

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

A. 510(k) Number:

K120504

B. Purpose for Submission:

New Device

C. Analyte:

Quality control materials for Cannabinoids (delta-9-THC), cocaine (benzoylecgonine), ethanol, lysergic acid diethylamide (LSD), methadone, methaqualone, opiates (morphine, free), oxazepam, phencyclidine (PCP), propoxyphene, secobarbital, d-Methamphetamine

D. Type of Test:

Not applicable

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek Urine Toxicology Control, Level S10

Liquichek Urine Toxicology Control, Level S10, MiniPak

Liquichek Urine Toxicology Control, Level S20

Liquichek Urine Toxicology Control, Level S20, MiniPak

Liquichek Urine Toxicology Control, Level S10 Low Opiate

Liquichek Urine Toxicology Control, Level S10 Low Opiate, MiniPak

Liquichek Urine Toxicology Control, Level S20 Low Opiate

Liquichek Urine Toxicology Control, Level S10 Low Opiate, MiniPak

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):
Refer to Indications for use.
2. Indication(s) for use:
Liquichek Urine Toxicology Control is intended for use as quality control urine to monitor the precision of laboratory urine toxicology screening procedures.
3. Special condition for use statement(s):
None
4. Special instrument Requirements:
Not applicable.

I. Device Description:

The product is prepared from human urine with addition of preservatives, stabilizers, constituents of animal origin, abused drugs and their metabolites. It is a liquid ready to use quality control material.

The serum of each donor, who contributed urine for this product, was tested by FDA accepted methods and found to be non-reactive for Hepatitis B surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Liquichek Urine Toxicology Control (Screen Series)
2. Predicate K number(s):
K033924
3. Comparison with predicate:

Showing in table 1, both devices have same matrix and both are quality control materials that measure similar analytes. These two devices are different in that the candidate device added two novel analytes - oxazepam and d-methamphetamine - and removed three analytes - nordiazepam, nortriptyline (TCA), and d-amphetamine. Since the preservative of the candidate device is a cocktail of antibiotics and it does not contain any hazardous materials, the candidate device does not require the hazard symbol.

Table 1. Similarities and differences between candidate and predicate device.

Characteristics	Liquichek Urine Toxicology Control (New Device)	Liquichek Urine Toxicology Control (Screen Series) (Predicate Device, K033924)
Similarities		
Intended Use	Liquichek Urine Toxicology Control is intended for use as quality control urine to monitor the precision of laboratory urine toxicology screening procedures.	Liquichek Urine Toxicology Control (Screen Series) is intended for use as quality control urine to monitor the precision of laboratory urine toxicology screening procedures.
Matrix	Human Urine	Human Urine
Form	Liquid	Liquid
Open vial stability	30 days at 2 °C to 8 °C	30 days at 2 °C to 8 °C
Differences		
Storage unopened (shelf Life)	-20 °C to -70 °C until expiration date	2 °C to 8 °C until expiration date
Closed Vial (Thawed) Stability	45 days at 2 °C to 8 °C	No Claim
Levels	Level S10, S20, S10 Low Opiate, S20 Low Opiate	Level S1, S2, S3, S1 Low Opiate, S2 Low Opiate
Analytes	Contains Cannabinoids (delta-9-THC) Cocaine (benzoylecgonine) Ethanol Lysergic acid diethylamide (LSD) Methadone Methaqualone Opiates (morphine, free) Phencyclidine (PCP) Propoxyphene Secobarbital Oxazepam d-Methamphetamine Does not contain: Nordiazepam Nortriptyline (TCA) d-Amphetamine	Contains Cannabinoids (delta-9-THC) Cocaine (benzoylecgonine) Ethanol Lysergic acid diethylamide (LSD) Methadone Methaqualone Opiates (morphine, free) Phencyclidine (PCP) Propoxyphene Secobarbital Nordiazepam Nortriptyline (TCA) d-Amphetamine Does not contain: Oxazepam d-Methamphetamine

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

The sponsor did not reference any standards in their submission.

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):

Candidate product consists of eight control materials. Controls are human urine spiked with known concentrations of drugs which were gravimetrically prepared. Expected concentrations were verified by reference laboratories. Minimum number of laboratories, replicate measurements, or assay systems is not, however, specified.

Although GC/MS and Enzyme Immunoassay (EIA) analysis is performed during stability studies, (see below), the traceability of control results to GC/MS and EIA is not specified or discussed by the sponsor.

Stability studies are summarized for these controls. Product claims include: (1) open vial: 30 days at 2 °C to 8 °C, (2) closed vial (Thawed): 45 days at 2 °C to 8 °C, and (3) shelf life stability: 2 years at -20 °C to -70 °C. The sponsor specifies the frequency of testing, the method for testing the materials (GC/MS or EIA), environmental conditions of storage, and acceptance criteria for the study (less than 10% variance comparing to time zero). Accelerated stability studies were employed by incubating controls at elevated temperatures (i.e. 25°C, 16 °C, 5 °C, etc.) to detect alterations in product performance more rapidly than would be seen under normal storage conditions of -20 °C to -70 °C. Estimated expiration date was predicted using a stability model with activation energy of the 20-kCal/mol or Arrhenius Model. On-going real time studies are long-term and being performed. All procedures appear to be compliance with standard for the industry.

Representative values of the materials are provided and look appropriate.

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.