



Food and Drug Administration  
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February 23, 2016

BIOCHEMICAL DIAGNOSTICS, INC  
ALLEN PANETZ  
PRESIDENT  
180 HEARTLAND BLVD  
EDGEWOOD NY 11717

Re: K153474

Trade/Device Name: Detectabuse® Stat-Skreen Liquid Control Urine,  
Detectabuse® Liquid Control Urine, AU/NZ  
Detectabuse® Liquid Control Urine, Immunoassay Series  
Detectabuse® Liquid Control Urine, Confirm Series  
Detectabuse® Liquid Control Urine, GC/MS  
Detectabuse® Liquid Control Urine Series, Single or Multi-  
Constituent

Regulation Number: 21 CFR 862.3280  
Regulation Name: Clinical toxicology control material  
Regulatory Class: I, reserved  
Product Code: DIF  
Dated: December 3, 2015  
Received: December 4, 2015

Dear Allen Panetz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
**Courtney H. Lias -S**

Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
k153474

### Device Name

Detectabuse® Stat-Screen Liquid Control Urine, Detectabuse® Liquid Control Urine, AU/NZ, Detectabuse® Liquid Control Urine, Immunoassay Series, Detectabuse® Liquid Control Urine, Confirm Series, Detectabuse® Liquid Control Urine, GC/MS, Detectabuse® Liquid Control Urine Series, Single or Multi-Constituent

### Indications for Use (Describe)

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 for the analytes listed in the package insert.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**Biochemical Diagnostics, Inc.**

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*An ISO 13485:2003 Company*

**Traditional 510(k) Submission**

**Number: K15347**

**A. 510(k) Number: K153474**

**Date of Summary Preparation**

January 15, 2016

**B. Purpose for Submission:** New Device

**C. Measurand:**

Quality control material for urine testing of:

Delta-9-THC-COOH, Benzoylcegonine, Phencyclidine(PCP), Morphine, Morphine -3-glucuronide, 6-Monoacetylmorphine(6-MAM), Codeine, Oxycodone, Buprenorphine, Fentanyl, d-Amphetamine, d-Methamphetamine, 3, 4-Methylenedioxymethamphetamine (MDMA), 3, 4-Methylenedioxyamphetamine (MDA), 3, 4-Methylenedioxy-N-ethylamphetamine (MDEA), Secobarbital, Phenobarbital, Butalbital, Oxazepam, Nordiazepam, Methadone, EDDP, Methaqualone, Propoxyphene, Norproxyphene, Nortriptyline, Cotinine, Ethanol, Amphetamines, Cannabinoids, Opiates, Barbiturates, Benzodiazepines, Hydrocodone, , Buprenorphine Glucuronide, Lysergic Acid, , Acetaminophen, Tramadol, Creatinine, pH, Specific Gravity.

**D. Type of Test:**

Not applicable

**E. Applicant:**

Biochemical Diagnostics, Inc.

180 Heartland Blvd

Edgewood, NY 11717

Phone: 631-595-9200

Fax: 631-595-9204

**Contact Person**

Allen Panetz

President

Phone: 631-595-9200 Ext. 3011

**F. Proprietary and Established Names:**

Product trade name: Detectabuse® Liquid Control Urine

Established Names Include:

Detectabuse® Stat-Screen® Liquid Control Urine

Detectabuse® Liquid Control Urine, AU/NZ

Detectabuse® Liquid Control Urine, Immunoassay Series

Detectabuse® Liquid Control Urine, Confirm Series

Detectabuse® Liquid Control Urine, GC/MS

Detectabuse® Liquid Control Urine Series, Single or Multi-Constituent

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
DIF	Class I, reserved	21 CFR 862.3280	Toxicology

**H. Intended Use:**

1. Intended use(s):

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 for the analytes listed in the package insert.

2. Indication(s) for use:

The Detectabuse® controls are designed to provide an estimation of the precision of a device test system, and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects, at levels established by SAMHSA, CAP/AACC, many state programs and device manufacturers QC requirements. 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 under the supervision of health care professionals as an integral part of good laboratory practices.

3. Special conditions for use statement(s):

Detectabuse® Liquid Control Urines are designed for *in vitro* diagnostic use only and are available in Negative, and concentrations ranging between Cutoff -80%, and 4X Cutoff levels. They should not be pipetted by mouth and the normal precautions for handling laboratory specimens should be applied. The products contain either sodium azide or a proprietary preservative compatible with products that are adversely affected by sodium azide.

