

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

A. 510(k) Number:

k042446

B. Purpose for Submission:

New Device

C. Analyte:

Urine Albumin, Albumin-to-Creatinine Ratio, Ascorbic Acid, Bilirubin, Blood, Creatinine, Glucose, hCG, Hemoglobin, Ketones, Leukocytes, Nitrite, Microalbumin, Protein-to-Creatinine Ratio, Protein (Total), pH, Urobilinogen, Specific Gravity

D. Type of Test:

Quantitative

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

qUAntify® Control; qUAntify® Plus Control

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1660 Quality Control Material (assayed and unassayed)
2. Classification:
Class I
3. Product Code:
JJW
4. Panel:
75

H. Intended Use:

1. Intended use(s):
Refer to Indications for use below.
2. Indication(s) for use:
qUAntify® Control and qUAntify® Plus Control are intended for use as an assayed quality control to monitor the precision of urinalysis test procedures for the analytes listed in the package insert.
3. Special condition for use statement(s):
For Prescription Use Only
4. Special instrument Requirements:
N/A

I. Device Description:

These products are liquid matrix solutions prepared with human erythrocytes and [leukocytes in qUAntify® Plus only], constituents of animal origin, chemicals, and preservatives. They are prepared as Level 1 and Level 2.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Liquicheck Urinalysis Control
2. Predicate K number(s):
k031231
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	qUAntify Control and qUAntify Plus Control are intended for use as an assayed quality control to monitor the precision of urinalysis test procedures for the analytes listed in the package insert.	For use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in the package insert.
<i>Analytes</i>	Albumin, Albumin-to-Creatinine Ratio, Ascorbic Acid, Bilirubin, Blood Creatinine, Glucose, hCG, Hemoglobin, Ketones, Leukocytes, Nitrite, Microalbumin, Protein-to-Creatinine Ratio, Protein (Total), pH, Urobilinogen, Specific Gravity, Crystals, Casts, Red Blood Cells, White Blood Cells	Bilirubin, Blood, Creatinine, Glucose, hCG, Ketones, Leukocytes, Nitrite, Microalbumin, Protein-to-Creatinine Ratio, Protein (Total), pH, Urobilinogen, Specific Gravity, Crystals, Casts, Red Blood Cells, White Blood Cells, Osmolality
Matrix	Liquid matrix solution	Human Urine

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 (controls, calibrators, or method):*
No traceability provided.
The product is a stabilized liquid product manufactured under rigid quality control standards. The value assignment data are generated through internal protocols with repeat analysis of the test kit or instrument used. The values are provided in the package insert. Stability studies have been performed to determine the open vial stability and shelf life for the product. Product stability claims are as follows:
Open vial stability: 31 days at 2 to 8 C or room temperature (18-25° C).
Shelf life: Two years at 2 to 8° C.
 - d. *Detection limit:*
N/A
 - e. *Analytical specificity:*
N/A
 - f. *Assay cut-off:*
N/A
2. Comparison studies:
- a. *Method comparison with predicate device:*
N/A
 - b. *Matrix comparison:*
N/A
3. Clinical studies:
- a. *Clinical sensitivity:*
N/A
 - b. *Clinical specificity:*
N/A
 - c. *Other clinical supportive data (when a and b are not applicable):*
N/A
4. Clinical cut-off:
N/A
5. Expected values/Reference range:
N/A

N. Conclusion:

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