510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k153474

B. Purpose for Submission:

New Device

C. Measurand:

Quality control material for Delta-9-THC-COOH, Benzoylecgonine, 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, Creatinine, pH, Specific Gravity Amphetamines, Cannabinoids, Opiates, Barbiturates, Benzodiazepines, Hydrocodone, Buprenorphine glucuronide, Lysergic Acid, Acetaminophen, Tramadol

D. Type of Test:

Not applicable

E. Applicant:

Biochemical Diagnostics, Inc.

F. Proprietary and Established Names:

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

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.3280, Clinical toxicology control material

2. Classification:

   Class I, Reserved

3. Product code:

   DIF

4. Panel:

   Toxicology (91)

H. Intended Use:

1. Intended use(s):

   See indication for use(s)

2. Indication(s) for use:
   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.

3. Special conditions for use statement(s):

   This is an in vitro diagnostic device

   For prescription use only

4. Special instrument requirements:

   Not applicable

I. Device Description:

The Detectabuse® Liquid Controls
Each bottle contains stabilized human based urine. The positive urine controls have been gravimetrically spiked with reference drug standards and /or appropriate metabolites. The negative controls are certified negative by a combination of immunoassay, GC/MS and/or LC/MS for the constituents listed on the target sheets. The products contain less than 1%

sodium azide as a preservative. For assays sensitive to such as ELISA we substitutes a proprietary preservative approved by the manufacturers and DEA.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Detectabuse® Liquid Control Urine

2. Predicate 510(k) number(s):
   k121122

3. Comparison with predicate:

Similarities		
Item	Candidate Device Detectabuse® liquid Control Urine (k153474)	Predicate Device Detectabuse® liquid Control Urine (k121122)
Intended Use	Quality control urine to monitor the performance of laboratory toxicology testing procedure	Same
Form	Liquid	Same
Matrix	Human urine	Same

Differences		
Item	Candidate Device Detectabuse® liquid Control Urine (k153474)	Predicate Device Detectabuse® liquid Control Urine (k121122
Analytes	Delta-9-THC-COOH, Benzoylecgonine, 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,	Delta-9-THC-COOH, Benzoylecgonine, 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,

Differences		
Item	Candidate Device Detectabuse® liquid Control Urine (k153474)	Predicate Device Detectabuse® liquid Control Urine (k121122
	Nordiazepam, Methadone, EDDP, Methaqualone, Propoxyphene, Norproxyphene, Nortriptyline, Cotinine, Ethanol, Creatinine, pH, Specific Gravity Amphetamines, Cannabinoids, Opiates, Barbiturates, Benzodiazepines, Hydrocodone, , , Buprenorphine glucuronide, Lysergic Acid, , Acetaminophen, Tramadol	Nordiazepam, Methadone, EDDP, Methaqualone, Propoxyphene, Norproxyphene, Nortriptyline, Cotinine, Ethanol, Creatinine, pH, Specific Gravity
Storage	Closed vial stable for 36 months when stored at 2-8°C with the exception of oxazepam (oxazepam stable for 6 months), 48 months when stored at -10 to -20°C. Open vial are stable for 31 days when stored at 2-8°C.	Closed vial are stable for 36 months when stored at 2-8°C with the exception of oxazepam, 48 months when stored at -10 to -20°C and protected from light with the exception of oxazepam. Open vial are stable for 30 days when stored at 2-8°C

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 controls are validated by certified independent laboratories by using either GC/MS, LC/MS, HPLC, or Immunoassay screening. The controls are manufactured using reference standards purchased from commercial vendors. 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).

Value Assignment:
The following procedure was used for value assignment

a. Assay Methodology used to assign values:
   Certified Independent laboratories test by 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.

Stability:
The stability protocols for open and closed vial were reviewed and found acceptable. The testing supports closed vial stability for 36 months when stored at 2-8°C with the exception of oxazepam (oxazepam is stable for 6 months) and 48 months when stored at -10 to -20°C. Open vials are stable for 31 days when stored at 2-8°C and 31 days when stored at room temperature (18-21°C).

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

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:

   Not applicable

5. Expected values/Reference range:

   Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.