4. Special instrument requirements:

Validation studies were conducted using the following methods:

- 1) GC/MS
- 2) LC/MS
- 3) Immunoassay Screening (immunoassay analyzer, Roche Cobas 6000 analyzer and/or immunoassay single use screening devices)

**I. Device Description:**

Each bottle contains stabilized human based urine. Multi-constituent and single constituent positive control urines have been gravimetrically 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. The products contain less than 1% sodium azide as a preservative. For assays sensitive to sodium azide such as ELISA we substitute a proprietary preservative approved by the manufacturers and DEA.

**J. Substantial Equivalence Information:**

1. Predicate device (K121122)

Modified device (K 153474)

**Detectabuse® Liquid Control Urine**

2. Comparison of Technological Characteristics

*Similarities and differences between new and predicate devices. Drug screening tests are for use with FDA approved test methods.*

Device	Predicate Device A (K121122)	Device (K153474)
<b>Characteristics</b>	<b>Detectabuse® Liquid Control Urine</b>	<b>Detectabuse® Liquid Control Urine includes: Stat-Skreen®, AU/NZ Skreen Immunoassay Series GC/MS, Confirm Series, Single or Multi-Constituent Series</b>
<b>Intended Use</b>	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 for the analytes listed in the package insert.	SAME
<b>Target Drug Levels (See package inserts for ng/mL target values)</b>	<b>GC/MS:</b> cutoff, cutoff -25%, cutoff +25% cutoff <b>Immunoassay:</b> cutoff, cutoff -25%, cutoff +25%, 3X	<b>Concentration ranges:</b> <b>Stat-Skreen</b> Negative and cutoff -80% to 4X cutoff <b>Immunoassay:</b> Negative and cutoff -80% to 4X cutoff <b>GC/MS and AU/NZ Skreen:</b> Negative and cutoff -80% to 4X cutoff <b>Confirm series:</b> Negative and cutoff -80% to 4X cutoff <b>Single or Multi-Constituent Series:</b> Negative and cutoff -80% to 4X cutoff

<b>Device</b>	<b>Predicate Device A (K121122)</b>	<b>Device (K153474)</b>
<b>Form</b>	Liquid	Liquid
<b>Matrix</b>	Human Urine	Human Urine
<b>Storage</b>	<p>A. The controls are stable until the expiration date when stored at -10 to -20°C and protected from light.</p> <p>B. The controls are stable until the expiration date when stored at 2-8°C.</p>	<p><b>Unopened</b></p> <p>A. The controls are stable until the expiration date when stored at -10 to -20°C and protected from light.</p> <p>B. The controls are stable until the expiration date when stored at 2-8°C.</p>
<b>Analytes</b>	<p>Delta-9-THC-COOH, Benzoyllecgonine , Phencyclidine (PCP), Codeine, Propoxyphene Methaqualone, Morphine -3-glucuronide, 6-Monoacetylmorphine, Morphine, d-Amphetamine, d-Methamphetamine , Secobarbital, Butalbital, Phenobarbital, Oxazepam, Methadone, MDMA, MDA, MDEA, Oxycodone, Buprenorphine, EDDP, Nordiazepam, Norpropoxyphene, Cotinine, Fentanyl, Ethanol, Nortriptyline, Creatinine, pH, Specific Gravity</p>	<p><b>Same analytes as predicate device A with the additional claims: Detectabuse® Liquid Control Urine includes:</b></p> <p><b>Stat-Skreen®, AU/NZ Skreen Immunoassay Series, GC/MS, Confirm Series, Single or Multi-Constituent Series:</b></p> <p>Cannabinoids, Opiates, Amphetamines, Benzodiazepines, Barbiturates, Hydrocodone, , Buprenorphine Glucuronide, Lysergic Acid, Acetaminophen, Tramadol</p>

**K. Standard/Guidance Document Referenced (if applicable):**

None were referenced.

