

- I. 510(k) Number: K031575
- II. Analyte: LiniCAL™ Protein 2 Calibration
verifiers Levels A-E for Olympus®AU
Analyzers
- III. Type of test: Calibration Verification Material
- IV. Applicant Information:
- A. Name of Applicant: CLINIQA Corporation
- B. Mailing Address: 1432 South Mission Road
Fairbrook, CA 92028
- C. Phone #: 760-728-5205
- D. Fax #: 760-728-2902
- E. E-mail address (optional):
- F. Contact: Ms. Carol Ruggiero
Director, Regulatory Affairs
- V. Establishment Registration: 2085064
- VI. Regulatory Information:
- A. Regulation section: Class 1
- B. Classification: 862.1660
- C. Product Code: JJY –Multi-analyte Quality Control
Material (assayed and un assayed)
- D. Panel:
- VII. **Intended Use (per labeling)**:
- CLINIQA LiniCAL™ Protein 2 Calibration Verifiers are intended for use in the clinical laboratory to verify calibration and /or assess linearity of the Olympus®AU Analyzers. Five assayed levels of Anti Streptolysin O, C-Reactive protein, Compliment C3, Compliment C4, Ferritin, Immunoglobulin A, Immunoglobulin G, Immunoglobulin M, Prealbumin and Transferrin are provided to allow monitoring of reportable range.
- A. Special Instrument Requirements: OLYMPUS® AU Analyzers

- B. Special condition for use statement(s): None
- C. Indication for use: Allow monitoring of reportable range.

Device description: CLINIQA LiniCAL™ Protein 2 Calibration Verifiers are human serum based material with preservatives and stabilizers (sodium azide). The product is sold in liquid form (ready to use). Level A is to assess the lower limit of the reportable range. Level E is for assessing upper limit of reportable range. Levels BCD are intermediate concentrations .

VI. Substantial Equivalence Information:

- A. Predicate Device(s): CLINIQA Corporation's LiniCAL™ Protein 1 Calibration Verifiers Levels A-E for Beckman Coulter Image™
- B. Predicate K number(s): K013332
- C. Comparison with predicate: Predicate is for calibration of Beckman Coulter Immage® while the current calibration verifier is for Olympus AU Analyzers. Both devices are serum based products manufactured using the same process. The devices are different in constituents and target concentrations. The current one is optimized for the Olympus AU Analyzers.
- D. Standard/Guidance document referenced (if applicable):
NCCLS EP6 –for evaluation of linearity

VII. Test Principle: Not applicable

VIII. Performance and Stability Studies:

Five levels of LiniCAL protein 2 Calibration Verifiers for Olympus AU Analyzers (5 lots) were prepared by mixing human serum based sub fractions containing Anti-Streptolysin O, C-Reactive protein, Compliment 3, Compliment 4, Ferritin, Immunoglobulin A, Immunoglobulin G, Immunoglobulin M, Pre-albumin, and Transferrin.

The manufacturing target concentrations are based on the performance of the Olympus AU Analyzer. The concentrations have been tested for all 5 levels. The base line recovery data for all 5 levels of calibrators indicated that the concentrations were within pre-specified limits (approximately 10-20% of target concentrations).

Stability was determined using accelerated temperatures estimated from different temperature settings (e.g. 2-8, 25, 37, and 45 degree centigrade) using Arrhenius plot/model.

For open vial stability the vials were kept at 2-8 degree centigrade and brought to room temperature and tested using Olympus AU 400 Analyzers and appropriate assay reagents.

The stability for unopened vial at 2-8 degree centigrade is projected as 3.0 years based on the accelerated study data. Open vial stability at 2-8 degree centigrade is projected as 30 days.

A. Analytical Performance:

1. *Precision (intra-assay)/Reproducibility:* Not applicable

2. *Linearity/assay reportable range:* Not applicable

3. *Traceability/controls:*

IFCC reference preparation for plasma proteins CRM 470
WHO standard for ASO

4. *Detection limit (functional sensitivity):* Not applicable

5. *Analytical Specificity:* Not applicable

B. Comparison studies: Not applicable

1. *Matrix comparison:*

2. *Method comparison:*

3. *Clinical sensitivity:*

4. *Clinical specificity:*

C. Cut-off: Not applicable

D. Expected values/Reference range:

ASO IU/dL - 120 for level A and level E
CRP mg/dL - 0.870 for level A for level E
C3 mg/dL - 39.0 for level A and 485 for level E
C4 mg/dL - level A 13.0 and 119 for level E
FER mg/dL - level A 14.9 and 344 for level E
IgA mg/dL - level A 59.3 and for level E 676
IgG mg/dL - level A 339 and for level E 2629
IgM mg/dL - level A 42.6 and for level E 432
PAB mg/dL - level A 7.40 and level E 65.0
TRF mg/dL - level A 102 and level E 627

X. Conclusion: CLINQA Corporation's (previously known as International Enzymes) LiniCAL™ Protein 2 Calibration Verifiers Levels A-E for Olympus AU Analyzers is substantially equivalent to CLINIQA Corporations LiniCAL Protein 1 calibration verifiers used for Beckman Coulter Immage™.