



The Detectabuse Liquid Controls 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.

Please read the entire package insert before using the Detectabuse® control urines.

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 ISO 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 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 to 8°C, however Oxazepam 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 to 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 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 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 stated in the package insert, 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.

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

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

Detectabuse Immunoassay Liquid Control Urine, 20 mL

SERIES I & I-H Target Sheet
(ng/mL)

SERIES II Target Sheet
(ng/mL)

SERIES III & III-H Target Sheet
(ng/mL)

	-25%	Cutoff	+25%	3X Cutoff	-25%	Cutoff	+25%	3X Cutoff	-25%	Cutoff	+25%	3X Cutoff
SAMHSA MANDATED												
Delta-9-thc-cooh	75	100	125	300	75	100	125	300	37.5	50	62.5	150
Benzoylcgonine	225	300	375	900	225	300	375	900	225	300	375	900
Phencyclidine (PCP)	19	25	31	75	19	25	31	75	19	25	31	75
Morphine (low)	225	300	375	900	225	300	375	900	225	300	375	900
Morphine (high)	1500	2000	2500	6000	---	---	---	---	1500	2000	2500	6000
d-Methamphetamine	750	1000	1250	3000	750	1000	1250	3000	750	1000	1250	3000
NON-MANDATED												
Secobarbital	225	300	375	900	150	200	250	600	225	300	375	900
Oxazepam	225	300	375	900	150	200	250	600	225	300	375	900
Methadone	225	300	375	900	225	300	375	900	225	300	375	900
Methaqualone	225	300	375	900	225	300	375	900	225	300	375	900
Propoxyphene	225	300	375	900	225	300	375	900	225	300	375	900

SERIES IV & IV-H Target Sheet
(ng/mL)

SERIES V & V-H Target Sheet
(ng/mL)

SERIES VI & VI-H Target Sheet
(ng/mL)

	-25%	Cutoff	+25%	3X Cutoff	-25%	Cutoff	+25%	3X Cutoff	-25%	Cutoff	+25%	3X Cutoff
SAMHSA MANDATED												
Delta-9-thc-cooh	37.5	50	62.5	150	37.5	50	62.5	150	37.5	50	62.5	150
Benzoylcgonine	225	300	375	900	225	300	375	900	225	300	375	900
Phencyclidine (PCP)	19	25	31	75	19	25	31	75	19	25	31	75
Morphine (low)	225	300	375	900	225	300	375	900	225	300	375	900
Morphine (high)	1500	2000	2500	6000	1500	2000	2500	6000	1500	2000	2500	6000
d-Methamphetamine	---	---	---	---	750	1000	1250	3000	750	1000	1250	3000
d-Amphetamine	750	1000	1250	3000	---	---	---	---	---	---	---	---
NON-MANDATED												
Secobarbital	150	200	250	600	150	200	250	600	150	200	250	600
Oxazepam	---	---	---	---	150	200	250	600	---	---	---	---
Nordiazepam	150	200	250	600	---	---	---	---	---	---	---	---
Lormetazepam	---	---	---	---	---	---	---	---	150	200	250	600
Methadone	225	300	375	900	225	300	375	900	225	300	375	900
Methaqualone	225	300	375	900	225	300	375	900	225	300	375	900
Propoxyphene	225	300	375	900	225	300	375	900	225	300	375	900

SERIES IX Target Sheet
(ng/mL)

SERIES X-H Target Sheet
(ng/mL)

	-25%	Cutoff	+25%	3X Cutoff	-25%	Cutoff	+25%	3X Cutoff
SAMHSA MANDATED								
DELTA-9-THC-COOH	37.5	50	62.5	150	37.5	50	62.5	150
BENZOYLECGONINE	225	300	375	900	112.5	150	187.5	450
PHENCYCLIDINE (PCP)	19	25	31	75	19	25	31	75
MORPHINE (LOW)	225	300	375	900	---	---	---	---
MORPHINE (HIGH)	---	---	---	---	1500	2000	2500	6000
D-METHAMPHETAMINE	750	1000	1250	3000	375	500	625	1500
MDMA	---	---	---	---	375	500	625	1500
6-ACETYLMORPHINE	---	---	---	---	7.5	10	12.5	30
NON-MANDATED								
SECOBARBITAL	225	300	375	900	150	200	250	600
OXAZEPAM	---	---	---	---	150	200	250	600
NORDIAZEPAM	---	---	---	---	---	---	---	---
LORMETAZEPAM	225	300	375	900	---	---	---	---
METHADONE	225	300	375	900	225	300	375	900
METHAQUALONE	225	300	375	900	225	300	375	900
PROPOXYPHENE	225	300	375	900	225	300	375	900

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



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ORDERING INFORMATION: Detectabuse Immunoassay Liquid Control Urine, 20 mL

CATALOG #	DESCRIPTION	CATALOG #	DESCRIPTION	CATALOG #	DESCRIPTION
LOW OPIATE					
19222001	Series I, cutoff -25%	LOW OPIATE cont'd		HIGH OPIATE cont'd	
19222501	Series I, cutoff +25%	19466908	*Series VI, 3X cutoff	19566743	*Series VI-H, cutoff -25%
19227101	*Series I, 3X cutoff	19499252	Series IX, cutoff -25%	19566858	*Series VI-H, cutoff +25%
19420325	Series II, cutoff -25%	19499756	Series IX, cutoff +25%	19566975	*Series VI-H, 3X cutoff
19420003	Series II, cutoff +25%	19499908	*Series IX, 3X cutoff	19601052	Series X-H, cutoff -25%
19422901	*Series II, 3X cutoff	HIGH OPIATE		19601056	Series X-H, cutoff +25%
19437252	Series III, cutoff -25%	19511252	Series I-H, cutoff -25%	19601908	*Series X-H, 3X cutoff
19437756	Series III, cutoff +25%	19511756	Series I-H, cutoff +25%		
19437908	*Series III, 3X cutoff	19511908	*Series I-H, 3Xcutoff	NEGATIVE	
19447252	Series IV, cutoff -25%	19533252	Series III-H, cutoff -25%	19700000	Negative Control Urine, 5 mL
19447756	Series IV, cutoff +25%	19533756	Series III-H, cutoff +25%	19223011	Negative Control Urine, 20 mL
19447908	*Series IV, 3X cutoff	19533908	*Series III-H, 3X cutoff	19227000	Negative Control Urine, 50 mL
19458252	Series V, cutoff -25%	19544252	Series IV-H, cutoff -25%		
19458756	Series V, cutoff +25%	19544756	Series IV-H, cutoff +25%		
19458908	*Series V, 3X cutoff	19544908	*Series IV-H, 3X cutoff		
19466252	Series VI, cutoff -25%	19555252	Series V-H, cutoff -25%		
19466756	Series VI, cutoff +25%	19555756	Series V-H, cutoff +25%		
		19555908	*Series V-H, 3X cutoff		

* Non-stock item, call for availability