**L. Test Principle:**

Not applicable

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

Not applicable

*b. Linearity/assay reportable range:*

Not applicable

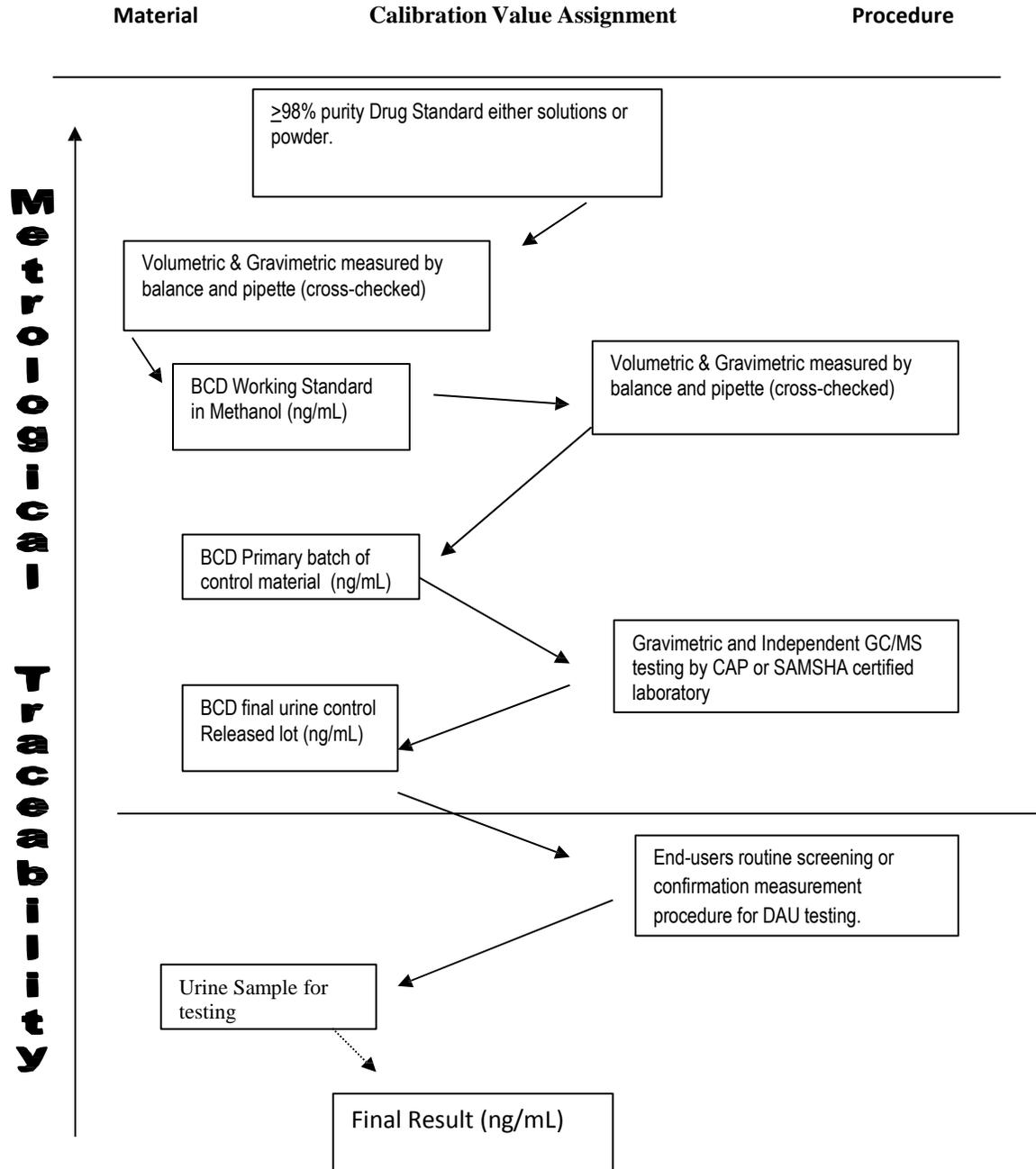
*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:

The drug values in the Detectabase® control are validated by SAMHSA or CAP certified independent laboratories by using either GC/MS, LC/MS, HPLC, or Immunoassay screening. The controls are manufactured using reference standards supplied by companies including Cerilliant and Alltech Corporation. Accuracy is certified by purity determination using analytical tools including GC/MS, LC/MS, and NMR. Gravimetric preparation is accomplished using balances calibrated with weights that are traceable to National Institute of Standards and Technology (NIST).

## Metrological Traceability of Values Assigned to Control Materials

Detectabuse® Liquid Control Urines have target value assignments for various drug constituents. Laboratories (or other end-users) are to use these target concentrations when performing screening or confirmation of drugs of abuse testing methods.



