

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

A. 510(k) Number:

k070741

B. Purpose for Submission:

New Device

C. Measurand:

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 Assayed and Unassayed General Chemistry Control 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[™] Assayed is intended for use as an assayed quality control material for the constituents listed in this package insert.
2. Indication(s) for use:
See Intended Use section above
3. Special conditions for use statement(s):
For In Vitro Diagnostic Use

For professional use
4. Special instrument requirements:
None

I. Device Description:

CLINIQA Liquid QC Assayed General Chemistry Control is prepared from human serum with purified extracts of human and animal origin, chemicals, and drugs.

Preservatives and stabilizers have been added to maintain product integrity. CLINIQA Liquid QC Assayed General Chemistry Control is a ready-to-use liquid control requiring no reconstitution.

Each serum/plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

The analyte constituents are as follows:

Constituent	Constituent
Acetaminophen	Haptoglobin
Acid Phosphatase	β hCG, total
Alanine Amonitransferase	IgA
Albumin	IgG
Alkaline Phosphatase	IgM
Alpha-1-Antitrypsin	Iron
Amikacin	Iron Binding Capacity, Unsaturated
Amylase	Lactate
Amylase Pancreatic	Lactate Dehydrogenase
Apolipoprotein A1	Lipase
Apolipoprotein B	Lithium
Aspartate Aminotransferase	Magnesium
Bicarbonate	Osmolality
Bilirubin Direct	Phenobarbital
Bilirubin Total	Phenytoin
C3	Phosphorous
C4	Potassium
Calcium	Prealbumin
Carbamazepine	Protein Total
Carbon Dioxide	Salicylate
Ceruloplasmin	Salicylate
Chloride	Sodium
Cholesterol, HDL	T3 Uptake
Cholesterol, LDL	T3 Free
Cholesterol Total	T3 Total
Cholinesterase	T4 Free

Constituent	Constituent
Cortisol	T4 Total
Creatine Kinase	Theophylline
Creatine Kinase MB	Thyroid Stimulating Hormone
Creatinine	Tobramycin
Digoxin	Transferrin
Ethanol	Triglycerides
Constituent	Urea
Ferritin	Uric Acid
Gamma Glutamyl Transferase	Valproic Acid
Gentamicin	Vitamin B12
Glucose	

J. Substantial Equivalence Information:

1. Predicate device name(s): Liquid Assayed Multiqual Control
2. Predicate 510(k) number(s): k043208
3. Comparison with predicate:
Both devices are serum-based products manufactured using the same processes.
The difference is the constituents and their target concentrations.

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

CLSI EP6-P, Evaluation of the Linearity of Quantitative Analytical Methods

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)*:
The Arrhenius model of accelerated elevated temperature studies were used to support CLINIQA Liquid QC™ Assayed General Chemistry Control Levels 1, 2, & 3 storage stability claims at 2-8°C. Vials of CLINIQA Liquid QC Assayed General Chemistry Control Levels 1, 2, & 3 have been on real time stability for over 10 months and demonstrate recovery consistent with the predicated stability claim. CLINIQA Liquid QC Assayed General Chemistry Control is stable until the expiration date on the vial label when stored unopened at or below -20°C. Once opened, CLINIQA Liquid QC Assayed General Chemistry Control is stable for 15 days when stored tightly capped at

2-8°C except Acid Phosphatase and Total and Direct Bilirubin are stable for 5 days.

Target values are provided to assist the laboratory until it has established its own mean and standard deviation. The values are usually method dependent. Variations can occur over time and between laboratories. These variations may be attributed to differences in laboratory technique, instrumentation, reagent lot, method modifications, and other systematic errors including random errors.

The expected values printed in the package insert were derived from replicate analyses of representative samples of the product and are specific to this lot of CLINIQA Liquid QC™ General Chemistry Control, Levels 1, 2 & 3. 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.

- 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:
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.