510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k121122

B. Purpose for Submission:
New Device

C. Analyte:
Quality control materials for Delta-9-THC-COOH, Benzoylecgonine , 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

D. Type of Test:
Not applicable

E. Applicant:
Biochemical Diagnostics, Inc.

F. Proprietary and Established Names:
Detectabuse® Liquid Control

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 indications for use below

2. Indication(s) for use:
   The Detectabuse® Liquid control 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 condition for use statement(s):
   For prescription use only

4. Special instrument Requirements:
   Not applicable.

I. Device Description:

Detectabuse® Liquid Control
Each bottle contains stabilized human based urine. Positive control urines have been gravimetrically spiked with 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 name(s):
   Detectabuse® Liquid Control Urine

2. Predicate K number(s):
   k925586

3. Comparison with predicates:

Device	Predicate Device (K925586)	Modified Device (K121122)
Intended Use	Same	Is intended for use as quality control urine to monitor the precision of laboratory urine toxicology testing procedures
Form	Same	Liquid
Matrix	Same	Human Urine
Storage	Closed vial: The controls are stable until the expiration date when stored at -10 to -20^{o}C and protected from light. The controls are stable until the expiration date when stored at 2-8^{o}C. Open vial: not available	Closed vial: The controls are stable until (1) 36 months when stored at 2-8^{o}C with the exception of oxazepam; (2) 48 months when stored at -10 to -20^{o}C and protected from light with the exception of oxazepam. Open vial: The controls are stable 30 days when stored at 2-8^{o}C.

Analytes	Delta-9-THC-COOH, Benzoylecgonine , Phencyclidine (PCP), Codeine, Propoxyphene Methaqualone, Morphine -3-glucuronide, 6-Monoacetylmorphine, Morphine, d-Amphetamine, d-Methamphetamine , Secobarbital, Butalbital, Phenobarbital, Oxazepam, Methadone	**Same analytes as predicate device A with the additional claims:** MDMA, MDA, MDEA, Oxycodone, Buprenorphine, EDDP, Nordiazepam, Norpropoxyphene, Cotinine, Fentanyl, Ethanol, Nortriptyline, Creatinine, pH, Specific Gravity

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 (controls, calibrators, or method):

a) Traceability

The controls are gravimetrically spiked with reference standards purchased from commercial vendors. The drug values printed within the package insert are validated by using GC/MS, LC/MS, HPLC, or Immunoassay screening.

b.) Stability

Stability studies have been performed to determine the open vial stability and shelf life stability of the Detectabuse® Liquid control.

Product claims are as follows: open vial stability is 30 days when stored tightly capped at 2-8°C; closed vial stability is 10 months at 2-8°C and 4 years at -10°C to -20°C.

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 available.

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 substantial equivalence decision.