



**Biochemical
Diagnostics, Inc.**

A Kova International Company

DETECTABUSE® CUSTOM 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 ISO certified manufacturers. Standards are certified by the manufacturer 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 Limitations 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 6 months or until the expiration date when stored at 2-8°C, however Oxazepam is stable for only 6 months.

After Opening:

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

B. Thaw controls as needed; allow to come to room temperature followed by gentle swirling before use.

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.

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 manufacturers 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.*

Please store product only frozen or refrigerated according to the storage and stability section; certain analytes are known to be heat labile, thus no claims can be made if controls are not stored as recommended.

DETECTABUSE CONTROLS, OXAZEPAM STABILITY: Oxazepam has known stability problems in urine stored refrigerated, and to a lesser degree, frozen. Our experience indicates that Oxazepam will not deteriorate more than 10% of target level for at least one year when stored frozen at -20°C. Further deteriorations may occur beyond this period although Oxazepam ordinarily tests positive throughout the control's shelf life.

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} 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.

DETECTABUSE® Custom Liquid Control Urine

Target Values (ng/mL)

COMBO-H		20mL fill	REF: 18002842	18002743	18002844
(20mL available as custom size only)		50 mL fill	REF: 18003084	18003085	18003086
Drugs	Constituents	Cutoff	Cutoff -50%	Cutoff +50%	3X cutoff
AMP	d-Amphetamine	1000	500	1500	3000
BAR	Secobarbital	300	150	450	900
BUP	Buprenorphine	10	5	15	30
BZO	Oxazepam	300	150	450	900
COC	Benzoyllecgonine	300	150	450	900
EDDP100	EDDP	100	50	150	300
MET	d-Methamphetamine	1000	500	1500	3000
MQL	Methaqualone	300	150	450	900
MTD	Methadone	300	150	450	900
OPI	Morphine	2000	1000	3000	6000
OXY	Oxycodone	100	50	150	300
PPX	d-Propoxyphene	300	150	450	900
PCP	Phencyclidine	25	12.5	37.5	75
TCA	Nortriptyline	1000	500	1500	3000
THC	Delta-9-THC-COOH	50	25	75	150
TRA	Tramadol	100	50	150	300

COMBO-U		20mL fill	REF: 18003087	18003088	18003089
Drugs	Constituents	Cutoff	Cutoff -50%	Cutoff +50%	3X / 2Xcutoff
AMP500	d-Amphetamine	500	250	750	1500
COC150	Benzoyllecgonine	150	75	225	450
MET500	d-Methamphetamine	500	250	750	1500
MOP	Morphine	300	150	450	900
THC20	Delta-9-THC-COOH	20	10	30	40 (2X)
KET	Ketamine*	1000	500	1500	3000
BUP5	Buprenorphine	5	2.5	7.5	15

COMBO-A		20mL fill	REF: 18003090	18003091	18003092
Drugs	Constituents	Cutoff	Cutoff -50%	Cutoff +50%	3X cutoff
AMP300	d-Amphetamine	300	150	450	900
BZO200	Oxazepam	200	100	300	600
MET300	d-Methamphetamine	300	150	450	900
EDDP300	EDDP	300	150	450	900
MOP100	Morphine	100	50	150	300
KET100	Ketamine*	100	50	150	300
THC150	Delta-9-THC-COOH	150	75	225	450

*Ketamine is International Use Only. Ketamine method is not available for diagnostics use for in the USA.