### **Value Assignment:**

The following procedure was used for value assignment

a. Assay Methodology used to assign values:

Certified Independent laboratories test by either GC/MS, LC/MS, or Immunoassay screening depending on validated test method that is in use at time of testing.

b. Data Collection:

A minimum of 3 data points are collected for each assay. Data collected from at least two test sites, testing performed within 1 week of receipt of test samples.

c. Value assignment Criteria:

An initial production batch is sampled as described in the protocol and single or multiple samples (depending on our past experience with the constituent(s), are ordinarily sent out to 4 or 5 certified laboratories, depending on the constituents being tested. Certain drug constituents are not routinely tested by all of our reference laboratories and, in this case, we identify at least 3 laboratories that are proficient in those constituents. Our target acceptance criteria is  $\pm 5\%$  of the target value, but if we cannot get  $\pm 5\%$  agreement from our testing laboratories we will accept  $\pm 10\%$ , particularly in the case of certain drugs that are not routinely tested for such as Propoxyphene and Methaqualone. If a testing laboratory does not report within 10% of target we ask that the sample be repeated. Once we have an acceptable convergence of values from all of the testing laboratories the lot is released. In the case of Stat-Screen® controls for on-site hand held devices, when available, the lot will also be tested on hand held devices listed for the constituents. In this case our criteria shall be that positive controls test positive and negative product tests negative on the device.

For our final testing of a lot by GC/MS or LC/MS at the end of its shelf life we aim for  $\pm 10\%$  of target value but will accept up to  $\pm 15\%$  for certain constituents such as Oxazepam that are known to have stability issues.

## **Stability Protocol K153474**

Biochemical Diagnostics performed stability testing on our Detectabuse® controls to verify the performance claims in our package inserts. Controls were tested at Room Temperature (18-21°C), Refrigerated (2-8°C), Frozen (-10 to -20°C). The protocol and conclusion are listed below.

### **Open Vial (2-8°C) Stability**

#### **Protocol:**

Refrigerated temperature on opened vial Detectabuse® controls was tested initially and again at 31 days. Controls run by Drugs of Abuse testing using FDA approved test methods.

#### **Conclusion:**

Data support the 31-day open bottle stability at 2-8°C for all analytes in the lots evaluated. All analytes tested passed specifications, Positive controls tested positive and Negative controls tested negative.

### **Closed Vial (2-8°C) Stability**

#### **Protocol:**

Refrigerated temperature on closed vial Detectabuse® controls were tested initially and repeated at 1 year and 3 years. Controls run by Drugs of Abuse testing using FDA approved test methods. At expiration date (3 years from manufacture), all drugs tested were stable within 12% of target or original test value done at time of manufacturing with the exception of Oxazepam which dropped 15-22% after one year refrigerated. At study conclusion of 3 years, all drugs were within 15% except Oxazepam which dropped to 25%.

#### **Conclusion:**

Refrigerated temperature storage is recommended until expiration date except for Oxazepam which showed a 15-22% drop when stored refrigerated unopened greater than 1 year. Results of other drugs found in our stock Detectabuse product line were within the acceptable criteria of +/-15% from target until expiration date. We do not recommend long term storage (more than six months) refrigerated based on the results of the Oxazepam testing this information is listed on the package insert under unopened Storage & Stability information and under Limitations.

#### **Limitations listed on package insert:**

**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.

### **Closed Vial (-10°C to -20°C) Stability**

**Protocol:** Multiple bottles of a single lot of individual or multi-constituent Detectabuse® controls were pulled from beginning, middle, and end of production, set aside and unopened bottles were assayed at time of manufacturing and again (unopened bottles) periodically. Studies are ongoing and sent for assay until expiration date. Studies carried out on product between 3 to 4 years frozen storage. Closed vial study samples were stored frozen within a temperature range of -10°C to -20°C. Study samples were tested by GC/MS or LC/MS using SAMHSA licensed laboratories or CAP inspected and certified as well as by our own in-house evaluations using GC/MS and/or FDA approved hand held devices.

**Conclusion:**

Multiple studies were conducted using various different lots, tested initially and repeated between 3 and 4 years. Drug levels were quantitated by GC/MS or LC/MS and, all drugs tested were stable within 15% of target or original test value done at time of manufacturing, this information was used to support the limitations listed in our package insert.

Room Temperature (18-21°C)

**Protocol:**

Several lots of Detectabuse Controls were selected and stored room temperature for up to 31 days. The controls are not recommended to be stored at room temperature, but room temperature storage can occur during delays in shipping or by customer error. This data is used to support stability claims for the constituents of Detectabuse controls. Study samples were tested by GC/MS or LC/MS using SAMHSA licensed laboratories or CAP inspected and certified as well as by our own in-house evaluations using GC/MS and/or FDA approved hand held devices.

