
- Treat controls as any other unknown urine samples that potentially contain infectious biological material.
- Keep the controls from exposing to direct sunlight.
- The controls contain sodium azide and in order to prevent the formation of explosive metal azides, dispose of waste by flushing with ample amounts of water or according to local regulations.

Oxazepam Stability

Oxazepam in urine is known to be unstable when refrigerated and, to a lesser degree, frozen². Experience has shown that Oxazepam will not deteriorate more than 10% of target level for at least one year when it is stored frozen at -20°C. Further deterioration may occur beyond this period although Oxazepam usually tests positive throughout the control's shelf life.

THC Stability

Urine drug controls are stable for the length of time under the storage conditions stated in the instructions. Despite 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 decline in THC level may happen from any THC sample including calibrators, controls and samples. The apparent loss of THC most often occurs from handling instead of from product instability. It is scientifically proven that THC-COOH binds to surfaces, especially to certain plastic materials³. To minimize adsorption loss, the following actions are recommended:

- I. Ideally, use glass pipettes or pour controls into sample cups. As another option, pipettes with disposable plastic tips may be used. Avoid using soft plastic transfer pipettes¹.
- II. Do not rinse the pipette back and forth into the controls.
- III. Volume to surface ratio of the sample should be as high as possible (i.e. when transferring, sample containers should be filled as much as possible with the sample). Avoid rough surfaced plastic containers.
- IV. Dip the pipette tip as shallow as possible into the control solution when pipetting.
- V. Do not return any remaining used control back into the original control solution. These same principles should be followed when aliquoting a control (or sample) for future use as well.

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. Karinen, R, Oiestad EL, et al. Comparison of the stability of stock solutions of drugs of abuse and other drugs stored in a freezer, refrigerator, and at ambient temperature for up to one year. *Journal of Analytical Toxicology* 35.8 (2011): 583-590.
3. Stout, PR, Horn CK, et al. Loss of THCCOOH from urine specimens stored in polypropylene and polyethylene containers at different temperatures. *Journal of Analytical Toxicology* 24.7 (2000): 567-571.

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