

Biochemical Diagnostics, Inc.

A Kova International Company

180 Heartland Blvd, Edgewood, NY 11717 • Phone (800) 223-4835

Fax (631) 595-9204 • www.biochemicaldiagnostics.com

CERTIFICATE OF ANALYSIS

Product Name: Detectabuse® Liquid Control Urine, Negative

Catalog#	19700000	Packaging:	5 mL vial
	19700010		10mL vial
	19223011		20 mL vial
	19227000		50 mL vial
	19227005		500 mL bottle
	19227010		1 liter bottle

Lot # N068-02

Exp. 2021-06-31

Manufactured with human based urine, certified to test negative by commonly used screening and confirmation methods for the following drugs: THC, benzodiazepines, cocaine (benzoylecgonine), opiates, amphetamines, barbiturates, PCP, ethanol, propoxyphene, methadone, methaqualone, meperidine, carisoprodol/meprobamate, tramadol, oxycodone, phenytoin, salicylate, acetaminophen, buprenorphine, 6-acetylmorphine, ecstasy, fentanyl, ketamine, nicotine and cotinine. Specific Gravity, pH, and Creatinine fall within the limits of normal human urine. Contains 0.05% Sodium Azide.

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 all 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.

The product passes our in-house Quality Control specifications for release.

INTENDED USE: The Detectabuse® controls are designed to monitor and validate the performance of drugs of abuse detection methods at levels established by SAMHSA, CAP/AACC and many state programs. The Detectabuse® control urines are compatible with all quantitative and qualitative drug detection procedures which are sufficiently sensitive to detect the control constituents. 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.

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. Specific gravity, pH, and creatinine fall within the limits of normal human urine.

DESCRIPTION: Each bottle contains stabilized human based urine. Negative control urines are certified negative by either immunoassay, GC/MS and/or LC/MS for the constituents listed on our drug positive target sheets.

STORAGE & STABILITY: Please refer to Limitations for detailed instructions.

Unopened Negative Controls:

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 2-8°C.

After Opening Negative Controls:

A. The Negative 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. Do not freeze in bulk plastic bottles.)

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

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

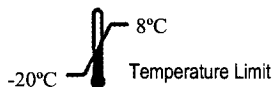
PROCEDURE: Allow controls to come to room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE. Pipette an appropriate aliquot of Detectabuse® control urine as required by the drugs of abuse test device or screening method

EXPECTED RESULTS: The negative control must test negative for all drugs included on our drug positive control sheets.

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 drugs of abuse detection 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.*

QA Approval: Omry Wabli 8/8/18



Refer to
Package Insert



For In Vitro
Diagnostic Use

