

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

A. 510(k) Number:

K081822

B. Purpose for Submission:

New Device

C. Measurand:

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, LY
(%/#), MO (%/#) NE (%/#), EO (%/#), BA (%/#), NRBC (%/#)

D. Type of Test:

Quantitative and Qualitative

E. Applicant:

Beckman Coulter, Inc.

F. Proprietary and Established Names:

COULTER[®] 6C Cell 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® 6C Cell Control is a hematology quality control material used to monitor the performance of COULTER hematology analyzers listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents.

The assigned values and expected ranges on the TABLE OF EXPECTED RESULTS can be used to monitor instrument performance. This product can also be used to establish your own laboratory mean.

2. Indication(s) for use:

COULTER® 6C Cell Control is a hematology quality control material used to monitor the performance of COULTER hematology analyzers listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents.

The assigned values and expected ranges on the TABLE OF EXPECTED RESULTS can be used to monitor instrument performance. This product can also be used to establish your own laboratory mean.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

For use on COULTER® UniCel DxH 800

I. Device Description:

COULTER® 6C Cell Control is a hematology quality control mixture intended to be used with automated cell counters and differential cell counters. It is prepared from stabilized human blood so that repeated measurements by an automated cell counter, or differential cell counter, can be made to monitor instrument daily performance. It consists of treated, stabilized human erythrocytes, a stabilized platelet sized component, and fixed erythrocytes that simulate leukocytes and nucleated red blood cells. Three levels of varying component concentrations (Level 1, Level 2, and Level 3) are supplied.

J. Substantial Equivalence Information:

1. Predicate device name(s):

COULTER® 5C® Cell Control, COULTER® PX Cell Control

2. Predicate K number(s):

K912133, K060464

3. Comparison with predicate:

Similarities	<i>COULTER® 6C Cell Control</i>	<i>COULTER® 5C® Cell Control</i>
Intended use	A hematology quality control material used to monitor the performance of COULTER hematology analyzers listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents. The assigned values and expected ranges on the TABLE OF EXPECTED RESULTS can be used to monitor instrument performance. This product can also be used to establish your own laboratory mean.	Same.
Product Description	Same plus integrated Nucleated Red Blood Cell analog.	Consist of treated, stabilized human erythrocytes in an isotonic medium. It also contains a stabilized platelet-sized component, and fixed erythrocytes to stimulate leukocytes.
Cellular Parameters	Same plus Nucleated Red Blood Cells.	Erythrocytes, Platelets, Lymphocytes, Monocytes, Neutrophils and Eosinophils
Assayed Parameters	Same plus NRBC% and NRBC#	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, LY (%/#), MO (%/#), NE (%/#), EO (%/#), BA (%/#)
Closed Vial Stability	95 days when stored at 2-8°C	Same

Differences		
<i>Item</i>	<i>COULTER® 6C Cell Control</i>	<i>COULTER® 5C® Cell Control</i>
Open vial stability	18 events over 16 days when stored at 2-8°C	13 events over 13 days when stored at 2-8°C

Differences		
Item	COULTER® 6C Cell Control	COULTER® 5C® Cell Control
Analyzers	UniCel® DxH 800	COULTER® LH 780, LH 750, GENS*S, STKS, LH 500, HmX, HmX w/ Autoloader, MAXM & MAXM w/ Autoloader

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

Not applicable.

L. Test Principle:

COULTER® 6C Cell Control is a reference product prepared from stabilized human blood. By design, COULTER® 6C Cell Control confirms and monitors instrument accuracy and precision performance by providing measurements for counting, sizing, hemoglobin determination, NRBC enumeration and White Blood Cell differentiation using VCSn technology.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Reproducibility and precision is captured within the range determination study.

