



**Biochemical
Diagnostics, Inc.**

A Kova International Company

DETECTABUSE® LIQUID CONTROL URINE

GC/MS (Low Opiate)

GC/MS-H (High Opiate)

CONFIRM 4 (2015 SAMHSA guidelines)

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 ensure 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

DETECTABUSE® Liquid Control Urine Target Values
GC/MS Target Values (ng/mL)

| CONSTITUENTS | Cutoff -25% | Cutoff | Cutoff +25% |
|-------------------------------|-------------|--------|-------------|
| SAMHSA MANDATED | | | |
| Delta-9-THC-COOH | 11 | 15 | 19 |
| Benzoyllecgonine | 113 | 150 | 188 |
| Phencyclidine (PCP) | 19 | 25 | 31 |
| Codeine (Low Opiate) | 225 | 300 | 375 |
| Codeine (High Opiate) | 1500 | 2000 | 2500 |
| *Total Morphine (Low Opiate) | 225 | 300 | 375 |
| *Total Morphine (High Opiate) | 1500 | 2000 | 2500 |
| **6-Monoacetylmorphine | 7.5 | 10 | 12.5 |
| d-Amphetamine | 375 | 500 | 625 |
| d-Methamphetamine | 375 | 500 | 625 |
| NON-MANDATED | | | |
| Secobarbital | 225 | 300 | 375 |
| Phenobarbital | 225 | 300 | 375 |
| Oxazepam | 225 | 300 | 375 |
| Methadone | 225 | 300 | 375 |
| Methaqualone | 225 | 300 | 375 |
| Propoxyphene | 225 | 300 | 375 |
| Butalbital | 225 | 300 | 375 |

* Contains Morphine-3-Glucuronide and Free Morphine (2:1)

** 6-MAM Only in High Opiate (-H) Control

Confirm 4 Target Values (ng/mL)

| CONSTITUENTS | Cutoff -60% | Cutoff-25% | Cutoff | Cutoff +25% |
|------------------------|-------------|------------|--------|-------------|
| SAMHSA MANDATED | | | | |
| Delta-9-THC-COOH | 6 | 11 | 15 | 18.75 |
| Benzoyllecgonine | 40 | 75 | 100 | 125 |
| Codeine | 800 | 1500 | 2000 | 2500 |
| *Total Morphine | 800 | 1500 | 2000 | 2500 |
| 6-Monoacetylmorphine | 4 | 7.5 | 10 | 12.5 |
| Hydrocodone | 40 | 75 | 100 | 125 |
| Hydromorphone | 40 | 75 | 100 | 125 |
| Oxycodone | 40 | 75 | 100 | 125 |
| Oxymorphone | 40 | 75 | 100 | 125 |
| Phencyclidine (PCP) | 10 | 19 | 25 | 31.25 |
| d-Methamphetamine | 100 | 187.5 | 250 | 312.5 |
| d-Amphetamine | 100 | 187.5 | 250 | 312.5 |
| MDMA | 100 | 187.5 | 250 | 312.5 |
| MDA | 100 | 187.5 | 250 | 312.5 |
| MDEA | 100 | 187.5 | 250 | 312.5 |

* Contains Morphine-3-Glucuronide and Free Morphine (2:1)

ORDERING INFORMATION:

| CATALOG # | DESCRIPTION | SIZE | CATALOG # | DESCRIPTION | SIZE |
|--------------------------|---------------------|-------|------------------|------------------------|-------|
| GC/MS LOW OPIATE | | | Confirm 4 | | |
| 19332001-10pk | GC/MS Cutoff -25% | 50 mL | 19582041-10pk | Confirm 4, Cutoff -60% | 50 mL |
| 19330000-10pk | GC/MS Cutoff | 50 mL | 19582026-10pk | Confirm 4, Cutoff -25% | 50 mL |
| 19332501-10pk | GC/MS Cutoff +25% | 50 mL | 19582002-10pk | Confirm 4, Cutoff | 50 mL |
| GC/MS HIGH OPIATE | | | 19582126-10pk | Confirm 4, Cutoff +25% | 50 mL |
| 19572251-10pk | GC/MS-H Cutoff -25% | 50 mL | NEGATIVE | | |
| 19572502-10pk | GC/MS-H Cutoff | 50 mL | 19227000-10pk | Negative Control Urine | 50 mL |
| 19572753-10pk | GC/MS-H Cutoff+25% | 50 mL | | | |

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 |

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