

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

A. 510(k) Number:

K033366

B. Analyte:

Urine Toxicology Control Material (Drug Mixture)

C. Type of Test:

Control Material

D. Applicant:

Bio-Rad Laboratories

E. Proprietary and Established Names:

Liquicheck Urine Toxicology Control

F. Regulatory Information:

1. Regulation section:
21CFR862.3280
2. Classification:
Class I
3. Product Code:
DIF
4. Panel:
91

G. Intended Use:

1. Intended use(s):
2. Indication(s) for use:
Liquicheck Qualitative Urine Urine Toxicology Control is intended for use as an assayed quality control urine to monitor the performance of laboratory procedures for qualitative urine toxicology.
3. Special condition for use statement(s):
4. Special instrument Requirements:

H. Device Description:

Liquicheck Qualitative Urine Toxicology Controls are prepared from human urine with added drugs of abuse and metabolites of drugs of abuse, preservatives, stabilizers and constituents of animal origin. They are in liquid form. They contain 11-Nor- Δ -THC-9-COOH, amphetamines (d-amphetamine, d-

methamphetamine and MDMA), secobarbital, nordiazepam, oxazepam, cannabinoids, cocaine, ethanol, LSD, methadone, methaqualone, morphine, phencyclidine, propoxyphene and nortriptyline.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Liquichek Qualitative Urine Toxicology Control
2. Predicate K number(s):
K001973
3. Comparison with predicate:
This control material is similar in composition to the predicate device, except that the new device contains MDMA.

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

K. Test Principle:

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

L. 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 of triplicate analyses of control solutions at 3 reference laboratories, using HPLC for nortriptyline, LC/MS/MS for LSD and GCMS for all other drugs. The manufacturer recommends that laboratories using Liquichek controls should use these results only as a reference and establish its own parameters for precision.

Open vial stability at 2-8 ° C is tested at 6 time points, the last of which (t_{final}) extends to 20% longer than the expiration date. Recovery of the sample tested at that time point is compared, by GCMS, to a freshly opened vial. Acceptance criteria are that t_{final} must be within +/- 10% of the T_{zero} value.

Real-time stability studies 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 2-8 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):

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

N/A

M. Conclusion:

I recommend that the Biorad Liquichek Toxicology Controls are substantially equivalent to the predicate device.