



# Biochemical Diagnostics, Inc.

A Kova International Company

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## CERTIFICATE OF ANALYSIS

**PRODUCT NAME: DETECTABUSE® STAT-SKREEN® LIQUID CONTROL URINE**

STAT-SKREEN Cutoff +50% CATALOG # 19470051, 20 mL

### Verified Value (ng/mL)

CONSTITUENTS	LOT #: 803885 EXP: 2021-03-31	
	Target	Verified
<b>SAMHSA Mandated</b>		
DELTA-9-THC-COOH	75	74
BENZOYLECGONINE	450	448
PHENCYCLIDINE (PCP)	37.5	37
MORPHINE	450	449
d-AMPHETAMINE	1500	1440
d-METHAMPHETAMINE	1500	1493
<b>Non-Mandated</b>		
SECOBARBITAL	450	439
OXAZEPAM	450	450
METHADONE	450	468
METHAQUALONE	450	477
d-PROPOXYPHENE	450	479
NORTRIPTYLINE	1500	1508

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 SAMHSA and/or CAP certified laboratories verified by GC/MS and/or LC/MS which, based on our experience, provide consistent, reliable results with predictable statistical bias within their acceptance criteria.

Because SAMHSA certified laboratories are permitted to accept values that fall within  $\pm 20\%$  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 Walsh 8/29/18