

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

A. 510(k) Number:

K040535

B. Analyte:

Alkaline phosphatase, alanine aminotransferase, amylase, aspartate aminotransferase, cholinesterase, creatine kinase, creatine kinase MB, lactic dehydrogenase, lipase, gamma glutamyl transferase, and pancreatic amylase

C. Type of Test:

Calibration Verification Material

D. Applicant:

Cliniqa Corporation

E. Proprietary and Established Names:

LiniCAL™ Enzyme Calibration Verifiers Levels A-E for Beckman Coulter Synchron® Systems

F. Regulatory Information:

1. Regulation section:
21 CFR §862.1660: Quality Control Material (Assayed and Unassayed)
2. Classification:
Class I (general controls)
3. Product Code:
JJY
4. Panel:
75 (Clinical Chemistry)

G. Intended Use:

1. Indication(s) for use:
LiniCAL™ Enzyme Calibration Verifiers Levels A-E for Beckman Coulter Synchron® Systems are assayed, liquid quality control products which may be used to evaluate the performance of the Beckman Coulter Synchron® Systems for alkaline phosphatase, alanine aminotransferase, amylase, aspartate aminotransferase, cholinesterase, creatine kinase, creatine kinase MB, lactic dehydrogenase, lipase, gamma glutamyl transferase, and pancreatic amylase at five useful concentrations.
2. Special condition for use statement(s):
none
3. Special instrument Requirements:
Beckman Coulter Synchron® Systems

H. Device Description:

CLINIQA LiniCAL™ Enzyme Calibration Verifiers are human serum protein based, containing assayed constituents of chemically defined origin, including the analytes listed above. Preservatives, stabilizers, and sodium azide have been added to maintain product integrity. They are manufactured without glycerol and glycol. The product is liquid ready to use.

Constituent concentrations in Level A are for assessment of the lower limit of the reportable range. Constituent concentrations in Level E are designed to challenge the upper limit of the reportable range. Due to variation of analytical methods, Level E may exceed the limit of linearity for some test systems. Level C is the midpoint of the constituent concentrations between Levels A and E, and Levels B and D are midpoints between Level C and the Level A and E respectively.

I. Substantial Equivalence Information:

1. Predicate device name(s):
LiniCAL Chemistry Calibration Verifiers Levels A-E for Beckman Coulter Synchron® Systems
2. Predicate K number(s):
K031921
3. Comparison with predicate:
Both products are serum-based, are manufactured using the same processes, and have the same intended use. The differences between the products are the constituents; the target concentrations of the constituents have been optimized for each test system.

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

The sponsor did not reference any standards.

K. Test Principle:

Not applicable.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Not applicable.
 - b. *Linearity/assay reportable range:*
Not applicable.
 - c. *Traceability (controls, calibrators, or method):*
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. A statistical method will be used to evaluate and remove outliers if the CV is greater than 10%. The

resulting data will be averaged to obtain a representative expected value for each constituent. Assignment of values shall be performed using Beckman Coulter Synchron® reagents, calibrators, and controls available at the time of assay.

The stability characteristics of LiniCAL™ Enzyme Calibration Verifiers Levels A-E for Beckman Coulter Synchron® Systems were determined using the Arrhenius model of accelerated elevated temperature studies to estimate product storage stability at 2-8°C. Samples from each level of Verifier were placed at 2-8°C, 32°C, 37°C, and 45°C for various times. Calculated days to failure at 2-8°C was determined mathematically from the time that the vial stored at a higher temperature failed to return $\geq 90\%$ of the baseline value. Unopened vial storage stability (2-8°C) was estimated at 3 years. Opened vial stability (2-8°C) was tested by removing vial from 2-8°C, holding them at room temperature for one to three hours, opening briefly, swirling gently, the resealing and returning them to 2-8°C. The data support the opened vial stability claim of 14 days at 2-8°C. The sponsor says that real-time stability testing is underway.

- 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

Representative Assigned Values of One Pilot Lot of Product

| Analyte | Units | Level A Lot XR0519 | Level B Lot XR0520 | Level C Lot XR0521 | Level D Lot XR0522 | Level E Lot XR0523 |
|----------------------------------|-------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Alkaline Phosphatase (ALP) | U/L | 20 | 203 | 385 | 568 | 750 |
| Alanine Aminotransferase (ALT) | U/L | 30 | 98 | 165 | 233 | 300 |
| Amylase (AMY) | U/L | 40 | 155 | 270 | 385 | 500 |
| Aspartate Aminotransferase (AST) | U/L | 30 | 123 | 215 | 308 | 400 |
| Cholinesterase (CHE) | U/L | 300 | 4725 | 9150 | 13500 | 18000 |
| Creatine Kinase (CK) | U/L | 10 | 230 | 420 | 610 | 800 |
| Creatine Kinase MB (CKMB) | U/L | 2 | 39 | 76 | 113 | 150 |
| Lactate Dehydrogenase (LDH-L) | U/L | 50 | 163 | 275 | 388 | 500 |
| Lipase (LIP) | U/L | 35 | 164 | 293 | 421 | 550 |
| Gamma Glutamyltransferase (GGT) | U/L | 15 | 186 | 358 | 529 | 700 |
| Pancreatic Amylase (PAM) | U/L | 15 | 111 | 208 | 304 | 400 |

Values were established on a Beckman Coulter Synchron® CX system.

M. Conclusion:

I recommend that LiniCAL™ Enzyme Calibration Verifiers Levels A-E for Beckman Coulter Synchron® Systems be found substantially equivalent to the predicate.