

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

A. 510(k) Number:

k070848

B. Purpose for Submission:

Premarket Notification 510(k) of intention to manufacture and market the Bio-Rad
Liquichek Urinalysis Control

C. Measurand:

Not Applicable – Urinalysis control material

D. Type of Test:

Quality control material

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Bio-Rad Laboratories, Liquichek™ Urinalysis Control

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1660 Quality control material (assayed and unassayed)

2. Classification:

Class I, (reserved)

3. Product code:

JJW

4. Panel:

H. Intended Use:

1. Intended use(s):

See Indications for use below

2. Indication(s) for use:

Liquichek Urinalysis Control is intended for use as assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in the package insert.

3. Special conditions for use statement(s):

For prescription Use

4. Special instrument requirements:

The specific analyzers are listed in the package insert.

I. Device Description:

The Bio-Rad Liquichek Urinalysis Control is prepared from human urine with added human electrolytes, simulated leukocytes, constituents of animal origin, pure chemicals, preservatives and stabilizers. The control is provided in liquid form for convenience and packaged as followed:

Bilevel	12x12 mL (6 per level)
Level 1	12x12 mL
Level 2	12x12 mL
Bilevel MiniPak	2x12 (1 per level)

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Liquichek Urinalysis Control

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

k031231

3. Comparison with predicate:

The Bio-Rad Liquichek Urinalysis Control k070848 were compared to the previously cleared Bio-Rad Liquichek Urinalysis Control 510(k) k031231. The table below lists the similarities and differences between the Predicate and Proposed device.

Characteristics	Bio-Rad Liquichek™ Urinalysis Control (New Device) k070848	Bio-Rad Liquichek™ Urinalysis Control (Predicate Device) k031231
Similarities		
Intended Use	Liquichek Urinalysis Control is intended for use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in this package insert	Liquichek Urinalysis Control is intended for use as an assayed quality control urine to monitor the precision of laboratory dipstick and microscopic testing procedures for analytes listed in this package insert
Form	Liquid	Liquid
Matrix	Urine	Urine
Storage	2° C to 8° C Until expiration date	2° C to 8° C Until expiration date
Open Vial	30 days at room temperature (18-25° C)	30 days at room temperature (18-25° C)
Preservatives	5-chloro-2-methyl-2H-isothiazol-3-one	5-chloro-2-methyl-2H-isothiazol-3-one
Squeezer Caps	Approved for use	Approved for use
Differences		
Analytes	Same analytes as the predicate device with the additional claims for color and clarity	Does not have claims for color and clarity

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

None were 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):

The Bio–Rad Liquichek Urinalysis Control is prepared from human urine with added human electrolytes, simulated leukocytes, constituents of animal origin, pure chemicals, preservatives and stabilizers. The manufacturer develops the target values and independent laboratories using the same protocol assay the material for each analyte/methodology for 20 times over a period of at least 10 days. The data are analyzed for each lot and ranges for each analyte/methodology are assigned by the manufacturer.

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek Urinalysis Control. Product claims are as follows:

Open vial: Once control is opened and stored tightly capped, all analytes will be stable for 30 days at room temperature (18-25° C).

Shelf life: 30 months when stored at (2-8° C).

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:

Specific ranges for each analyte/methodology are listed in the package insert. The manufacturer recommends in the labeling that each laboratory 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.