

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

A. 510(k) Number:

K033924

B. Analyte:

Cannabinoids (delta-9-THC), amphetamines (d-amphetamine), barbiturates (secobarbital), benzodiazepines (nordiazepam), cocaine (benzoylecgonine), ethanol, lysergic acid diethylamide (LSD), methadone, methaqualone, opiates (morphine, free), PCP, propoxyphene, TCA (nortryptiline)

C. Type of Test:

Quality Control material

D. Applicant:

Bio-Rad Laboratories

E. Proprietary and Established Names:

Liquichek Urine Toxicology Control (Screen Series), to include:

Liquichek Urine Toxicology S1 Control
Liquichek Urine Toxicology S2 Control
Liquichek Urine Toxicology S3 Control
Liquichek Urine Toxicology S1 Low Opiate Control
Liquichek Urine Toxicology S2 Low Opiate Control
Liquichek Urine Toxicology S1E Control
Liquichek Urine Toxicology S2E Control
Liquichek Urine Toxicology S1E Low Opiate Control
Liquichek Urine Toxicology S2E Low Opiate Control

F. Regulatory Information:

1. Regulation section:
862.3280, Clinical Toxicology Control Material, Drug Mixture Control Materials
2. Classification:
I, reserved
3. Product Code:
DIF
4. Panel:
Toxicology (91)

G. Intended Use:

1. Intended use(s):
Refer to Indications for use.
2. Indication(s) for use:
The product is intended for use as a quality control urine to monitor the performance of urine toxicology screening procedures.

The device is for in vitro diagnostic use.
The device is for prescription use.
3. Special condition for use statement(s):
None.
4. Special instrument Requirements:
Not applicable.

H. Device Description:

The product is a liquid ready to use quality control material.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Liquichek Urine Toxicology Control Levels S1, S2, and S3
2. Predicate K number(s):
K021411
3. Comparison with predicate:

Both devices have the same matrix and both are quality control materials that measure the same analytes. The devices are different in that the candidate device has added two new levels; the S1E Low Opiate and S2E Low Opiate levels. The preservative of the candidate device is a cocktail of antibiotics not requiring the hazard symbol, whereas the predicate include 0.1% sodium azide which required a hazard symbol.

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

The sponsor did not reference any standards in their submission.

K. Test Principle:

Not applicable.

L. 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):

The product consists of nine levels of control material. Controls are human urine spiked with known concentrations of drug. The materials are gravimetrically prepared. The expected concentrations are verified by reference laboratories. The minimum number of laboratories, replicate measurements, or assay systems is not, however, specified.

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

Stability studies are summarized for the controls. The sponsor specifies the frequency of testing, the method for testing the materials (GC/MS), environmental conditions of storage, and acceptance criteria for the study (10% drift from time zero). Accelerated studies are being used by the sponsor to estimate the expiration date, however, on-going real time studies are also being performed. All procedures appear to be standard for the industry.

Representative values of the materials are provided and seem 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):

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

M. Conclusion:

I recommend that this device be found substantially equivalent to the predicate device.