

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

A. 510(k) Number:

k093577

B. Purpose for Submission:

New Device

C. Measurand:

Quality control material for urine opiates

D. Type of Test:

Not applicable

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek Opiate Control, Level 1

Liquichek Opiate Control, Level 2

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DIF	Class I, reserved	862.3280	Toxicology 91

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

Liquichek Opiate 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 conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

The package insert includes ranges for GC/MS and EIA methods.

I. Device Description:

Liquichek Opiate Control is prepared from human urine with added drugs of abuse, metabolites of drugs of abuse, preservatives, stabilizers and constituents of animal origin. The control is provided in liquid form for convenience.

The Liquichek Opiate Control consists of two levels: Level 1 and Level 2. The Level 1 Control contains drugs of abuse and metabolites of drugs of abuse added during manufacture at concentrations approximately 25 to 50% below cutoff levels. The Level 2 Control contains drugs of abuse and metabolites of drugs of abuse added during manufacture at concentrations approximately 25 to 50% above cutoff levels.

All human source materials used to produce this product have been tested for HbsAG, anti-HCV, HIV-1 and HIV-2 and found to be non-reactive by FDA licensed tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Liquichek™ Urine Toxicology Control Levels S1E and S2E

2. Predicate K number(s):

k022707

3. Comparison with predicate:

Similarities		
Characteristics	Bio-Rad Liquichek Opiate Control (New Device)	Bio-Rad Liquichek Urine Toxicology Control (Predicate Device k022707)
Intended Use	Liquichek Opiate Control is intended for use as quality	Liquichek Urine Toxicology Control is intended for use as

	control urine to monitor the precision of laboratory urine toxicology testing procedures for the analytes listed in the package insert.	quality control urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures.
Form	Liquid	Liquid
Matrix	Urine	Urine
Open Vial	30 days at 2-8°C	30 days at 2-8°C

Differences		
Storage (unopened)	-20° to -70°C until expiration date	2-8°C until expiration date
Fill Volume	5ml	10 ml
Analytes	Contains: Buprenorphine, EDDP, Fentanyl, Methadone, 6-monoacetylmorphine (6-MAM,6-AM),Oxycodone,	Contains: d-Methamphetamine, Secobarbital, Lormetazepam, 11-Nor-Δ-9-THC-9-COOH, Benzoylcegonine, Ethanol, LSD, Methadone, Methaqualone Morphine (Free), Phencyclidine, Propoxyphene, Nortriptyline, Creatinine, Specific Gravity, pH

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

None 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, Stability, Expected values (controls, calibrators, or methods):

Drug concentrations of Liquichek Opiate Control Levels 1 and 2 are verified by gas chromatography/mass spectrometry (GC/MS) and enzyme immunoassay (EIA) methods. The printed values, within the package insert, are based upon replicate assays of representative samples by participating laboratories in accordance with an established protocol. The data are analyzed for each lot and ranges for each analyte are assigned by the manufacturer.

Stability studies have been performed to determine the open vial stability and shelf life stability of the Liquichek Opiate control. Product claims are as follows: open vial stability is 30 days when stored tightly capped at 2-8°C; closed vial stability is 3 years when stored at -20 to -70°C. Real time stability testing is ongoing.

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:

The target values for each analyte are within the package insert. The labeling states that the representative values are provided for informational purposes only and each laboratory should establish its own parameters of precision.

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.