

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 a combination of immunoassay, GC/MS and/or LC/MS for the constituents listed on our target sheets.

Detectabuse Immunoassay Liquid Controls Urine, 20 mL

CAT. #	DESCRIPTION	CAT. #	DESCRIPTION
19222001	Series I, cutoff -25% (Low Opiate)	19458252	Series V, cutoff -25% (Low Opiate)
19222501	Series I, cutoff +25% (Low Opiate)	19458756	Series V, cutoff +25% (Low Opiate)
19227101	Series I, 3X cutoff (Low Opiate)	19458908	Series V, 3X cutoff (Low Opiate)
19511252	Series I-H, cutoff -25%(High Opiate)	19555252	Series V-H, cutoff -25% (High Opiate)
19511756	Series I-H, cutoff +25% (High Opiate)	19555756	Series V-H, cutoff +25% (High Opiate)
18511908	Series I-H, 3Xcutoff (High Opiate)	19555908	Series V-H, 3X cutoff (High Opiate)
19420325	Series II, cutoff -25% (Low Opiate)	19466252	Series VI, cutoff -25% (Low Opiate)
19420003	Series II, cutoff +25% (Low Opiate)	19466756	Series VI, cutoff +25% (Low Opiate)
19422901	Series II, 3X cutoff (Low Opiate)	19466908	Series VI, 3X cutoff (Low Opiate)
19437252	Series III, cutoff -25% (Low Opiate)	19566743	Series VI-H, cutoff -25% (High Opiate)
19437756	Series III, cutoff +25% (Low Opiate)	19566858	Series VI-H, cutoff +25% (High Opiatte)
19437908	Series III, 3X cutoff (Low Opiate)	19566975	Series VI-H, 3X cutoff (High Opiate)
19533252	Series III-H,cutoff -25% (High Opiate)	19499252	Series IX, cutoff -25% (Low Opiate)
19533756	Series III-H, cutoff +25% (High Opiate)	19499756	Series IX, cutoff +25% (Low Opiate)
19533908	Series III-H, 3X cutoff (High Opiate)	19499908	Series IX, 3X cutoff (Low Opiate)
19447252	Series IV, cutoff -25% (Low Opiate)	19599743	Series IX-H, cutoff -25% (High Opiate)
19447756	Series IV, cutoff +25% (Low Opiate)	19599858	Series IX-H, cutoff +25% (High Opiate)
19447908	Series IV, 3X cutoff (Low Opiate)	19599975	Series IX-H, 3X cutoff (High Opiate)
19544252	Series IV-H, cutoff- 25% (High Opiate)	19601052	Series X-H, cutoff -25% (High Opiate)
19544756	Series IV-H, cutoff +25% (High Opiate)	19601056	Series X-H, cutoff +25% (High Opiate)
19544908	Series IV-H, 3X cutoff (High Opiate)	* 19601908	Series X-H, 3X cutoff (High Opiate)

19700000	Negative, 5 mL	* Special Order Only
19223011	Negative, 20 mL	
19227000	Negative, 50 mL	

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.

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.

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 stated in the package insert, 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.



Biochemical
Diagnostics, Inc.

SERIES I and I-H TARGET SHEET (ng/mL)				
SAMHSA Mandated	-25%	cutoff	+25%	3X cutoff
DELTA-9-THC-COOH	75	100	125	300
BENZOYLECGONINE	225	300	375	900
PCP	19	25	31	75
MORPHINE (Low Opiate Control)	225	300	375	900
MORPHINE (High Opiate Control)	1500	2000	2500	6000
d-METHAMPHETAMINE	750	1000	1250	3000
Non-Mandated				
SECOBARBITAL	225	300	375	900
OXAZEPAM	225	300	375	900
METHADONE	225	300	375	900
METHAQUALONE	225	300	375	900
PROPOXYPHENE	225	300	375	900

SERIES V and V-H TARGET SHEET (ng/mL)				
SAMHSA Mandated	-25%	cutoff	+25%	3x cutoff
DELTA-9-THC-COOH	37.5	50	62.5	150
BENZOYLECGONINE	225	300	375	900
PCP	19	25	31	75
MORPHINE (Low Opiate Control)	225	300	375	900
MORPHINE (High Opiate Control)	1500	2000	2500	6000
d-METHAMPHETAMINE	750	1000	1250	3000
Non-Mandated				
SECOBARBITAL	150	200	250	600
OXAZEPAM	150	200	250	600
METHADONE	225	300	375	900
METHAQUALONE	225	300	375	900
PROPOXYPHENE	225	300	375	900

