INTENDED USE

The Detectabuse 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 Detectabuse control urines 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 good laboratory practices.*

SUMMARY AND EXPLANATION

The DEA exempt Detectabuse 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 EMIT®, ONLINE™ and GC/MS for the constituents listed on our target sheets.

Detectabuse Immunoassay Liquid Controls Urine, 20 mL

CAT. #	DESCRIPTION	CAT. #	DESCRIPTION
1922200-1	Series I, cutoff -25% (Low Opiate)	1944725-2	Series IV, cutoff -25% (Low Opiate)
1922000-0	Series I, Cutoff (Low Opiate)	1944750-4	Series IV, Cutoff (Low Opiate)
1922250-1	Series I, cutoff +25% (Low Opiate)	1944775-6	Series IV, cutoff +25% (Low Opiate)
1922710-1	Series I, 3X cutoff (Low Opiate)	1944790-8	Series IV, 3X cutoff (Low Opiate)
1951125-2	Series I-H, cutoff -25% (High Opiate)	1954425-2	Series IV-H, cutoff- 25% (High Opiate)
1951150-4	Series I-H, Cutoff (High Opiate)	1954450-4	Series IV-H, Cutoff (High Opiate)
1951175-6	Series I-H, cutoff +25% (High Opiate)	1954475-6	Series IV-H, cutoff 25% (High Opiate)
1951190-8	Series I-H, 3Xcutoff (High Opiate)	1954490-8	Series IV-H, 3X cutoff (High Opiate)
1942032-5	Series II, cutoff -25% (Low Opiate)	1945825-2	Series V, cutoff -25% (Low Opiate)
1942270-0	Series II. Cutoff (Low Opiate)	1945850-4	Series V, Cutoff (Low Opiate)
1942000-3	Series II, cutoff +25% (Low Opiate)	1945875-6	Series V, cutoff +25% (Low Opiate)
1942290-1	Series II, 3X cutoff (Low Opiate)	1945890-8	Series V, 3X cutoff (Low Opiate)
1943725-2	Series III, cutoff -25% (Low Opiate)	1955525-2	Series V-H, cutoff -25% (High Opiate)
1943750-4	Series III, Cutoff (Low Opiate)	1955550-4	Series V-H, Cutoff (High Opiate)
1943775-6	Series III, cutoff +25% (Low Opiate)	1955575-6	Series V-H, cutoff +25% (High Opiate)
1943790-8	Series III, 3X cutoff (Low Opiate)	1955590-8	Series V-H, 3X cutoff (High Opiate)
1953325-2	Series III-H, cutoff -25% (High Opiate)	1922301-1	Negative, 20 mL
1953375-6	Series III-H, cutoff +25% (High Opiate)	1922700-0	Negative, 50 mL
1953350-4	Series III-H, Cutoff (High Opiate)		
1953390-8	Series III-H, 3X cutoff (High Opiate)		

CUTOFF TARGET VALUES (ng/mL)

SAMHSA Mandated	SERIES I	SERIES II	SERIES III	SERIES IV	SERIES V
Delta-9-THC-COOH	100	100	50	50	50
Benzoylecgonine	300	300	300	300	300
Phencyclidine (PCP)	25	25	25	25	25
Total Morphine (Low Opiate Control)	300	300	300	300	300
Total Morphine (High Opiate Control)	2000	N/A	2000	2000	2000
d-Amphetamine	----------	----------	----------	1000	----------
d-Methamphetamine	1000	1000	1000	----------	1000
Non-Mandated					
Secobarbital	300	200	300	200	200
Oxazepam	300	200	300	----------	200
Nordiazepam	----------	----------	----------	200	----------
Methadone	300	300	300	300	300
Methaqualone	300	300	300	300	300
Propoxyphene	300	300	300	300	300
Negative Control	Negative for the constituents listed on our target sheets				

PRECAUTIONS

For in vitro diagnostic use only

Please read the entire package insert before using the Detectabuse 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.

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.

STORAGE & STABILITY - Please refer to Technical Note 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. 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

A. Allow controls to come to room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE.

B. Pipette an appropriate aliquot of Detectabuse control urine as required by the drugs of abuse test device or screening method.

TECHNICAL NOTE

DETECTABUSE CONTROLS, THC STABILITY

Detectabuse 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 Detectabuse 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.

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

DETECTABUSE 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.

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 Detectabuse 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.

EXPECTED RESULTS

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

June 2005

Biochemical Diagnostics, Inc.
180 Heartland Blvd., Edgewood, NY 11717 • Phone (631) 595-9200 Fax (631) 595-9204

DETECTABUSE™

LIQUID

CONTROL

URINE

IMMUNOASSAY SCREEN

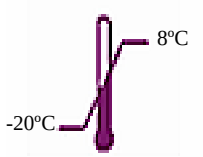
Series I , II, III, IV, V

Series I-H, III-H, IV-H, V-H

Controls prepared from human based urine available as a negative and at various constituent target levels to monitor the performance of qualitative or quantitative procedures for the detection of drugs in urine.

Target levels available:
Negative, Cutoff, Cutoff -25%, Cutoff +25%, 3X Cutoff.

Please read the entire package insert before using the Detectabuse control urines.



Temperature Limit


Consult Instructions for Use

For In Vitro Diagnostic Use