



Biochemical Diagnostics, Inc.

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DETECTABUSE™

LIQUID

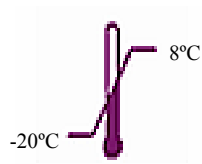
CONTROL

URINE

ETHYL GLUCURONIDE

Controls prepared from human based urine available as a negative and various constituent target levels to monitor the performance of qualitative or quantitative procedures for the detection of Ethyl glucuronide in Urine.

Target levels available: Negative, 100 ng/mL, 250 ng/mL and 500 ng/mL



Temperature Limit



Consult Instructions For Use



For In Vitro Diagnostics Use Only

Rev. March 2006

Please read the entire package insert before using the Detectabuse control urines.

Website: www.biochemicaldiagnostics.com

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. 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 manufactures 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 EMIT®, ONLINE™, GC/MS and/or LC/MS for the constituents listed on our target sheets.

Detectabuse™ Ethyl glucuronide

Target Values

Negative	0 ng/mL
Ethyl glucuronide	100 ng/mL
Ethyl glucuronide	250 ng/mL
Ethyl glucuronide	500 ng/mL

EMIT® is a trademark of SYVA Co. (Dade Behring), Palo Alto, CA

ONLINE™ is a trademark of Roche Diagnostics Corp., Indianapolis, IN

CATALOG #	DESCRIPTION	
19900010	Detectabuse Liquid Control Urine, Ethyl Glucuronide, 100 ng/mL	20 mL
19900025	Detectabuse Liquid Control Urine, Ethyl Glucuronide, 250 ng/mL	20 mL
19900050	Detectabuse Liquid Control Urine, Ethyl Glucuronide, 500 ng/mL	20 mL
19223011	Detectabuse Liquid Control Urine, Negative	20 mL

For information on our other Detectabuse™ products please contact us or refer to our

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.

STORAGE & STABILITY :

Unopened:

A. The controls are stable until the expiration date when stored at -10 to -20°C or 2-8°C and protected from light.

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 aliquoted and frozen)
- B. The 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

A. Allow controls to come to room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE.

B. Pipette an appropriate aliquot of Detectabuse™ Liquid Control Urine as required by the test method.

LIMITATIONS OF PROCEDURE

This control is meant to be used to validate the performance of drug screening and confirmation 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.

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.