Biochemical Diagnostics, Inc.
A Kova International Company

DETECTABUSE® LIQUID CONTROL URINE

GC/MS (Low Opiate)
GC/MS-H (High Opiate)
CONFIRM 4 (2015 SAMHSA guidelines)

The Detectabuse® Liquid Control Urines are 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.

INTENDED USE
The Detectabuse® Liquid control is an In Vitro Diagnostic (IVD) device, for prescription use only, that 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 ensure 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 manufacturers 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. 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.*

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 Oxazepam and/or 6-MAM is stable for only 6 months.

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 confirmation method.

Expected Results
The positive Detectabuse control must test positive. 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 GC/MS confirmation 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 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, our studies indicates that Oxazepam will deteriorate when stored refrigerated for longer than 6 months.

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. 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.

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® Liquid Control Urine

GC/MS Target Values (ng/mL)

CONSTITUENTS	Cutoff -25%	Cutoff	Cutoff +25%
SAMHSA MANDATED			
Delta-9-THC-COOH	11	15	19
Benzoylecgonine	113	150	188
Phencyclidine (PCP)	19	25	31
Codeine (Low Opiate)	225	300	375
Codeine (High Opiate)	1500	2000	2500
*Total Morphine (Low Opiate)	225	300	375
*Total Morphine (High Opiate)	1500	2000	2500
****6-Monoacetylmorphine**	7.5	10	12.5
d-Amphetamine	375	500	625
d-Methamphetamine	375	500	625
NON-MANDATED			
Secobarbital	225	300	375
Phenobarbital	225	300	375
Oxazepam	225	300	375
Methadone	225	300	375
Methaqualone	225	300	375
Propoxyphene	225	300	375
Butalbital	225	300	375

* Contains Morphine-3-Glucuronide and Free Morphine (2:1)
****** **6-MAM Only in High Opiate (-H) Control**

Confirm 4 Target Values (ng/mL)

CONSTITUENTS	Cutoff -60%	Cutoff-25%	Cutoff	Cutoff +25%
SAMHSA MANDATED				
Delta-9-THC-COOH	6	11	15	18.75
Benzoylecgonine	40	75	100	125
Codeine	800	1500	2000	2500
*Total Morphine	800	1500	2000	2500
6-Monoacetylmorphine	4	7.5	10	12.5
Hydrocodone	40	75	100	125
Hydromorphone	40	75	100	125
Oxycodone	40	75	100	125
Oxymorphone	40	75	100	125
Phencyclidine (PCP)	10	19	25	31.25
d-Methamphetamine	100	187.5	250	312.5
d-Amphetamine	100	187.5	250	312.5
MDMA	100	187.5	250	312.5
MDA	100	187.5	250	312.5
MDEA	100	187.5	250	312.5

* Contains Morphine-3-Glucuronide and Free Morphine (2:1)

ORDERING INFORMATION:

CATALOG #	DESCRIPTION	SIZE
GC/MS LOW OPIATE		
19332001	GC/MS Cutoff -25%	50 mL
19330000	GC/MS Cutoff	50 mL
19332501	GC/MS Cutoff +25%	50 mL
GC/MS HIGH OPIATE		
19572251	GC/MS-H Cutoff -25%	50 mL
19572502	GC/MS-H Cutoff	50 mL
19572753	GC/MS-H Cutoff+25%	50 mL

CATALOG #	DESCRIPTION	SIZE
Confirm 4 HIGH OPIATE		
19582041	Confirm 4, Cutoff -60%	50 mL
19582026	Confirm 4, Cutoff -25%	50 mL
19582002	Confirm 4, Cutoff	50 mL
19582126	Confirm 4, Cutoff +25%	50mL
NEGATIVE		
19227000	Negative Control Urine	50 mL

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For additional information on our other Detectabuse products please contact us or refer to our website.

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SYMBOL LEGEND	
	Consult Instructions for Use
	Temperature Limits
IVD	*In Vitro* Diagnostic Medical Device
LOT	Batch Code
REF	Product Catalog Number
	Manufacturers Identification
	Use by Date
	Caution, Consult Accompanying Documents
Rx only	For Prescription Use Only