# *i*Screen™ Urine Drug Controls: Negative, High Positive

INTENDED USE: The *i*Screen Urine Drug 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 *i*Screen 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 *i*Screen Urine Drug Control 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 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:

A. The controls are stable until the expiration date when stored at -20 to -10 C and protected from light.

B. The controls are stable until the expiration date when stored at -20 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)

A. The controls are stable for six months or until the expiration date, whichever comes first, when stored at -20 to -10 C.

B. The controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at -20 to 8 C.

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 *i*Screen 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 *i*Screen 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 manufacturers instructions when using this product; changes in reagents, sample requirement, or methodology may effect test results. Although target values are provided with the *i*Screen 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.*

*i*SCREEN 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.

*i*SCREEN URINE DRUG CONTROLS, THC STABILITY: *i*Screen 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 *i*Screen 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.

iScreen™ Urine Drug Controls

Target Values (ng/mL)

| Drug Assay Class | Drug | Negative Control | High Positive Control |
|---|---|---|---|
| Amphetamine | d-Amphetamine | 0 | 3000 |
| Methamphetamine | d-Methamphetamine | 0 | 3000 |
| MDMA | 3,4 Methylenedioxy-N-methylamphetamine | 0 | 1500 |
| Barbiturates | Secobarbital | 0 | 900 |
| Benzodiazepines | Oxazepam | 0 | 900 |
| Buprenorphine | Buprenorphine | 0 | 30 |
| Cocaine | Benzoylecgonine | 0 | 900 |
| Methadone | (±) Methadone | 0 | 900 |
| Methaqualone | Methaqualone | 0 | 900 |
| PCP | Phencyclidine (PCP) | 0 | 75 |
| Opiates | Morphine (High Opiate) | 0 | 6000 |
| Oxycodone | Oxycodone | 0 | 300 |
| Propoxyphene | d-Propoxyphene | 0 | 900 |
| THC | Delta-9-THC-COOH | 0 | 150 |
| Tricyclic Antidepressants | Nortriptyline | 0 | 3000 |

| CATALOG # | DESCRIPTION | CONFIGURATION |
|---|---|---|
| 19470000 | *i*Screen Negative Urine Drug Control | 1 X 5.0 mL |
| 19470081 | *i*Screen High Positive Urine Drug Control | 1 X 5.0 mL |
| 21947 | *i*Screen Urine Drug Control Kit | 19470000: 1 X 5mL Negative Control<br>19470081: 1 X 5mL High Positive Control |

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

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



Manufactured for

inverness medical

Orlando, FL 32810 USA



PN: 21947PI RevA 2009/02