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

A. 510(k) Number: K040927

B. Purpose of Submission: Change in the constituents and their target concentrations in the previously cleared product: LiniCAL™ Protein 4 Calibration Verifiers Levels A – E for Beckman Coulter Immage ™ (K022885)

C. Analyte: Rheumatoid Factor

D. Type of Test: Calibration Verification Material

E. Applicant: CLINIQA Corporation

F. Proprietary and Established Names: LiniCAL™ Protein 1 Calibration Verifiers Levels A – E for Olympus® AU Analyzers

G. Regulatory Information:
  1. Regulation section: 21 CFR §862.1660 Quality control material (assayed and unassayed).

  2. Classification: Class I

  3. Product Code: JJX

  4. Panel: 75

H. Intended Use:
  1. Intended use(s):

  LiniCAL™ Protein 1 Calibration Verifiers Levels A – E are assayed, liquid, quality control products which may be used to evaluate the performance of Olympus® AU Analyzers test system for Rheumatoid Factor (RF). These products are intended for use in the clinical laboratory to verify calibration and/or assess linearity of the Olympus® AU Analyzers. Five assayed levels are provided to allow monitoring of the reportable range.

  2. Indication(s) for use:

  LiniCAL™ Protein 1 Calibration Verifiers Levels A – E for Olympus® AU Analyzers is intended for use as an assayed quality control material for analysis.

3. <u>Special condition for use statement(s):</u>   Prescription Use

4. <u>Special instrument Requirements:</u>   The intended instruments are stated in the package insert.

I. Device Description:

LiniCAL™ Protein 1 Calibration Verifiers are human serum-based, containing constituents of human origin. Preservatives, stabilizers, and sodium azide have been added to maintain product integrity. LiniCAL™ Protein 1 Calibration Verifiers are manufactured without glycol thereby affording reproducibility pipetting characteristics and minimizing undesirable matrix effects. 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 portable 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.

J. Substantial Equivalence Information:
1. <u>Predicate device name(s):</u>

> LiniCAL™ Protein 4 Calibration Verifiers Levels A – E for Beckman Coulter Immage™

2. <u>Predicate K number(s):</u>

> K022885

3. <u>Comparison with predicate:</u>

General Information	LiniCAL™ Protein 4 Calibration Verifiers Levels A – E for Beckman Coulter Immage™	LiniCAL™ Protein 1 Calibration Verifiers Levels A – E for Olympus® AU Analyzers
501(k) Number	K022885	K040927
Product Code	JJY	JJX
Intended Use	For use in the clinical laboratory to verify calibration and/or assess linearity of the Beckman Coulter Immage® Protein Systems. Five assayed levels are provided to allow monitoring of the reportable range.	For use in the clinical laboratory to verify calibration and/or assess linearity of the Olympus® AU Analyzers. Five assayed levels are provided to allow monitoring of the reportable range.
Stability Claims	Stable until the expiration date on the vial label when stored	Stable until the expiration date on the vial label when stored

	unopened at 2-8 °C. Once opened, Clinical LiniCAL Protein 4 Calibration Verifiers are stable for 14 days when stored tightly capped at 2-8 °C.	unopened at 2-8 °C. Once opened, Clinical LiniCAL Protein 1 Calibration Verifiers are stable for 30 days when stored tightly capped at 2-8 °C.
Constituents	ALB[2]	
	PAB[2]	
	RF[3]	RF
Levels available	Five	Five
Contents	5x1.5 mL vial each level	5x1 mL vial each level

K. Standard/Guidance Document Referenced (if applicable):
FDA guidance "Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material".

L. Test Principle: NA

K. Performance Characteristics (if/when applicable):
1. Analytical performance:
   a. *Precision/Reproducibility*: NA

   b. *Linearity/assay reportable range:* NA

   c. *Traceability (controls, calibrators, or method):* The reagents, calibrators and controls used were those supplied by the manufacturer.

   Five level of LiniCAL™ Protein 1 Calibration Verifiers Levels A – E for Olympus® AU Analyzers, were prepared by blending together human serum based sub fractions containing RF to achieve the manufacturing targets listed in the following table 1:

   Table 1:

MANUFACTURING TARGETS					
Protein	Level A	Level B	Level C	Level D	Level E
RF (IU/mL)	27.0±7.4%	118±15.3%	237±15.2%	356±14.9%	490±6.1%

   The manufacturing targets are based on the performance of the Olympus® AU Analyzers.

The baseline recovery data for LiniCAL™ Protein 1 Calibration
Calibration Verifiers Levels A – E for Olympus® AU Analyzers are
listed in the following table 2:

Table 2:

BASELINE RECOVERY DATA					
Protein	Level A	Level B	Level C	Level D	Level E
RF (IU/mL)	29.0	109	214	324	501

The stability characteristics of LiniCAL™ Protein 1 Calibration
Verifiers Levels A – E for Olympus® AU Analyzers were determined
using real time stability studies to estimate product storage stability at 2-
8 °C by linear regression. The following assumption was made: if 90-
110% of the activity of the listed constituent is retained when compared
to a reference vial of the same lot stored at -70 °C and tested in the same
run, that constituent is considered to be stable for the real time period at
2-8 °C.

After each of the five levels of LiniCAL™ Protein 1 Calibration
Verifiers Levels A – E for Olympus® AU Analyzers was filled and
labeled, vials were placed at 2-8 °C and -70 °C. For real time stability
studies, vials were removed from 2-8 °C at selected time intervals and
tested. Vials placed at -70 °C were used for reference. Vials were
subsequently tested using Olympus® AU400 according to
manufacturer's instructions.

For open vial studies, "TEST" vials were removed from 2-8 °C, allowed
to warm to room temperature for 1-3 hours, opened briefly, swirled
gently, and resealed and placed back at 2-8 °C. "Baseline" vials were
maintained at 2-8 °C throughout the study interval. This procedure was
followed daily.

All vials were tested in-house using Olympus® AU400. The attached
data table (page 23 -28 of submitted 510(k) notice) contains the real time
stability data being used to substantiate the stability claims proposed.

The "Calculated Months to Failure" values were derived using linear
regression analysis to estimate failure at less than 90% or greater than
110% of original recovery of each constituent for each level. Based on
these failure estimates from the real time stability data, the predicted
storage stability of the product for Unopened Vial at 2-8 °C = 3.0 years,
and Open Vial at 2-8 °C = 30 days.

Minimum of 12 data points will be used to determine the mean (expected) values which are obtained from replicate assays obtained by multiple laboratories. Within and between assay Standard Deviations and Coefficient Variations (CV) will be calculated for each set of data. The Dixon Method for removing outliers from data sets of 3 through 25 observations will be used to analyze data sets with CVs greater than 10%. No more than 10% of a set of data will be removed as a statistical outlier. The data will be statistically averaged to obtain a representative expected value for each constituent.

    d. *Detection limit: NA*

    e. *Analytical specificity: NA*

    f. *Assay cut-off: NA*

2. <u>Comparison studies:</u>
    a. *Method comparison with predicate device: NA*

    b. *Matrix comparison: NA*

3. <u>Clinical studies:</u>
    a. *Clinical sensitivity: NA*

    b. *Clinical specificity: NA*

    c. *Other clinical supportive data (when a and b are not applicable):NA*

4. <u>Clinical cut-off:</u> NA

5. <u>Expected values/Reference range</u>: NA

N. Conclusion:
The submitted material in this premarket notification for LiniCAL™ Protein 1 Calibration Verifiers Levels A – E for Olympus® AU Analyzers is complete and supports a substantially equivalence decision based on the performance/stability and real time stability data.