



Biochemical Diagnostics, Inc.

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DETECTABUSE® STAT-SKREEN® LIQUID CONTROL URINE

INTENDED USE: The Detectabuse® 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 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 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. 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 thawed/frozen up to 5 times)

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 Detectabuse control urine as required by the drugs of abuse test device or screening method

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

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.

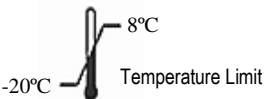
Do not use beyond the expiration date.

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.*

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.

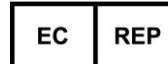
DETECTABUSE CONTROLS, THC STABILITY: Detectabuse controls are stable for the length of time under the storage conditions stated in the package insert. In spite of this fact, under certain conditions, there may be observed a gradual decline in THC levels, over time, from continuous use of a single bottle 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. 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.



Refer to
Package Insert



For In Vitro
Diagnostic Use



EMERGO EUROPE
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The Netherlands



DETECTABUSE® Liquid Control Urine,

Stat-Skreen® (Low Opiate) or Stat-Skreen-H® (High Opiate) Target Values (ng/mL)

SAMHSA MANDATED	Negative	-50%	-25%	Cutoff	+25%	+50%	2X	3X
Delta-9-THC-COOH	0	25	37.5	50	62.5	75	100	150
Benzoylcegonine	0	150	225	300	375	450	600	900
Phencyclidine (PCP)	0	12.5	19	25	31	37.5	50	75
Morphine (Low Opiate)	0	150	225	300	375	450	600	900
Morphine (High Opiate)	0	1000	1500	2000	2500	3000	4000	6000
d-Amphetamine	0	500	750	1000	1250	1500	2000	3000
d-Methamphetamine	0	500	750	1000	1250	1500	2000	3000
NON-MANDATED								
Secobarbital	0	150	225	300	375	450	600	900
Oxazepam	0	150	225	300	375	450	600	900
Methadone	0	150	225	300	375	450	600	900
Methaqualone	0	150	225	300	375	450	600	900
Propoxyphene	0	150	225	300	375	450	600	900
Nortriptyline	0	500	750	1000	1250	1500	2000	3000
MDMA**	0	-	-	500	-	-	1000	-
Oxycodone (OXY)	0	-	-	100	-	-	200	-
Buprenorphine (BUP)	0	-	-	10	-	-	20	-

** 3,4 Methylenedioxyethyl-amphetamine

CATALOG # / DESCRIPTION	
5mL	
19700000	Negative (Negative Control is Negative for the constituents listed on our target sheets)
19001066	Stat-Skreen with MDMA, OXY & BUP, 2X Cutoff (Low Opiate Controls)
19001081	Stat-Skreen-H with MDMA, OXY & BUP, 2X Cutoff (High Opiate Controls)
19470010	MDMA, OXY & BUP, Cutoff -50% (MDMA 250 ng/mL, OXY 50 ng/mL, BUP 5 ng/mL)
19470011	MDMA, OXY & BUP, Cutoff +50% (MDMA 750 ng/mL, OXY 150 ng/mL, BUP 15 ng/mL)
19000102	Cotinine Liquid Control Urine*, 400 ng/mL 5 mL
*Cotinine is a metabolite of Nicotine, used to monitor the performance of Nicotine detection devices	
19000959	JWH-018 5-Pentanoic Acid**, 100 ng/mL 5 mL
19000960	JWH-073 4-Butanoic Acid**, 100 ng/mL 5 mL
** Metabolites of Synthetic THC, used to monitor the performance of K2/Spice detection devices.	
20 mL (High Opiate Controls)	20 mL (Low Opiate Controls)
19470071	Stat-Skreen-H, Cutoff -50%
19470073	Stat-Skreen-H, Cutoff -25%
19470072	Stat-Skreen-H, Cutoff +25%
19470070	Stat-Skreen-H, Cutoff +50%
19470075	Stat-Skreen-H, 3X Cutoff
19002081	Stat-Skreen-H with MDMA, OXY & BUP, 2X Cutoff
19470052	Stat-Skreen, Cutoff -50%
19470054	Stat-Skreen, Cutoff -25%
19470053	Stat-Skreen, Cutoff +25%
19470051	Stat-Skreen, Cutoff +50%
19470055	Stat-Skreen, 3X Cutoff
19002066	Stat-Skreen with MDMA, OXY & BUP, 2X Cutoff
19223011	Negative, 20mL (Negative Control is Negative for the constituents listed on our target sheets)
18000000-18900000	Detectabuse® Custom Control Urine*** Bottle Sizes Vary
***Refer to Custom Target Sheets for specific constituents.	

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