SERIES II TARGET SHEET (ng/mL)				
SAMHSA Mandated	-25%	cutoff	+25%	3x cutoff
DELTA-9-THC-COOH	75	100	125	300
BENZOYLECGONINE	225	300	375	900
PCP	19	25	31	75
MORPHINE (Low Opiate Control)	225	300	375	900
d-METHAMPHETAMINE	750	1000	1250	3000
Non-Mandated				
SECOBARBITAL	150	200	250	600
OXAZEPAM	150	200	250	600
METHADONE	225	300	375	900
METHAQUALONE	225	300	375	900
PROPOXYPHENE	225	300	375	900

SERIES VI and VI-H TARGET SHEET (ng/mL)				
SAMHSA Mandated	-25%	cutoff	+25%	3X cutoff
DELTA-9-THC-COOH	37.5	50	62.5	150
BENZOYLECGONINE	225	300	375	900
PCP	19	25	31	75
MORPHINE (Low Opiate Control)	225	300	375	900
MORPHINE (High Opiate Control)	1500	2000	2500	6000
d-METHAMPHETAMINE	750	1000	1250	3000
Non-Mandated				
SECOBARBITAL	150	200	250	600
LORMETAZEPAM	150	200	250	600
METHADONE	225	300	375	900
METHAQUALONE	225	300	375	900
PROPOXYPHENE	225	300	375	900

SERIES III and III-H TARGET SHEET (ng/mL)				
SAMHSA Mandated	-25%	cutoff	+25%	3X cutoff
ELTA-9-THC-COOH	37.5	50	62.5	150
BENZOYLECGONINE	225	300	375	900
PCP	19	25	31	75
MORPHINE (Low Opiate Control)	225	300	375	900
MORPHINE (High Opiate Control)	1500	2000	2500	6000
d-METHAMPHETAMINE	750	1000	1250	3000
Non-Mandated				
SECOBARBITAL	225	300	375	900
OXAZEPAM	225	300	375	900
METHADONE	225	300	375	900
METHAQUALONE	225	300	375	900
PROPOXYPHENE	225	300	375	900

SERIES IX and IX-H TARGET SHEET (ng/mL)				
SAMHSA Mandated	-25%	cutoff	+25%	3x cutoff
DELTA-9-THC-COOH	37.5	50	62.5	150
BENZOYLECGONINE	225	300	375	900
PCP	19	25	31	75
MORPHINE (Low Opiate Control)	225	300	375	900
MORPHINE (High Opiate Control)	1500	2000	2500	6000
d-METHAMPHETAMINE	750	1000	1250	3000
Non-Mandated				
SECOBARBITAL	225	300	375	900
LORMETAZEPAM	225	300	375	900
METHADONE	225	300	375	900
METHAQUALONE	225	300	375	900
PROPOXYPHENE	225	300	375	900

SERIES IV AND IV-H TARGET SHEET (ng/mL)				
SAMHSA Mandated	-25%	cutoff	+25%	3X cutoff
DELTA-9-THC-COOH	37.5	50	62.5	150
BENZOYLECGONINE	225	300	375	900
PCP	19	25	31	75
MORPHINE (Low Opiate Control)	225	300	375	900
MORPHINE (High Opiate Control)	1500	2000	2500	6000
d-AMPHETAMINE	750	1000	1250	3000
Non-Mandated				
SECOBARBITAL	150	200	250	600
NORDIAZEPAM	150	200	250	600
METHADONE	225	300	375	900
METHAQUALONE	225	300	375	900
PROPOXYPHENE	225	300	375	900

SERIES X-H TARGET SHEET (ng/mL)				
SAMHSA Mandated	- 25 %	cutoff	+25%	3x cutoff
DELTA-9-THC-COOH	37.5	50	62.5	150
BENZOYLECGONINE	112.5	150	187.5	450
PHENCYCLIDINE (PCP)	18.75	25	31.5	75
MORPHINE	1500	2000	2500	6000
d-METHAMPHETAMINE	375	500	625	1500
MDMA	375	500	625	1500
6-ACETYLMORPHINE	7.50	10	12.5	30
SAMHSA-Non-Mandated				
SECOBARBITAL	150	200	250	600
OXAZEPAM	150	200	250	600
METHADONE	225	300	375	900
METHAQUALONE	225	300	375	900
d-PROPOXYPHENE	225	300	375	900

DETECTABUSE™
LIQUID CONTROL
URINE

IMMUNOASSAY SCREEN

Series I, II, III, IV, V, VI, IX

Series I-H, III-H, IV-H, V-H, IV-H, IX-H,
X-H (New SAMHSA guidelines)

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:
Cutoff -25%, Cutoff +25%
3X Cutoff
Negative
(for the constituents listed on our target sheets)

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

Temperature Limit Consult Instructions for Use For In Vitro Diagnostic Use



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