**Biochemical Diagnostics, Inc.**
A Kova International Company
180 Heartland Blvd, Edgewood, NY 11717● Phone (800) 223-4835
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# MANUFACTURING SPECIFICATIONS FOR DETECTABUSE® CUSTOM LIQUID CONTROL URINE

Custom drug urine controls are manufactured with analytical toxicology standards to the desired target level of customer specified drug constituents. Although target values are provided, each laboratory should run these controls as unknowns in order to establish "in-house" assay values.

Biochemical Diagnostics, Inc., is an FDA licensed manufacturing facility and as such, we manufacture all in vitro diagnostic products under the guidelines of current GMP and other applicable governing regulations. In addition, all of our liquid control urine products are manufactured in compliance with the directive 98/79/EC of the European Parliament and of the Council and carry the CE mark.

Biochemical Diagnostics Liquid Control Urine is manufactured from negative, human based urine which was determined to be below detection limits for common drugs of abuse and/or common therapeutic drugs, then spiked with the specified constituents. All reference standards used in manufacturing are at least 98% minimum purity. Specific gravity, pH and creatinine fall within the normal limits of human urine. Contains 0.05% sodium azide.

Refer to Package insert for more information.

This product passes our in-house quality control release specifications.

| Catalog # | Description | Lot # | Expiration Date |
|---|---|---|---|
| 18008613 | DETECTABUSE® CUSTOM LIQUID CONTROL URINE FENTANYL 5ng/mL, 5mL | CC02329 | 2026-12-31 |

**QA Approval**: Amy Walsh Digitally signed by Amy Walsh Date: 2023.12.13 07:09:18 -05'00'

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# DETECTABUSE® CUSTOM LIQUID CONTROL URINE PACKAGE INSERT

**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.

**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 -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 thawed/frozen up to 5 times)
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:**

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 (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 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.

*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, 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 | | Temperature Limits |
| IVD | *In Vitro* Diagnostic Medical Device | REF | Product Catalog Number |
| LOT | Batch Code | UDI | Unique Device Identifier |
| | Manufacturers Identification | | Country of Manufacture |
| | Use by Date | Rx only | For Prescription Use Only |

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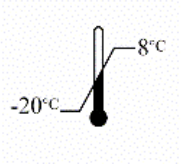


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