

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

K043584

B. Purpose for Submission:

Reason for submission: Addition of an analyte - B-type Natriuretic Peptide – to an existing control and removal of the previously approved analytes.

C. Measurand:

B-type Natriuretic Peptide (BNP)

D. Type of Test:

Quality control material

E. Applicant:

Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, California 92618

F. Proprietary and Established Names:

Liquichek BNP Control, Liquichek Cardiac Markers Control LT

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 BNP Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for B-type Natriuretic Peptide (BNP) testing.

2. Indication(s) for use:

Liquichek BNP Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for B-type Natriuretic Peptide (BNP) testing.

3. Special conditions for use statement(s):

For Prescription Use Only

4. Special instrument requirements:

Varies with test instrument

I. Device Description:

The product is prepared from human serum with added constituents of animal origin, preservatives, and stabilizers. The control is provided in liquid form for convenience.

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:

The currently marketed predicate device claims the presence of 7 analytes. The concentrations of these analytes vary slightly between batches and with the particular product subset. The proposed device replaces these 7 existing analytes with one new analyte.

Similarities		
Item	Device	Predicate(K040277)
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based

Differences		
Item	Device	Predicate
Storage (Unopened)	-20°C to -70°C Until expiration date	-20°C or colder Until expiration date
Stability (Open Vial)	20 days at 2-8°C	All analytes 10 days, NT-proBNP 4 days at 2-8°C
Analytes		
	<u>Does not contain:</u> <ul style="list-style-type: none"> • CK-MB Isoenzyme • Digitoxin • Homocysteine • Myoglobin • N-terminal pro-B-type Natriuretic Peptide (NT-pro BNP) • Troponin I • Troponin T 	<u>Contains:</u> <ul style="list-style-type: none"> • CK-MB Isoenzyme • Digitoxin • Homocysteine • Myoglobin • N-terminal pro-B-type Natriuretic Peptide (NT-pro BNP) • Troponin I • Troponin T
	<u>Contains:</u> <ul style="list-style-type: none"> • B-type Natriuretic Peptide (BNP) 	<u>Does not contain:</u> <ul style="list-style-type: none"> • B-type Natriuretic Peptide (BNP)

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

None

L. Test Principle:

The product under submission is used by technicians to confirm the performance of lab or clinical instruments. The specific test varies with the instrument verified.

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):*

Expected Values

Liquichek BNP Control is prepared from human serum to which purified biochemical material (tissue extracts of animal origin), chemicals, preservatives, and stabilizers have been added.

Lot specific mean values and ranges are provided to the user via the product insert.

Biorad obtains these values either from the manufacture of the reagents or from analysis of the material by independent reference laboratories. These values are obtained from repeated measurements on a representative sampling of the manufactured lot.

Stability

The stability of the component analytes are the primary criteria for acceptance. Stability is measured by:

- Open vial aging which mimics handling by the users of the product. These studies involve verifying concentration of the analyte when the product is stored capped but unsealed at 2 °C to 8 °C.
- Accelerated Stability Testing which involves storing tested samples at elevated temperatures in an effort to predict their long-term performance.

The open vial study time is typically defined to be at least 20% longer than the claimed open vial stability for the product and determined at at least three time points: T_{Zero} , T_{Final} , and $T_{Final+20\%}$. Commercially available controls with characteristics comparable to the Liquichek BNP Control are assayed to ensure the accuracy and precision of the testing methods. The failure criteria is defined as the concentration at T_{Final} differing from the initial concentration, concentration at T_{Zero} , by more than 10%.

These studies are performed on pilot lots at elevated temperatures (i.e. 47°C, 41°C, 35°C, etc.) in order to observe changes in product performance more rapidly than would be seen under normal storage conditions of -20 to -70°C. Several vials are tested and on each assay day, commercially available controls with characteristics comparable to the Liquichek BNP Control are assayed to ensure the accuracy and precision of the testing methods. Several time points are generated for each temperature to predict the shelf life using a stability model with activation energy of the 20-kCal/mol.

Test data provided by the manufacturer indicates that the predicate and pre-

market device show similar, limited degradation of the analytes as a function of time. The change in analyte concentration is within the limits specified by the product inserts.

- 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.

O. Conclusion:

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