Drugs of Abuse Controls, 2X Cutoff, 20mL Pos/Neg

REF: DTG-DOACTLS

INTENDED USE: The Clarity Drugs of Abuse Liquid control is intended for use as quality control urine to monitor the precision of laboratory urine toxicology testing procedures for the analytes listed in the package insert.

SUMMARY AND EXPLANATION: The DEA exempt Clarity Drugs of Abuse 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 combination of immunoassay, GC/MS and/or LC/MS for the constituents listed on our target sheets.

STORAGE & STABILITY - Please refer to Limitations 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. 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: Allow controls to come to room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE. Transfer an appropriate aliquot of Clarity Drugs of Abuse control urine as required by the drugs of abuse test device or screening method.

EXPECTED RESULTS: The positive Clarity Drugs of Abuse control must test positive on the drugs of abuse test device or screening method. The negative control must test negative. Clarity Diagnostics will (upon request), supply assay values derived from our contract assay laboratories and customer base on a particular lot of control material.

PRECAUTIONS: For In Vitro Diagnostic Use Only. Please read the entire package insert before using the Clarity Drugs of Abuse control. 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 effect test results. Although target values are provided with the Clarity Drugs of Abuse 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.

CLARITY DRUGS OF ABUSE 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.

CLARITY DRUGS OF ABUSE CONTROLS, THC STABILITY: Clarity Drugs of Abuse 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 Clarity Drugs of Abuse controls) which may contain THC: **1.** It is preferable to 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.

Drug	Cutoff	Drug	Cutoff
Delta-9-THC-COOH (THC)	100	Secobarbital (BAR)	600
Benzoylecgonine (BZD/BZO)	600	Oxazepam (BZD, BZO)	600
Phencyclidine (PCP)	50	Methadone (MTD)	600
Morphine (High Opiate, MOR, OPI)	4000	Methaqualone	600
d-Amphetamine (AMP)	2000	Propoxyphene (PPX)	600
d-Methamphetamine (MAMP)	2000	Nortriptyline (TCA)	2000
Oxycodone (OXY)	200	Methylenedioxymethyl-amphetamine (MDMA)	1000
Buprenorphine (BUP)	20		

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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.

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