



DETECTABUSE® DOA-SKREEN & STAT-SKREEN®17
LIQUID CONTROL 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 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

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® Liquid Control Urine

**Stat-Skreen®17, DOA-SKREEN (Low Opiate) or Stat-Skreen®17H, DOA-SKREEN-H (High Opiate)
Target Values (ng/mL)**

Catalog #	1900010		19003020	19003030	19003066	19003081
	NEGATIVE		DOA-SKREEN	DOA-SKREEN-H	STAT-SKREEN®17	STAT-SKREEN®17H
CONSTITUENTS	Negative	Cutoff	2X Cutoff	2X Cutoff	2X Cutoff	2X Cutoff
Delta-9-THC-COOH	None Detected	50	100	100	100	100
Benzoyllecgonine	None Detected	150/300	300	300	600	600
Phencyclidine PCP	None Detected	25	50	50	50	50
Morphine	None Detected	300/2000	600	4000	600	4000
d-Amphetamine	None Detected	500/1000	1000	1000	2000	2000
d-Methamphetamine	None Detected	500/1000	1000	1000	2000	2000
Secobarbital	None Detected	300	600	600	600	600
Oxazepam	None Detected	300	600	600	600	600
Methadone	None Detected	300	600	600	600	600
Propoxyphene	None Detected	300	600	600	600	600
Nortriptyline	None Detected	1000	2000	2000	2000	2000
Oxycodone	None Detected	100	200	200	200	200
MDMA*	None Detected	500	1000	1000	1000	1000
Buprenorphine	None Detected	10	20	20	20	20
Bup. Glucuronide	None Detected	10	20	20	20	20
EDDP	None Detected	300	600	600	600	600
Norfentanyl	None Detected	varies	50	50	50	50

* 3,4 Methylendioxyethylmethyl-amphetamine

ORDERING INFORMATION:

CATALOG #	DESCRIPTION
702001	DOA-SKREEN, 2x10mL Kitbox Containing: 1900010 NEGATIVE, 10ml & 19003020 DOA-SKREEN, POSITIVE, 10mL
702002	DOA-SKREEN-H, 2x10mL Kitbox Containing: 1900010 NEGATIVE, 10ml & 19003030 DOA-SKREEN-H, POSITIVE, 10mL
702003	STAT-SKREEN®17, 2x10mL Kitbox Containing: 1900010 NEGATIVE, 10ml & 19003066 STAT-SKREEN 17, POSITIVE, 10mL
702004	STAT-SKREEN®17H, 2x10mL Kitbox Containing: 1900010 NEGATIVE, 10ml & 19003081 STAT-SKREEN 17H, POSITIVE, 10mL
1900010-6pk	NEGATIVE, 6 x 10mL
19003020-6pk	DOA-SKREEN, POSITIVE (2X CUTOFF) 6 x 10mL
19003030-6pk	DOA-SKREEN-H, POSITIVE (2X CUTOFF) 6 x 10mL
19003066-6pk	STAT-SKREEN®17, POSITIVE (2X CUTOFF) 6 x 10mL
19003081-6pk	STAT-SKREEN®17H, POSITIVE (2X CUTOFF) 6x10mL



Biochemical Diagnostics, Inc.
180 Heartland Blvd.
Edgewood, NY 11717 USA

Phone: (631) 595-9200
Email: support@biochemicaldiagnostics.com
Website: www.biochemicaldiagnostics.com



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

