

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

A. 510(k) Number:

k050537

B. Purpose for Submission:

Marketing of a laboratory control

C. Measurand:

B-type Natriuretic Peptide (BNP), Creatine Kinase (Total), C-Reactive Protein (CRP), Homocysteine, Digitoxin, N-terminal pro-B-type Natriuretic Peptide (NT-proBNP), CK-MB, Myoglobin, Troponin I, Troponin T

D. Type of Test:

The product is used as a quality control serum to monitor the precision of laboratory testing procedures.

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek™ Cardiac Markers Plus Control
Liquichek™ Cardiac Markers Plus Control LT
Liquichek™ Cardiac Markers Plus Control LT Low

G. Regulatory Information:

1. Regulation section:
21CFR862.1660 Quality control material (assayed and unassayed).
2. Classification:
Class I
3. Product code:
JJY

4. Panel:

(75) Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Liquichek™ Cardiac Markers Plus Control, Liquichek™ Cardiac Markers Plus Control LT, and Liquichek™ Cardiac Markers Plus Control LT Low are intended for use as quality control serum to monitor the precision of laboratory testing procedures listing in the package insert.

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™ Cardiac Markers Plus Control, Liquichek™ Cardiac Markers Plus Control LT, and Liquichek™ Cardiac Markers Plus Control LT Low are prepared from human serum with added constituents of human and animal original, preservatives, and stabilizers. The controls are in liquid form.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Liquichek™ Cardiac Markers Control LT

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

k040277

3. Comparison with predicate:

Similarities		
Item or Characteristic	Device	Predicate
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based

Differences		
Item or Characteristic	Device	Predicate
Storage (Unopened)	-20° C to -70° C Until expiration date	-20° C or colder Until expiration date
:Open Vial Claim	All Analytes 20 days at 2-8° C	All Analytes 10 days, except NT-proBNP 5 days at 2-8° C
Analytes	<u>Contains:</u> B-type Natriuretic Peptide (BNP), Creatine Kinase (Total), C-Reactive Protein (CRP), Homocysteine, Digitoxin, N-terminal pro-B-type Natriuretic Peptide (NT-proBNP), CK-MB, Myoglobin, Troponin I, Troponin T	<u>Contains:</u> Homocysteine, Digitoxin, N-terminal pro-B-type Natriuretic Peptide (NT-proBNP), CK-MB Isoenzyme, Myoglobin, Troponin I, Troponin T <u>Does not contain:</u> B-type Natriuretic Peptide (BNP), Creatine Kinase (Total), C-Reactive Protein (CRP),

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

None were referenced in the submission.

L. Test Principle:

NA

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 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.

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 acceptance criterion is defined as T final being $\pm 10\%$ T zero. The results are as follows:

Shelf life stability: 3 years at -20 to -70°C

Open vial stability: 20 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:

Not Applicable

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 treat as potential infectious.

O. Conclusion:

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