



**Biochemical
Diagnostics, Inc.**

A Kova International Company

DETECTABUSE® LIQUID CONTROL URINE
PI-006K: IMMUNOASSAY SCREEN KITBOXES
SERIES III, IV, IV-H, V, VI, X-H, XV-H

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.

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}.

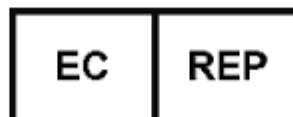
REFERENCES

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



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**Detectabuse® Liquid Control Urine, Immunoassay Screen
Target Values (ng/mL)**

Constituents	Series X-H				Series XV-H				Series III		
	-25%	Cutoff	+25%	3X Cutoff	-25%	Cutoff	+25%	3X Cutoff	-25%	Cutoff	+25%
Delta-9-THC-COOH	37.5	50	62.5	150	37.5	50	62.5	150	37.5	50	62.5
Benzoylcegonine	112.5	150	187.5	450	112.5	150	187.5	450	225	300	375
Phencyclidine (PCP)	19	25	31.5	75	19	25	31.5	75	19	25	31
Morphine	1500	2000	2500	6000	1500	2000	2500	6000	225	300	375
d-Methamphetamine	375	500	625	1500	375	500	625	1500	750	1000	1250
MDMA	375	500	625	1500	375	500	625	1500	---	---	---
6-Acetylmorphine	7.5	10	12.5	30	7.5	10	12.5	30	---	---	---
Hydrocodone	---	---	---	---	225	300	375	900	---	---	---
Oxycodone	---	---	---	---	75	100	125	300	---	---	---
Secobarbital	150	200	250	600	150	200	250	600	225	300	375
Oxazepam	150	200	250	600	150	200	250	600	225	300	375
Methadone	225	300	375	900	225	300	375	900	225	300	375
Methaqualone	225	300	375	900	225	300	375	900	225	300	375
Propoxyphene	225	300	375	900	225	300	375	900	225	300	375

Constituents	Series IV			Series V			Series VI			
	-25%	Cutoff	+25%	-25%	Cutoff	+25%	-25%	Cutoff	+25%	3X Cutoff
Delta-9-THC-COOH	37.5	50	62.5	37.5	50	62.5	37.5	50	62.5	150
Benzoylcegonine	225	300	375	225	300	375	225	300	375	900
Phencyclidine (PCP)	19	25	31	19	25	31	19	25	31	75
Morphine (low)	225	300	375	225	300	375	225	300	375	900
Morphine (high)	1500	2000	2500	---	---	---	---	---	---	---
d-Methamphetamine	---	---	---	750	1000	1250	750	1000	1250	3000
d-Amphetamine	750	1000	1250	---	---	---	---	---	---	---
Secobarbital	150	200	250	150	200	250	150	200	250	600
Oxazepam	---	---	---	150	200	250	---	---	---	---
Nordiazepam	150	200	250	---	---	---	---	---	---	---
Lormetazepam	---	---	---	---	---	---	150	200	250	600
Methadone	225	300	375	225	300	375	225	300	375	900
Methaqualone	225	300	375	225	300	375	225	300	375	900
Propoxyphene	225	300	375	225	300	375	225	300	375	900

CATALOG #	DESCRIPTION (20mL)	CATALOG #	DESCRIPTION (20mL)	CATALOG	DESCRIPTION
LOW OPIATE (300ng/mL cutoff)		HIGH OPIATE (2000ng/mL cutoff)		19700000-6pk 19000010-6pk	NEGATIVE, 5mL NEGATIVE, 10mL
19437252-6pk 19437756-6pk	Series III, Cutoff -25% Series III, Cutoff +25%	19544252-6pk 19544756-6pk	Series IV-H, Cutoff -25% Series IV-H, Cutoff +25%		
19447252-6pk 19447756-6pk	Series IV, Cutoff -25% Series IV, Cutoff +25%	19601052-6pk 19601056-6pk 19601908-6pk	Series X-H, Cutoff -25% Series X-H, Cutoff +25% Series X-H, 3X Cutoff	19223011-6pk 19227000-10pk	NEGATIVE, 20mL NEGATIVE, 50mL
19458252-6pk 19458756-6pk	Series V, Cutoff -25% Series V, Cutoff +25%	19601057-6pk 19601058-6pk 19601059-6pk	Series XV-H, Cutoff -25% Series XV-H, Cutoff +25% Series XV-H, 3X Cutoff		
19466252-6pk 19466756-6pk 19466908-6pk	Series VI, Cutoff -25% Series VI, Cutoff +25% Series VI, 3X Cutoff				6pk = 6 pack box 10pk = 10 pack box

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