

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

A. 510(k) Number:

k052053

B. Purpose for Submission:

New device

C. Measurand:

Urine Toxicology Control Material (Drug Mixture) for the following analytes: Amphetamines (d-Amphetamine, d-Methamphetamine and MDMA), Barbiturates (Secobarbital), Benzodiazepines (Nordiazepam and Oxazepam), Cannabinoids (11-Nor- Δ -9-THC-9-COOH), Cocaine (Benzoylecgonine), Ethanol, LSD, Methadone, Methaqualone, Opiates (Morphine, free), Oxycodone, Phencyclidine, Propoxyphene and TCA (Nortriptyline).

D. Type of Test:

Control Material

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquicheck Urine Toxicology Control

G. Regulatory Information:

1. Regulation section:

21 CFR§862.3280

2. Classification:

Class I, reserved

3. Product code:

DIF

4. Panel:

91

H. Intended Use:

1. Intended use(s):

See indications for use

2. Indication(s) for use:

Liquichek Qualitative 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 conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Not applicable

I. Device Description:

Liquichek 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. The control is provided in liquid form. The control contains Amphetamines (d-Amphetamine, d-Methamphetamine and MDMA), Barbiturates (Secobarbital), Benzodiazepines (Nordiazepam and Oxazepam), Cannabinoids (11-Nor- Δ -9-THC-9-COOH), Cocaine (Benzoylecgonine), Ethanol, LSD, Methadone, Methaqualone, Opiates (Morphine, free), Oxycodone, Phencyclidine, Propoxyphene and TCA (Nortriptyline).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Liquichek Qualitative Urine Toxicology Control

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

k033366

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Liquichek Qualitative Urine Toxicology Control is intended for use as an assayed quality control urine to monitor the performance of laboratory procedures for qualitative urine toxicology.	Liquichek Qualitative Urine Toxicology Control is intended for use as an assayed quality control urine to monitor the performance of laboratory procedures for qualitative urine toxicology.
Form	Liquid	Liquid
Matrix	Urine	Urine
Storage (unopened)	2-8°C until expiration date	2-8°C until expiration date
Open Vial	30 days at 2-8°C or 18-25°C	30 days at 2-8°C or 18-25°C

Differences		
Item	Device	Predicate
Analytes	Amphetamines (d-Amphetamine, d-Methamphetamine and MDMA), Barbiturates (Secobarbital), Benzodiazepines (Nordiazepam and Oxazepam), Cannabinoids (11-Nor- Δ -9-THC-9-COOH), Cocaine (Benzoylecgonine), Ethanol, LSD, Methadone, Methaqualone, Opiates (Morphine, free), Oxycodone, Phencyclidine, Propoxyphene and TCA (Nortriptyline).	Amphetamines (d-Amphetamine, d-Methamphetamine and MDMA), Barbiturates (Secobarbital), Benzodiazepines (Nordiazepam and Oxazepam), Cannabinoids (11-Nor- Δ -9-THC-9-COOH), Cocaine (Benzoylecgonine), Ethanol, LSD, Methadone, Methaqualone, Opiates (Morphine, free), Phencyclidine, Propoxyphene and TCA (Nortriptyline). Does not contain Oxycodone

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

None Referenced

L. Test Principle:

Not applicable. This submission is for clearance of control material.

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):*

Value assignment is based on multiple days and duplicate 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 Liquicheck controls should use these results only as a reference and establish its own parameters for performance.

Open vial stability 2-8 °C was tested at 6 time points (0, 8, 14, 22, 30 and 39 days), the last of which (T_{final}) extends to 20% longer than the expiration date of the control. The acceptance criterion was defined as positive reactions for Positive control and negative reactions for Negative control at both T_{zero} and T_{Final} test points.

Closed stability was determined using an accelerated stability study and the product was predicated to have a 3 year shelf life when stored at 2-8°C. The product was tested at three elevated temperatures and the shelf stability was predicated using a stability model with activation energy of 20-kCal/mole. Acceptance criterion was defined as positive reactions for Positive control and negative reactions for Negative control at accelerated period of time equivalent to ≥ 3 years at normal storage conditions.

Real-time stability studies are ongoing. The test vials have been stored at 2-8°C and at -20°C (pseudo T_{zero}) and will be tested at several time points. The qualitative results for each time point will be compared against T_{zero} values. Failure is assumed to have taken place when the analyte qualitative results do not indicate a positive reaction for Positive control and negative reaction for negative control.

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 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.