

DETECTABUSE[®] LIQUID CONTROL URINE, STAT-SKREEN[®] PACKAGE INSERT

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 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 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 Limitations for detailed instructions.

Unopened:

- The controls are stable until the expiration date when stored at 2° to 8°C (Oxazepam is stable for only 6 months).
- Store -10° to -20°C to extend the Oxazepam stability, up to 3 years or until expiration date, whichever comes first.

After Opening:

- The controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at 2° to 8°C.
- The controls are stable for 6 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.

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 supply assay values upon request.

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 manufacturer's instructions when using this product; changes in reagents, sample requirement, or methodology may affect 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 indicate that Oxazepam will deteriorate when stored refrigerated for longer than 6 months from date of receipt.

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}.

REFERENCES

- Blanc JA, Manneh VA, et al. Adsorption losses from urine-based cannabinoid calibrators during routine use. Clin Chem 1993; 39:1705-1712
- 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, STAT-SKREEN® (Low Opiate) & STAT-SKREEN®-H (High Opiate)

Target Values (ng/mL)

TEST	SAMHSA MANDATED	Negative	-50%	-25%	Cutoff	+25%	+50%	2X	3X
THC	Delta-9-THC-COOH	0	25	37.5	50	62.5	75	100	150
COC	Benzoylcegonine	0	150	225	300	375	450	600	900
PCP	Phencyclidine	0	12.5	19	25	31	37.5	50	75
OPI/MOR	Morphine (Low Opiate)	0	150	225	300	375	450	600	900
	Morphine (High Opiate)	0	1000	1500	2000	2500	3000	4000	6000
AMP	d-Amphetamine	0	500	750	1000	1250	1500	2000	3000
MET	d-Methamphetamine	0	500	750	1000	1250	1500	2000	3000
NON-MANDATED									
BARB	Secobarbital	0	150	225	300	375	450	600	900
BZO	Oxazepam	0	150	225	300	375	450	600	900
MTD	Methadone	0	150	225	300	375	450	600	900
MQL	Methaqualone	0	150	225	300	375	450	600	900
PPX	Propoxyphene	0	150	225	300	375	450	600	900
TCA	Nortriptyline	0	500	750	1000	1250	1500	2000	3000
MDMA	3,4 Methylene-dioxy-methyl-amphetamine (MDMA)	0	-	-	500	-	-	1000	-
OXY	Oxycodone	0	-	-	100	-	-	200	-
BUP	Buprenorphine	0	-	-	10	-	-	20	-

ORDERING INFORMATION

CATALOG #	DESCRIPTION	SIZE
LOW OPIATE:		
19470052	STAT-SKREEN®, Cutoff -50%	20 mL
19470054	STAT-SKREEN®, Cutoff -25%	20 mL
19470053	STAT-SKREEN®, Cutoff +25%	20 mL
19470051	STAT-SKREEN®, Cutoff +50%	20 mL
19470055	STAT-SKREEN®, 3X Cutoff	20 mL
19002066	STAT-SKREEN® with MDMA, OXY & BUP, 2X Cutoff	20 mL
19001066	STAT-SKREEN® with MDMA, OXY & BUP, 2X Cutoff	5 mL
HIGH OPIATE:		
19470071	STAT-SKREEN®-H, Cutoff -50%	20 mL
19470073	STAT-SKREEN®-H, Cutoff -25%	20 mL
19470072	STAT-SKREEN®-H, Cutoff +25%	20 mL
19470070	STAT-SKREEN®-H, Cutoff +50%	20 mL
19470075	STAT-SKREEN®-H, 3X Cutoff	20 mL
19002081	STAT-SKREEN®-H with MDMA, OXY & BUP, 2X Cutoff	20 mL
19001081	STAT-SKREEN®-H with MDMA, OXY & BUP, 2X Cutoff	5 mL

CATALOG #	DESCRIPTION	SIZE
19900025	Ethyl Glucuronide, 250 ng/mL	20 mL
19900050	Ethyl Glucuronide, 500 ng/mL	20 mL
19900100	Ethyl Glucuronide, 1000 ng/mL	20 mL
19000102	l-Cotinine, 400 ng/mL	5 mL
19470010	MDMA, OXY & BUP, Cutoff -50% <small>(MDMA 250ng/mL, OXY 50ng/mL, BUP 5ng/mL)</small>	5 mL
19470011	MDMA, OXY & BUP, Cutoff +50% <small>(MDMA 750ng/mL, OXY 150ng/mL, BUP 15ng/mL)</small>	5 mL
19000959	JWH-018 5-Pentanoic Acid**, 100ng/mL	5 mL
19000960	JWH-073 4-Butanoic Acid**, 100ng/mL	5 mL
<small>** Metabolites of Synthetic THC, used to monitor the performance of K2/Spice detection devices.</small>		
NEGATIVE:		
19700000	Negative Control Urine	5 mL
19223011	Negative Control Urine	20 mL
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
	In Vitro Diagnostic Medical Device
	Batch Code
	Product Catalog Number
	Unique Device Identification
	Country of Manufacture
	Manufacturers Identification
	Use by Date
	Caution, Consult Accompanying Documents
	For Prescription Use Only