

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

A. 510(k) Number:

k072835

B. Purpose for Submission:

Marketing of laboratory control materials

C. Measurand:

Microalbumin and creatinine in urine

D. Type of Test:

This product is used as a quality control material to monitor the precision of laboratory testing procedures for microalbumin and creatinine in urine.

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek™ Microalbumin Control Level 1

Liquichek™ Microalbumin Control Level 2

Liquichek™ Microalbumin Control Level MiniPak

G. Regulatory Information:

1. Regulation section:

21CFR862.1660 Quality control material (assayed and unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJY

4. Panel:

(75) Chemistry

H. Intended Use:

1. Intended use(s):

Liquichek Microalbumin Control is intended for use as an assayed quality control urine to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

2. Indication(s) for use:

See intended use (above).

3. Special conditions for use statement(s):

For Prescription Use Only

4. Special instrument requirements:
Values are listed in the package insert for several analyzers.

I. Device Description:

Liquichek™ Microalbumin Control is prepared from human urine with added constituents of human origin, chemicals, preservatives and stabilizers. The control is provided in liquid form in 10 mL vials for both level 1 and level 2.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Liquichek™ Urine Chemistry Control
2. Predicate K number(s):
k020817
3. Comparison with predicate:

Similarities		
Item or Characteristic	Device	Predicate
Form	Liquid, level 1 and 2	Liquid, level 1 and 2
Matrix	Human urine based	Human urine based
Shelf Storage Claim (Unopened)	2 to 8° C Until expiration date	2 to 8° C Until expiration date
Open Vial Claim	30 days at 2 to 8° C	30 days at 2 to 8° C

Differences		
Item	Device	Predicate
Analytes	<u>Contains:</u> Microalbumin and creatinine only	<u>Contains:</u> - Amylase - Calcium - Chloride - Cortisol - Glucose - Magnesium - Osmolality - pH - Phosphorus - Potassium - Pregnancy - Protein, Total - Sodium - Specific Gravity - Urea - Urea Nitrogen - Uric Acid

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

None were referenced in the submission.

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):*

No information on traceability was provided. The mean values were derived from replicate analysis. The tests listed in the labeling were performed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents. The sponsor recommends in the labeling that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

Stability studies assayed for both microalbumin and creatinine. Accelerated stability studies were performed to support shelf life of the product. Real time studies are on-going for the life of the product. The sponsor's acceptance criterion is defined as T_{final} being $\pm 10\% T_{\text{zero}}$.

Shelf life stability: 2 years at 2 to 8° C.

Open vial stability: 30 days at 2 to 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:

The expected mean and assay range for specific analyzers are provided in the labeling. The sponsor recommends in the labeling that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10 including warning statements for biological source material and to be treated as infectious material with the added caution that it is for professional user.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.