

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

A. 510(k) Number:

k083554

B. Purpose for Submission:

New Device

C. Measurand:

Quality control materials for multiple constituents listed in the package insert

D. Type of Test:

N/A

E. Applicant:

CLINIQA Corporation

F. Proprietary and Established Names:

CLINIQA[®] Liquid QC[™] ImmunoAssay Controls, 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 (assayed and unassayed)
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
CLINIQA[®] Liquid QC[™] ImmunoAssay Controls, Levels 1, 2, & 3 are assayed, liquid, quality control products which may be used to evaluate the performance of clinical methods for immunoassay analytes listed in the product insert.
2. Indication(s) for use:
See Intended Use section above
3. Special conditions for use statement(s):
For prescription use
For In Vitro Diagnostic Use

4. Special instrument requirements:

Specific instruments and methodologies are listed in the package insert

I. Device Description:

CLINIQA[®] Liquid QC[™] ImmunoAssay Controls, Levels 1, 2, & 3 are provided at three levels to assist in the monitoring of analytical systems within the clinical range. The three levels of control materials which contain human source material and added constituents are provided in two vials (5 mL each).

Each human 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 approved test methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Liquimmune[®] ImmunoAssay Controls Levels 1-3

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

k011731

3. Comparison with predicate:

The subject and predicate devices are serum-based products manufactured using the same processes. The difference between the products is the constituents and their target concentrations, which have been optimized for each test system.

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

None were 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):*

No traceability was provided.

The protocols for establishing stability were reviewed and found to be adequate. Open-vial stability testing was performed. The accelerated stability data generated substantiate the proposed stability claims for CLINIQA[®] Liquid QC[™] ImmunoAssay Controls, Levels 1, 2, & 3. Data supports the

sponsors proposed stability claims of unopened vial storage stability at -20°C of 3.0 years and open vial stability at 2-8°C of 30 days, with the following exceptions: free PSA of 7 days, insulin of 15 days and folate of 15 days.

Assignment of values is performed using the reagents, calibrators, and controls available at the time of assay by the manufacturer. The raw data obtained for each method are averaged to obtain the mean. The standard deviations (SD) and coefficient of variations (CV) are calculated for each set of data and an expected range is calculated for each analyte in the control material. Some analytes in this control product are endogenous. The mean and expected range for each analyte are presented in the lot-specific insert. The manufacturer recommends that each laboratory establish their own control ranges.

- 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 table in the package insert lists the expected values for each analyte.

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.