

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

A. 510(k) Number:

k050682

B. Purpose for Submission:

New Device

C. Analyte:

Urine Toxicology Control Material (Drug Mixture) for the following analytes:
Amphetamine, Methamphetamine, Secobarbital, Amobarbital, Butalbital,
Phenobarbital, Phenobarbital, Nordazepam, α -hydroxyalprazolam,
Tetrahydrocannabinol, Benzoylcegonine, Ethanol, LSD, Methadone, Methaqualone,
Morphine-3- β -glucuronide, Codeine, Phencyclidine, Norpropoxyphene, Creatinine,
Methylenedioxymethamphetamine (MDMA), Methylenedioxyamphetamine (MDA)
and Methylenedioxyethylamphetamine (MDEA).

D. Type of Test:

Control Material

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek Urine Toxicology 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:
91

H. Intended Use:

1. Intended use(s):
See Indications for Use below.
2. Indication(s) for use:
Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.

3. Special condition for use statement(s):
N/A
4. Special instrument Requirements:
N/A

I. Device Description:

Liquichek Urine Toxicology Control is prepared from human urine with added drugs of abuse and metabolites of drugs of abuse, preservatives, stabilizers and constituents of animal origin. The control is provided in liquid form and at several levels that are shown in the package insert. The control contains Amphetamine, Methamphetamine, Secobarbital, Amobarbital, Butalbital, Phenobarbital, Phenobarbital, Nordazepam, α -hydroxyalprazolam, Tetrahydrocannabinol, Benzoylcegonine, Ethanol, LSD, Methadone, Methaqualone, Morphine-3- β -glucuronide, Codeine, Phencyclidine, Norpropoxyphene, Creatinine, Methylenedioxyamphetamine (MDMA), Methylenedioxyamphetamine (MDA) and Methylenedioxyethylamphetamine (MDEA). Gravimetric reference values and GC analyses are listed in the package insert.

The serum from each donor contributing urine for this product was tested by FDA accepted methods and found 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
2. Predicate K number(s):
k033404
3. Comparison with predicate:
This control material is similar in composition to the predicate device, except that the new device contains MDMA, MDA and MDEA in control level 1.

Similarities		
Item	Device	Predicate
Device Name	LiquiChek Urine Toxicology Control (Level 1)	LiquiChek Urine Toxicology (Level 1)
Intended Use	Intended for use as a quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.	Intended for use as a quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.
Matrix	Urine	Urine
Stability	30 days once opened	30 days once opened

Differences		
Item	Device	Predicate
Components	Amphetamine, Methamphetamine, Secobarbital, Amobarbital, Butalbital, Phenobarbital, Phenobarbital, Nordazepam, α -hydroxyalprazolam, Tetrahydrocannabinol, Benzoyllecgonine, Ethanol, LSD, Methadone, Methaqualone, Morphine-3- β -glucuronide, Codeine, Phencyclidine, Norpropoxyphene, Creatinine, Methylenedioxymethamphetamine (MDMA), Methylenedioxyamphetamine (MDA) and Methylenedioxyethylamphetamine (MDEA).	Amphetamine, Methamphetamine, Secobarbital, Amobarbital, Butalbital, Phenobarbital, Phenobarbital, Nordazepam, α -hydroxyalprazolam, Tetrahydrocannabinol, Benzoyllecgonine, Ethanol, LSD, Methadone, Methaqualone, Morphine-3- β -glucuronide, Codeine, Phencyclidine, Norpropoxyphene, Creatinine

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

None Referenced

L. Test Principle:

N/A. This 510(k) describes control material only.

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

N/A

b. *Linearity/assay reportable range:*

N/A

c. *Traceability (controls, calibrators, or method):*

Value assignment is based on the average from triplicate analysis of control solutions at 3 reference laboratories using Gas Chromatography. Approximate GC and gravimetric values are listed in the package insert. The sponsor recommends that each laboratory using Liquichek controls should use these results only as a reference and should establish its own parameters for precision.

Open vial stability 2-8 °C was tested at 6 time points (1, 8, 14, 22, 29 and 36 days), the last of which (T_{final}) extends to 20% longer than the expiration date of the control. Recovery of the sample tested at the last time point was compared, by GC/MS, to a freshly opened vial. Acceptance criteria are that T_{final} must be within +/- 10% of the T_{zero} value.

Closed stability was determined using an accelerated stability study and the product was predicted to have a 4 year shelf life when stored at 2-8 °C. The product was tested at three elevated temperatures and the shelf stability was predicted using a stability model with activation energy of 20-kCal/mole. Acceptance criteria are defined as recovery values at each time point that are within +/- 10% of the values determined for vials at the T_{zero} .

Real time closed vial stability are ongoing. Acceptance criteria are defined as recovery values at each time point that are within +/-10% of the values determined for vials stored at 2-8v °C or -20 °C.

- d. *Detection limit:*
N/A
- e. *Analytical specificity:*
N/A
- f. *Assay cut-off:*
N/A
- 2. Comparison studies:
 - a. *Method comparison with predicate device:*
N/A
 - b. *Matrix comparison:*
N/A
- 3. Clinical studies:
 - a. *Clinical sensitivity:*
N/A
 - b. *Clinical specificity:*
N/A
 - c. *Other clinical supportive data (when a and b are not applicable):*
N/A
- 4. Clinical cut-off:
N/A
- 5. Expected values/Reference range:
N/A

N. Conclusion:

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