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

A. 510(k) Number:

K081641

B. Purpose for Submission:

New Device

C. Measurand:

White Blood Cells (WBC), Red Blood Cells (RBC), Hemoglobin (HGB), Platelets (PLT)

D. Type of Test:

Quantitative

E. Applicant:

Beckman Coulter, Inc.

F. Proprietary and Established Names:

COULTER® LIN-X Linearity Control

G. Regulatory Information:

1. Regulation section:

    21 CFR 864.8625

2. Classification:

    Class II

3. Product code:

    JPK

4. Panel:

81 (Hematology)

H. Intended Use:

1. Intended use(s):

COULTER LIN-X linearity controls are intended to assess calibration and verify the reportable range of COULTER cellular analysis systems listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents.

2. Indication(s) for use:

COULTER LIN-X linearity controls are intended to assess calibration and verify the reportable range of COULTER cellular analysis systems listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

For use on the COULTER LH750 and COULTER LH780Hematology Analyzer, and the UniCel DxH 800 Cellular Analysis System.

I. Device Description:

COULTER LIN-X Linearity Control is a reference product prepared from treated, stabilized human erythrocytes in an isotonic medium. LIN-X Linearity Control also contains a stabilized, platelet-sized component, and fixed erythrocytes to simulate leukocytes. The WBC, RBC, HGB and PLT concentrations span the instrument's reportable range. Results from repeated measurements for each concentration are compared to the established expected range to assess the instrument's calibration and verify the reportable range.

COULTER LIN-X Linearity Control is a multi-level control product manufactured in vial (3.3ml) configurations (levels 0-11).

J. Substantial Equivalence Information:

1. Predicate device name(s):

COULTER® LIN-C® Linearity Control (Cleared as COULTER® Linearity Controls)

CBC-Line Hematology Linearity Kit, R&D Systems, Inc.

2. Predicate K number(s):

K955334, K061064
K942822

3. Comparison with predicate:

Similarities		
	COULTER® LIN-X Linearity Control	*COULTER® LIN-C® Linearity Control*
Intended use	Same except calibration assessment added.	COULTER LIN-C linearity controls are intended to verify the reportable range of COULTER hematology analyzers
Final Product Form	Same except twelve levels (Levels 0-11)	Eleven levels (Levels 0-10), liquid, ready to use reagent
Cellular Parameters	Same	Erythrocytes, Platelets, Monocytes
Range Covered	Same for WBC, RBC, and HGB PLT: 0 - 5000 x 10^3	WBC: 0 - 400 x 10^3 RBC: 0 - 8.0 x 10^6 HGB: 0 - 25 PLT: 0 - 3000 x 10^3
Expected Values Provided	• Assay values and expected ranges provided for each assayed parameter per level which result in a narrower acceptable recovery range relative to LIN-C controls for most parameter levels. • Acceptable maximum value recovery provided for Level 0.	Acceptable ranges (low and high values) provided for each assayed parameter per level.
Open vial stability	7 days when stored at 2 - 8°C	Same
Closed Vial Stability	120 Days when stored at 2 8°C	Same

Differences		
Item	*COULTER® LIN-X Linearity Control*	*COULTER® LIN-C® Linearity Control*
Analyzers	COULTER® LH 750, COULTER® LH 780, COULTER® UniCel® DxH 800 Cellular Analysis System	COULTER® LH 780, LH 750, LH 500, GenS, HmX, MaxM, MaxM A/L, Onyx, AcT Series, AcT Diff, AcT Diff 2, MD, MD II, T Series, JT, JT2/3, STKS

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

Not applicable.

L. Test Principle:

CLIA requires that laboratories establish and verify the performance specification, accuracy, precision and reportable range, of new instrumentation upon installation, following significant preventive maintenance, unusual trends / shifts in control recovery or when recommended by the instrument manufacturer. COULTER LIN-X Linearity controls can be used on calibrated instruments to comply with these guidelines. The product's WBC, RBC, HGB and PLT concentrations span the instrument's reportable range. Results from repeated measurements for each concentration are compared to the established expected range, to asses the instrument's calibration and to verity the reportable range.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Reproducibility and precision is captured within the range determination study with data generated from two studies: 1) closed vial stability and 2) open vial stability.

   b. *Linearity/assay reportable range:*

   Not applicable.

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

   Value assignment: Value assignments for each lot are determined on validated systems using Beckman Coulter reagents on appropriate instruments. One hundred ten (110) vials from each lot are taken randomly throughout the production run. For each values assignment process, two assay runs are required on the appropriate instrument on separate days. Four to six sample tubes are analyzed for each assay run. An assay computer system is used to determine the number of replicates required for each assay run and analyze the data in real time. Zero biased, equilibration adjusted data and the raw instrument assay run data is used to determine the final value assignment. The value assignments are confirmed by analyzing one to two tubes for a total of 10 aspirations on the appropriate instrument.

   Open vial stability: Open vial testing consists of six aspirations from two vials per level repeated once a month. Multiple lots of the new level of LIN-X Linearity Control (Level 10) were tested monthly. Two vials were evaluated at each time point. For samples analyzed on the LH 750, 1:1 dilutions were prepared at each time point since the Platelet count exceeded the linear range of the instrument. On the LH 750 Hematology Analyzer, a single run was performed on Day 1 to initiate the open vial condition followed by six runs on

Day 7 to validate the open vial claim of seven days. On the DxH 800 Cellular Analysis System, six runs were performed on both Day 1 and Day 7. The mean recovered values were compared to the assay values and expected ranges for the additional level.

Closed vial stability: Closed vial testing consisted of six aspirations taken from one vial per level approximately 3 times per month. Multiple lots of the new level of LIN-X Linearity Control (Level 10) were tested 3 times per month. For samples analyzed on the LH 750, 1:1 dilutions were prepared at each time point since the Platelet count exceeded the linear range of the test instrument. The mean recovered values were compared to the assay values and expected ranges for the additional level.

Calibration Assessment Study: LIN-X linearity controls and CBC-Line linearity controls (predicate) were tested on four instruments to demonstrate that they yield equivalent results for calibration assessment / verification. LIN-X linearity control results were assess against the assay values and expected ranges.

Table 1: Summary Statistics for Level 10 Platelet on LH 750 with LH Series Reagents

	Set 2	Set 3	Set 4	Set 5
Mean	4949	4741	4741	4504
SD	228.3	355.5	355.5	158.4
%CV	4.6	7.5	7.5	3.5

Table 2: Summary Statistics for Level 10 Platelet on LH 750 with System V Reagents

	Set 2	Set 3	Set 4	Set 5
Mean	4831	4704	5170	4645
SD	244.5	330.0	174.5	148.3
%CV	5.1	7.0	3.4	3.2

Table 3: Summary Statistics for Level 10 Platelet on DxH 800 Cellular Analysis System

	9021BC-853
Mean	5072
SD	112.7
%CV	2.2

d. *Detection limit:*

Not applicable.

    e. Analytical specificity:

Not applicable.

    f. Assay cut-off:

Not applicable.

2. <u>Comparison studies:</u>

    a. Method comparison with predicate device:

Not applicable.

    b. Matrix comparison:

Not applicable.

3. <u>Clinical studies:</u>

    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. <u>Clinical cut-off</u>**:**

Not applicable.

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

The expected ranges were established for each level statistically, based on data collected on multiple instruments and lots controls using specific Beckman Coulter reagents. Total variability is calculated for each parameter. The expected ranges are based on system performance and provided in the Table of Expected Results.

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.