

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

A. 510(k) Number:

k062916

B. Purpose for Submission:

New Device

C. Measurand:

Cardiac Markers: CK-MB, hs-CRP, Digoxin, Myoglobin, cTnI, Troponin T, and NT ProBNP

D. Type of Test:

Quality control material

E. Applicant:

Cliniqa Corporation

F. Proprietary and Established Names:

CLINIQA Liquid QC Cardiac Marker Control SP, Levels 1, 2, & 3

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1660 Quality control material (assayed and unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJY, multi-analyte controls, all kinds (assayed and unassayed)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indication(s) for use section below.

2. Indication(s) for use:

CLINIQA Liquid QC Cardiac Marker Control SP, Levels 1, 2, & 3 are intended for use as assayed quality control material for CK-MB, hs-CRP, Digoxin, Myoglobin, cTnI, Troponin T, and NT ProBNP analysis.

3. Special conditions for use statement(s):

Prescription Use Only

4. Special instrument requirements:

The controls material is assayed for the following instruments:
CK MB – Beckman Access

hs-CRP – Roche Integra
 Digoxin - Beckman Access
 Myoglobin - Beckman Access
 cTnI – OCD Vitros ECI
 TnT – Roche Elecsys
 NT ProBNP - OCD Vitros ECI

I. Device Description:

CLINIQA Liquid QC Cardiac Marker Control SP, Levels 1, 2, & 3 are human serum based, containing constituents of human origin and purified biochemicals. Preservatives, stabilizers and sodium azide have been added to maintain product integrity. CLINIQA Liquid QC Cardiac Marker Control SP, Levels 1, 2, & 3 are provided in liquid form, and are ready to use.

J. Substantial Equivalence Information:

1. Predicate device name(s): MAS Cardioimmune XL, Microgenics Corporation.
2. Predicate 510(k) number(s): k061196
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Cardiac Marker Control	Cardiac Marker Control
Origin	Human serum	Human serum
Analyte	CK MB hs-CRP Myoglobin cTroponin I Troponin T NT ProBNP	CK MB hs-CRP Myoglobin Troponin I Troponin T NT ProBNP
Stability (opened)	30 days at 2-8 °C for: hs-CRP Myoglobin cTroponin I	30 days at 2-8 °C for: hs-CRP Myoglobin Troponin I

Differences		
Item	Device	Predicate
Analyte	Digoxin Not Present Not Present	Digitoxin BNP homocysteine
Stability (opened)	30 days at 2-8 °C for: CK MB Troponin T NT ProBNP	15 days at 2-8 °C for: CK MB Troponin T NT ProBNP

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

Not applicable.

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):*

Traceability

The sponsor has not provided any information regarding the traceability of the values assigned to the product. Assays used to establish the assignment of values will be run by at least two laboratories. A minimum of 12 data points will be used to determine the mean (expected) value. Within and between assay standard deviations and coefficient of variations (CV) will be calculated for each set of data. The Dixon Method for removing outliers from data sets of 3 through 25 observations will be used to analyze data sets with CVs greater than 10%. No more than 10% of a set of data will be removed as a statistical outlier. The resulting data will be statistically averaged to obtain a representative expected value for each constituent. All values are assigned with the instrument manufacturer's reagents available at the time of assay.

Stability

Stability characteristics of the CLINIQA Liquid QC Cardiac Marker Control SP, Levels 1, 2, & 3 were determined using the Arrhenius model of accelerated elevated temperature studies to predict estimated storage stability at 2 - 8 °C. All samples were tested on the Roche Integra, Ortho Clinical Diagnostics Vitros ECI, Roche Elecsys, or Beckman Coulter Access. The data submitted supports an open vial stability of 30 days and an unopened vial stability of 2 years at 2-8 °C for the CLINIQA Liquid QC Cardiac Marker Control SP, Levels 1, 2, & 3. Real time stability studies are ongoing.

Expected Values

The expected values are derived from replicate analyses of representative samples of the product and are specific to each lot. Consensus testing data used to establish the expected values were derived from multiple laboratories. All values are assigned with the instrument manufacturer's reagents available

at the time of assay.

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.

5. Clinical cut-off:
Not applicable.

6. 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.