

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

A. 510(k) Number:

k032074

B. Analyte:

Ammonia, Alcohol (ethanol), albumin (microalbumin), protein (microprotein), and Salicylate

C. Type of Test:

Calibration Verification Material

D. Applicant:

Cliniqa Corporation

E. Proprietary and Established Names:

LiniCAL Esoterics Calibration Verifiers Levels A-E for Beckman Coulter Synchron® Analyzers

F. Regulatory Information:

1. Regulation section:
862.1660 for Quality Control Material (Assayed and Unassayed)
2. Classification:
I
3. Product Code:
JJY
4. Panel:
75

G. Intended Use:

1. Indication(s) for use:
CLINIQA LiniCAL™ Esoterics Calibration Verifiers are intended for use in the clinical laboratory to verify calibration and/or assess linearity of the Beckman Coulter Synchron® Analyzers. Five assayed levels of AMM (ammonia), ETOH (alcohol), MA (microalbumin), M-TP (microprotein) and SALY (salicylate) are provided to allow monitoring of the reportable range.
2. Special condition for use statement(s):
Not applicable.
3. Special instrument Requirements:
Beckman Coulter Synchron® Analyzers

H. Device Description:

CLINIQA LiniCAL™ Esoterics Calibration Verifiers are human serum protein based, containing assayed constituents of chemically defined origin, including Immunoglobulin Fraction (IF), human albumin, ACS Reagent Grade of alcohol, ammonium chloride, and the sodium salt, Salicylic acid. Preservatives, stabilizers, and sodium azide have been added to maintain product integrity. They are manufactured without glycerol and glycol. The product is provided in liquid form and is ready to use.

Constituent concentrations in Level A are at the low end to allow assessment of the lower limit of the reportable range. Constituent concentrations in Level E are at the high end and 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. Levels B, C, and D provide intermediate constituent concentrations over the reportable range.

I. Substantial Equivalence Information:

1. Predicate device name(s):

LiniCAL Protein 1 Calibration Verifiers Levels A-E for Beckman Coulter Immage

2. Predicate K number(s):

K013332

3. Comparison with predicate:

Both are serum based products into which protein has been added, and they are manufactured using the same processes. They differ in terms of the constituents and their target concentrations.

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. Values are assigned by the following process:

Assays used to establish the values will be run by at least three laboratory groups, and will incorporate at least one independent control. A statistical method will be used to evaluate data for possible Outliers. After Outlier analysis, the data will be averaged to obtain a representative expected value for each constituent.

Assignment of values shall be performed using the Beckman Coulter Synchron® Analyzer reagents and calibrators, and independent controls available at the time of assay.

Stability: Real time stability studies of the first three lots of manufactured product will take place to establish expiration dating. Stability data is recorded at 3 month intervals over the life of the product to at least 110% of the expiration date. Vials of the

calibration verifiers are stored at 2-8 Degrees C. and are compared at each time point to vials stored at -70 degrees C. Each analyte in the product is tested at all five levels and should remain within 10% of the original value.

- 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):*
4. Clinical cut-off:
Not applicable.
5. Expected values/Reference range:

Representative Assigned Values From One Lot of Product

| Analyte | Method | Units | Level A Lot 123456 | Level B Lot 123457 | Level C Lot 123458 | Level D Lot 123459 | Level E Lot 123460 |
|---------|----------|--------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| AMM | SYNCHRON | µmol/L | 21.5 | 241 | 451 | 683 | 891 |
| ETOH | SYNCHRON | mg/dL | 12.0 | 147 | 269 | 413 | 531 |
| MA | SYNCHRON | mg/dL | 1.05 | 5.65 | 12.7 | 19.8 | 25.9 |
| M-TP | SYNCHRON | mg/dL | 8.0 | 49.5 | 68.5 | 101 | 123 |
| SALY | SYNCHRON | mg/dL | 6.05 | 25.5 | 46.1 | 68.2 | 86.1 |

M. Conclusion:

Substantially equivalent to predicate device.