

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

A. 510(k) Number:

k040277

B. Analyte:

CK-MB, Digitoxin, Homocysteine, Myoglobin, Troponin I, Troponin T, NT-proBNP

C. Type of Test:

Quality Control Material

D. Applicant:

Bio-Rad Laboratories

E. Proprietary and Established Names:

Liquichek™ Cardiac Markers Control LT

F. Regulatory Information:

1. Regulation section:
21 CFR 862.1660
2. Classification:
Class I
3. Product Code:
JJY
4. Panel:
75

G. Intended Use:

1. Indication(s) for use:
For use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert
2. Special condition for use statement(s):
NA
3. Special instrument Requirements:
Values are listed for several analyzers

H. Device Description:

Liquichek Cardiac Markers Control LT are human serum based controls which are supplied frozen at levels 1, 2, 3 and low level. The product is prepared from human serum with added constituents of human and animal origin, preservatives and stabilizers and supplied in liquid form. Each level is supplied as 6 x 3 ml. vials. The vials are thawed at room temperature before use. Stability studies have been performed to determine the open vial stability and shelf life. The shelf life is 2 years

at -20° C. The open vial stability is 10 days at 2-8° C except for NT-proBNP. NT-proBNP is stable for 5 days at 2-8° C.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Liquichek™ Cardiac Markers Control LT
2. Predicate K number(s):
k021498
3. Comparison with predicate:

Similarities		
Item	Liquichek Cardiac Markers LT K040277	Liquichek Cardiac Markers LT K021498
Intended use	Similar	Similar
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Storage	- 20 ° C or colder	- 20 ° C or colder
Differences		
Item	Liquichek Cardiac Markers LT K040277	Liquichek Cardiac Markers LT K021498
Number of levels	1, 2, 3, and low level	1, 2, and 3 (does not contain low level)
Analytes	NT-proBNP, CK-MB, digitoxin, homocysteine, myoglobin, troponin I, troponin T	CK-MB, digitoxin, homocysteine, myoglobin, troponin I, troponin T Does not contain NT-proBNP

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

None referenced

K. Test Principle:

NA

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
NA
 - b. *Linearity/assay reportable range:*
NA
 - c. *Traceability (controls, calibrators, or method):*
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.

