

DETECTABUSE[®] AU/NZ SKREEN LIQUID CONTROL URINE: Australian-New Zealand Target Levels

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 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 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:

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

After Opening:

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

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

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, AU/NZ SKREEN

Target Values (ng/mL)

TEST	TARGET VALUES	-50%	-30%	-25%	Cutoff	+25%	+50%	3X
THC	Delta-9-THC-COOH	25	35	37.5	50	62.5	75	150
COC	Benzoylcgonine	150	210	225	300	375	450	900
OPI/MOR	Morphine	150	210	225	300	375	450	900
MET	d-Methamphetamine	150	210	225	300	375	450	900
AMP	d-Amphetamine	150	210	225	300	375	450	900
BARB	Secobarbital	150	210	225	300	375	450	900
BZO	Oxazepam	100	140	150	200	250	300	600
MTD	Methadone	150	210	225	300	375	450	900
PPX	Propoxyphene	150	210	225	300	375	450	900
TCA	Nortriptyline	500	700	750	1000	1250	1500	3000

ORDERING INFORMATION:

CATALOG #	DESCRIPTION	SIZE
19480100	DETECTABUSE® LIQ CTRL URINE, AU/NZ SKREEN, Cutoff -50%	5 mL
19480200	DETECTABUSE® LIQ CTRL URINE, AU/NZ SKREEN, Cutoff +50%	5 mL
19481100	DETECTABUSE® LIQ CTRL URINE, AU/NZ SKREEN, Cutoff -50%	20 mL
19482200	DETECTABUSE® LIQ CTRL URINE, AU/NZ SKREEN, Cutoff +50%	20 mL
18001419	DETECTABUSE® LIQ CTRL URINE, AU/NZ SKREEN, Cutoff -30%*	20 mL
18001420	DETECTABUSE® LIQ CTRL URINE, AU/NZ SKREEN, Cutoff -25%*	20 mL
18001421	DETECTABUSE® LIQ CTRL URINE, AU/NZ SKREEN, Cutoff +25%*	20 mL
18001422	DETECTABUSE® LIQ CTRL URINE, AU/NZ SKREEN, 3X Cutoff *	20 mL

* Call for availability of -30%, -25%, +25% and 3X Cutoff levels of AU/NZ SKREEN controls



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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