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

A. 510(k) Number:

k150300

B. Purpose for Submission:

Modification of previously cleared control (k050537) to add additional analytes

C. Measurand:

Multi-analyte quality control materials

D. Type of Test:

Not applicable

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek Cardiac Markers Plus Control LT

1. Regulation section:

   21 CFR 862.1660

2. Classification:

   Class I, Reserved

3. Product code:

   JJY

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See the indications for use statements below.

2. Indication(s) for use:

   Liquichek Cardiac Markers Plus Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

   The following analytes are listed in the package insert:
   B-type Natriuretic Peptide (BNP)
   CK-MB Isoenzyme
   C-Reactive Protein (CRP)
   Creatine Kinase (CK)
   D-dimer
   Digitoxin
   Homocysteine
   Myeloperoxidase (MPO)
   Myoglobin
   N-terminal pro-Brain Natriuretic
   Peptide (NT-proBNP)
   Troponin I
   Troponin T

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   See product insert for instruments requirements.

I. Device Description:

Liquichek Cardiac Markers Plus Control LT is prepared from human serum with added constituents of human and animal origin, stabilizers and preservatives. This product is provided in liquid form for convenience in the following configurations. This product contains the following analytes;

Description	Configuration
Liquichek Cardiac Markers Plus Control LT, Level Low	6 x 3 mL

Description	Configuration
Liquichek Cardiac Markers Plus Control LT, Level 1	6 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level 2	6 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level 3	6 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level 1A	6 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level 1B	6 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level 1C	6 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level Low MiniPak	1 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level 1 MiniPak	1 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level 2 MiniPak	1 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level 3 MiniPak	1 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level 1A MiniPak	1 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level 1B MiniPak	1 x 3 mL
Liquichek Cardiac Markers Plus Control LT, Level 1C MiniPak	1 x 3 mL

The sponsor has the following caution statement in their labeling: Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bio-Rad Laboratories Liquichek Cardiac Markers Plus Control LT

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

   k050537

3. Comparison with predicate:

SIMILARITIES		
	Candidate Device	Predicate Device (k050537)
Intended Use	Liquichek Cardiac Markers Plus Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.	Same
Form	Liquid	Same
Base Matrix	Human Serum	Same
Thawed and Open Stability	▪ N-terminal pro-Brain Natriuretic Peptide (NT-proBNP): 15 days at 2 to 8ºC ▪ Troponin I: 10 days at 2 to 8ºC ▪ B-type Natriuretic Peptide (BNP): 8 days at 2 to 8ºC ▪ Troponin T: 4 days at 2 to 8ºC ▪ All other analytes: 20 days at 2 to 8ºC	Same
Frozen Aliquot Stability	30 days at -20 to -70ºC	Same
Shelf Life	36 months at -20 to -70°C	Same
Analytes	B-type Natriuretic Peptide (BNP) CK-MB Isoenzyme C-Reactive Protein (CRP) Creatine Kinase (CK) Digitoxin Homocysteine Myoglobin N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) Troponin I Troponin T	Same

DIFFERENCES		
	Candidate Device	Predicate Device (k050537)
Analytes	Contains: D-dimer Myeloperoxidase (MPO)	Does not contain: D-dimer Myeloperoxidase (MPO)

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

None was 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, Stability, Expected values (controls, calibrators, or methods):

Value Assignment:

The mean values and the corresponding ±3SD ranges printed in the package inserts were derived from replicate analyses and are specific for each lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

Stability Studies:

Real time stability studies were performed to establish thawed and opened stability claims. Thawed and open vial stability when stored at 2ºC to 8ºC is as follows: N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) is15 days, Troponin 1 is 10 days, B-type Natriuretic Peptide (BNP) is 8 days, Troponin T is 4 days and all other analytes are 20 days. Frozen aliquot stability is 30 days at when stored at –20ºC to

–70ºC. Accelerated stability studies were performed for establishing the shelf life stability. The shelf life of the Liquichek Cardiac Markers Plus Control LT is 36 months from the date of manufacture when stored at –20ºC to –70ºC. Real time studies are ongoing. Shelf life and open-vial stability studies protocols and acceptance criteria were reviewed and found to be acceptable.

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:

   Expected values for the representative analyzers are provided as a guide in the labeling for each specific lot.

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.