



# Biochemical Diagnostics, Inc.

A Kova International Company

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## CERTIFICATE OF ANALYSIS

**PRODUCT NAME:** DETECTABUSE® LIQUID CONTROL URINE, COTININE, 400 ng/mL 5 mL

**CATALOG #:** 19000102

<u>Constituent</u>	<u>Lot #</u>	<u>Expiration Date</u>	<u>Verified Value</u>
I-Cotinine	SC00025	2021-11-30	425 ng/mL

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 spiked with the specified constituents. All drug 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.

Controls are assayed by independent laboratories which, based on our experience, provide consistent, reliable results with predictable statistical bias within their acceptance criteria.

Because Independent laboratories are permitted to accept GC/MS values that deviate more than  $\pm 20\%$  of assigned control values for SAMHSA mandated drugs, and an often looser criteria for non-mandated drugs, your assay values, or those obtained from other outside laboratories may be biased at either extreme of their acceptance criteria and may not match the BCD values.

Please contact us for guidance regarding these issues.

For storage, stability or additional information refer to package insert.

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

QA Approval: Amy W. A. 11/27/18