**Conclusion:**

All drugs tested for 31 days by GC/MS or LC/MS and/or FDA approved hand held devices tested within 18% of target value or original test value done at time of manufacture.

**Summary Table:**

Evaluation Parameter	Acceptance Criteria	Specification	Pass / Fail
Open Bottle Stability at 2-8°C	31 days	Real time study done for 31 days	Pass
Close Bottle Stability – Product Shelf Life (2-8°C)	36 months	Storage of Oxazepam will be negatively affected, >6 months	Pass with exception
Close Bottle Stability – Product Shelf Life -10°C to -20°C	Up to 4 years	Real time study, several lots tested. Values within ±15%	Pass
Room Temperature (open vial) Stability- Product Shelf Life (18°C to 21°C)	31 days	Real time study, several lots tested. Values within ±18%	Pass

## **Stability protocols, with acceptance criteria, for the Detectabuse® Liquid Controls Urine for ongoing stability testing of on-market product lots**

Additional on-going stability studies are done on random lots of each formulation to ensure continued performance; customer satisfaction surveys are also conducted quarterly to receive feedback on product performance. Negative customer feedback on product performance will trigger retesting if warranted after investigation. Controls are tested initially, and if no negative feedback, repeated every 6 months until endpoint of study, unless otherwise indicated in a specific study protocol. A normal testing protocol is designed to mimic the end users use of the product in accordance with the package insert instructions.

*d. Detection limit:*

Not applicable

*e. Analytical specificity:*

Not applicable

*f. Assay cut-off:*

Not applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

Not applicable

*b. Matrix comparison:*

Not applicable

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable

*b. Clinical specificity:*

Not applicable

*c. Other clinical supportive data (when a. and b. are not applicable):*

Not applicable

4. Clinical cut-off:

Clinical cut-off levels are determined by the SAMHSA (Substance Abuse and Mental Health Services Administration) or by individual Laboratory Directors.

5. Expected values/Reference range are formulated anywhere between -80% of the confirmation test cutoff concentrations and 4X of the initial test cutoff concentrations: All drugs (ng/mL) except acetaminophen and ethanol (mg/dl)

<b>Constituents</b>	<b>Negative Level</b>	<b>-80% Confirmatory</b>	<b>Cutoff Initial/Confirmatory</b>	<b>4X Initial</b>
Delta-9-THC-COOH	0	3	50/15	200
Cannabinoids	0	3	50/15	200
Benzoylecgonine	0	20	150/100	600
Phencyclidine (PCP)	0	5	25/25	100
Opiates (Low)	0	60	300/300	1200
Opiates(High)	0	400	2000/2000	8000
Opiates (Low Opiates)	0	60	300/300	1200
Opiates (High Opiates)	0	400	2000/2000	8000
Morphine (Low Opiate)	0	60	300/300	1200
Codeine (Low Opiate)	0	60	300/300	1200
Morphine (High Opiate)	0	400	2000/2000	8000
Codeine (High Opiate)	0	400	2000/2000	8000
Amphetamines	0	100	500/250	2000
Amphetamine	0	100	500/250	2000
Methamphetamine	0	100	500/250	2000
Barbiturates	0	60	400/300	1600
Secobarbital, Phenobarbital, Butalbital	0	60	500/300	2000
Benzodiazepines	0	60	500/300	2000
Oxazepam, Lorazepam, Nordiazepam	0	60	300/300	1200
Methadone, EDDP	0	60	300/300	1200
Methaqualone	0	60	300/300	1200
Propoxyphene	0	60	300/300	1200
Nortriptyline	0	100	1000/500	4000
MDMA, MDEA, MDA	0	50	500/250	2000
Oxycodone	0	10	100/50	400
Hydrocodone	0	20	300/100	1200
Buprenorphine	0	1	10/5	40
Buprenorphine Glucuronide	0	1	12.5/5	50
6-MAM	0	1	10/5	40
Cotinine	0	10	200/50	800
Fentanyl	0	0.2	25/1.0	100
Tramadol	0	10	100/50	400
Lysergic Acid	0	0.1	0.5/0.5	2.0
Acetaminophen (mg/dL)	0	1	10/5	40
Ethanol (mg/dL)	0	10	100/50	400

**N. Summary Statement:**

Detectabuse® controls are stabilized with the same proprietary method as our other stabilized Detectabuse® liquid urine controls and have tested to be equivalent in performance and stability. The above substantial equivalence comparison demonstrates that the stabilized Detectabuse® control is as safe and effective and performs the same as the predicate device.