

Professional Cup Urine Drug Controls: Negative, Positive

Intended Use

The Alere™ Professional Cup Urine Drug Controls are designed to monitor and validate the performance of drugs of abuse detection methods at levels established by SAMHSA, CAP/IAACC and many state programs. The Alere™ Professional Cup Urine Drug 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. This product is intended to be used by health care professionals as an integral part of a quality control system.

Summary and Explanation

The DEA exempt Alere™ Professional Cup Urine Drug Control product line of controls is manufactured using a human based matrix that has been stabilized to ensure 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. Negative control urines are certified negative by immunoassay screening methods and GC/MS for the constituents listed in the Target Analyte Table below.

Storage & Stability

Please refer to Limitations for detailed instructions.

Unopened:

- The controls are stable until the expiration date when stored at -20 to -10°C and protected from light.
- The controls are stable until the expiration date when stored at 2 to 8°C. However, no stability claims can be made for Oxazepam as it may deteriorate over time when stored refrigerated.

After Opening:

(Controls can be aliquoted and frozen)

- The controls are stable for six months or until the expiration date, whichever comes first, when stored at -20 to -10°C.
- The controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at 2 to 8°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. Pipette an appropriate aliquot of Alere™ Professional Cup Urine Drug Control sample as required by the drugs of abuse test device or screening method.

Expected Results

The positive control must test positive on the drugs of abuse test device or screening method. The negative control must test negative.

Precautions

For In Vitro Diagnostic Use Only.

Please read the entire package insert before using the Alere™ Professional Cup Urine Drug 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

This control is meant to be used to validate the performance of immunoassay drug screening methods. Consult test manufacturer’s instructions when using this product; changes in reagents, sample requirement, or methodology may affect test results. Although target values are provided with the Alere iScreen® Urine

Drug 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.*

Alere™ Professional Cup Urine Drug

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.

Alere™ Professional Cup Urine Drug

Controls, THC Stability

Alere™ Professional Cup Urine Drug 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 Alere™ Professional Cup Urine Drug 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.

Alere™ Professional Cup Urine Drug Controls: Target Values (ng/mL)

Drug Assay Class	Drug	Negative Control	Positive Control
Amphetamine	d-Amphetamine	0	3000
Barbiturates	Secobarbital	0	900
Buprenorphine	Buprenorphine Glucuronide	0	30
Benzodiazepines	Oxazepam	0	900
Cocaine	Benzoylcegonine	0	900
MDMA	3,4-Methylenedioxyamphetamine	0	1500
Methodone	Methodone	0	900
Methamphetamine	d-Methamphetamine	0	3000
Opiates	Morphine (High Opiate)	0	6000
Oxycodone	Oxycodone	0	300
PCP	Phencyclidine (PCP)	0	75
Propoxyphene	d-Propoxyphene	0	900
THC	Delta-9-THC-COOH	0	150
Tricyclic Antidepressants	Nortriptyline	0	3000

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.

Technical Assistance:

Alere: 800.340.4029

Alere Toxicology Services-Products Division: 800.340.4029



Manufactured by:
Alere Toxicology Services - Products Division
 Portsmouth, VA 23704 USA

Glossary of Symbols	
Symbol	Used For
	Use by YYYY-MM
	Batch code/Lot Number
	Catalog number
	Consult instructions for use
	In vitro diagnostic medical device
	Store at -20°C to 8°C

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PN: 4000152-01 9/13



LOW VOLUME CONTROL PROCEDURE

- 1** Place the Alere™ Professional Cup Urine Control kit on its side, open flap and slide the white low volume procedure stand out of the box.



Place kit on its side.



Remove controls using the stand's hook.



Place smooth side of the white low volume procedure stand on flat surface.

- 2** Empty contents of the positive or negative control into the cup, and then secure the lid on the cup to prepare for reading the results.



Empty the contents of the control into the cup.

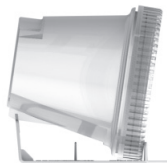


Secure the lid.

- 3** Place the cup onto the white volume procedure stand with bottom toward the bottom arrows. Line up front of cup to the back of the front wall. Wait 5 minutes to read results.



Place cup onto the procedure stand.



Ensure cup is centered and lid touches the front wall of the procedure stand



Read results in 5 minutes.