

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

A. 510(k) Number:

k080973

B. Purpose for Submission:

New Device

C. Measurand:

Quality control materials for multi constituents listed in the package insert

D. Type of Test:

N/A

E. Applicant:

CLINIQA Corporation

F. Proprietary and Established Names:

CLINIQA Liquid QC™ Complete Cardiac Marker Control, Levels 1, 2, and 3

CLINIQA Liquid QC™ Cardiac Marker Control – Low

CLINIQA LiniCAL™ Cardiac Marker Calibration Verifiers Levels A –D

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 (assayed and unassayed)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

CLINIQA® Liquid QC™ Complete Cardiac Marker Control Levels 1, 2, and 3 is intended for use as an assayed quality control material for cardiac markers listed in the product insert. CLINIQA Liquid QC Complete Cardiac Marker Control is not intended for use as a standard.

CLINIQA Liquid QC Cardiac Marker Controls, Low is intended for use as an assayed quality control material for cardiac markers listed in the product insert. CLINIQA Liquid QC Complete Cardiac Marker Control is not intended for use as a standard.

LiniCAL Cardiac Marker Calibration Verifiers, Levels A-D are intended for use in the clinical laboratory to verify calibration and/or assess linearity of the analyzers listed in the product insert. Four assayed levels of analytes listed in the product insert are provided to allow monitoring of the reportable range

2. Indication(s) for use:

See intended use section above.

3. Special conditions for use statement(s):

For *In Vitro* Diagnostic Use

For prescription use

4. Special instrument requirements:

Instruments listed in the package insert include the following: Biosite Triage, Roche Integra™, and Roche Elecsys™.

I. Device Description:

CLINIQA® Liquid QC™ Complete Cardiac Marker Control Levels 1, 2, and 3 are prepared from a human plasma protein matrix, fortified to target levels with human source materials and reagent grade chemicals to achieve the levels. Preservatives, stabilizers and sodium azide have been added to maintain product integrity.

CLINIQA® Liquid QC™ Complete Cardiac Marker Control Levels 1, 2, and 3 is a ready-to-use liquid control requiring no reconstitution.

CLINIQA Liquid QC Complete Cardiac Marker Control is prepared from a human plasma protein matrix, fortified to target levels with human source materials and reagent grade chemicals to achieve the levels. Preservatives, stabilizers and sodium azide have been added to maintain product integrity. CLINIQA Liquid QC Complete Cardiac Marker Control is a ready-to-use liquid control requiring no reconstitution.

CLINIQA LiniCAL™ Cardiac Marker Calibration Verifiers Levels A –D is prepared from a human plasma protein matrix, fortified to target levels with human source materials and reagent grade chemicals to achieve the levels. Preservatives, stabilizers and sodium azide have been added to maintain product integrity. CLINIQA LiniCAL™ Cardiac Marker Calibration Verifiers Levels A –D is a ready-to-use liquid control requiring no reconstitution.

Each plasma donor unit used to manufacture this product was tested for Hepatitis B Surface Antigen (HBsAg), HIV-1 antigen, antibody to Hepatitis C Virus (HCV), and antibody to HIV-1/2 and found non-reactive using FDA accepted test methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Triage® Profiler S.O.B.™ (Shortness of Breath) Controls

Liquichek™ Cardiac Markers Plus Control LT – Level Low ()

2. Predicate 510(k) number(s):
k040459; k050537
3. Comparison with predicate:
All devices are plasma protein based products. The difference between the products is the constituents and their target concentrations, which have been optimized for each test system stated in the package insert.

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):*
No traceability was provided.

The protocols for establishing stability were reviewed and are adequate. The open-vial stability was performed. The accelerated stability data generated substantiate the proposed stability claims for CLINIQA Liquid QC Complete Cardiac Marker Control, Levels 1, 2, and 3, CLINICA LiniCAL Cardiac Marker Calibration Verifier, Levels A-D, and CLINIQA Liquid QC Cardiac Marker Control – Low.

Vials CLINIQA Liquid QC Complete Cardiac Marker Control, Levels 1, 2, and 3, CLINICA LiniCAL Cardiac Marker Calibration Verifier, Levels A-D, and CLINIQA Liquid QC Cardiac Marker Control – Low will have been on real time stability for 8 months and demonstrate recovery consistent with the predicted stability claim of 2.0 years. The recovery of each analyte will be monitored throughout the stability claim period.

CLINIQA Liquid QC Complete Cardiac Marker Control, Levels 1, 2, and 3, is stable until the expiration date on the vial label when stored at or below - 20°C. Once thawed, CLINIQA Liquid QC Complete Cardiac Marker Control, Levels 1, 2, and 3 is stable for 30 days when stored tightly capped at 2-8°C.

CLINIQA Liquid QC Complete Cardiac Marker Control, Low is stable until the expiration date on the vial label when stored at or below - 20°C. Once thawed, CLINIQA Liquid QC Cardiac Marker Control, Low is stable for 30 days when stored tightly capped at 2-8°C.

CLINICA LiniCAL Cardiac Marker Calibration Verifier, Levels A-D is stable until the expiration date on the vial label when stored at or below - 20°C. Once thawed, CLINICA LiniCAL Cardiac Marker Calibration Verifier, Levels A-D is stable for 30 days when stored tightly capped at 2-8°C.

The expected values printed in the package inserts were derived from replicate analyses of representative samples of the product and are applicable to the specific lot of CLINIQA Liquid QC Complete Cardiac Control, Levels 1, 2, and 3, CLINIQA LiniCAL™ Cardiac Marker Calibration Verifiers Levels A – D, or CLINIQA Liquid QC Cardiac Marker Control, Low. Consensus testing data used to establish the expected values were derived from multiple laboratories. All values have been assigned with the instrument manufacturer’s reagents available at the time of assay. The sponsor indicates in the labeling that subsequent instrument or reagent modifications may invalidate these expected values.

- 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:
The expected values for each test system are provided in the labeling.

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.