Table 1a: Level 1 Summary Statistics

	WBC	RBC	Hgb	HCT	MCV	MCH	MCHC	RDW	RDW-SD	PLT	MPV
Lot 1 (Red data series)											
Mean	3.2	1.89	5.2	15.4	81.4	27.5	33.8	16.9	49.5	71	9.3
SD	0.04	0.02	0.04	0.23	1.72	0.17	0.69	0.22	1.27	1.55	0.33
%CV	1.3	0.9	0.8	1.5	2.1	0.6	2.0	1.3	2.6	2.2	3.5
Lot 2 (Yellow data series)											
Mean	3.2	1.73	4.6	13.9	80.5	26.9	33.4	17.1	49.1	71	9.1
SD	0.04	0.02	0.04	0.29	2.35	0.21	0.86	0.35	0.67	1.83	0.31
%CV	1.2	1.2	0.8	2.1	2.9	0.8	2.6	2.1	1.4	2.6	3.4
Lot 3 (Green data series)											
Mean	3.2	1.79	4.9	14.5	80.8	27.4	33.9	15.2	44.8	70	9.1
SD	0.04	0.02	0.04	0.14	1.01	0.16	0.40	0.35	0.87	1.67	0.32
%CV	1.2	1.0	0.7	1.0	1.3	0.6	1.2	2.3	1.9	2.4	3.6

Table 1b: Level 1 Summary Statistics

	Ly%	Ly#	Mo%	Mo#	Ne%	Ne#	Eo%	Eo#	Ba%	Ba#	NRBC%	NRBC#
Lot 1 (Red data series)												
Mean	40.6	1.31	6.1	0.2	48.9	1.6	4.3	0.1	0.0	0.0	0.5	0.02
SD	0.74	0.03	0.37	0.01	0.68	0.03	0.33	0.01	0.02	0.00	0.14	0.00
%CV	1.8	2.2	6.0	6.2	1.4	2.1	7.6	7.4	88.1	87.9	27.9	28.0
Lot 2 (Yellow data series)												
Mean	41.3	1.31	6.4	0.2	50.0	1.6	2.3	0.1	0.0	0	0.5	0.02
SD	0.75	0.03	0.37	0.01	0.76	0.03	0.45	0.01	0.02	0.00	0.11	0.00
%CV	1.8	2.1	5.8	6.1	1.5	1.9	19.2	19.4	83.2	83.3	22.3	22.3
Lot 3 (Green data series)												
Mean	40.5	1.31	6.2	0.2	49.1	1.6	4.2	0.1	0.0	0	0.5	0.02
SD	0.74	0.03	0.36	0.01	0.74	0.03	0.32	0.01	0.02	0.00	0.12	0.00
%CV	1.8	2.0	5.8	6.1	1.5	2.1	7.5	7.6	99.1	99.1	25.1	25.6

Table 2a: Level 2 Summary Statistics

	WBC	RBC	Hgb	HCT	MCV	MCH	MCHC	RDW	RDW-SD	PLT	MPV
Lot 1 (Red data series)											
Mean	21.4	4.01	12.8	36.2	90.2	31.8	35.2	14.9	49.6	436	9.6
SD	0.22	0.04	0.10	0.39	0.68	0.28	0.41	0.17	0.81	8.84	0.36
%CV	1.0	1.0	0.8	1.1	0.7	0.9	1.2	1.1	1.6	2.0	3.7
Lot 2 (Yellow data series)											
Mean	21.4	4.00	12.4	35.2	87.9	31.0	35.3	15.2	49.4	435	9.6
SD	0.21	0.03	0.11	0.39	0.88	0.26	0.47	0.24	1.24	8.69	0.35
%CV	1.0	0.8	0.9	1.1	1.0	0.8	1.3	1.6	2.5	2.0	3.6
Lot 3 (Green data series)											
Mean	21.8	4.05	12.6	35.5	87.8	31.0	35.3	14.2	46.4	431	9.6
SD	0.26	0.04	0.12	0.36	0.50	0.32	0.39	0.24	0.80	7.82	0.34
%CV	1.2	1.0	1.0	1.0	0.6	1.0	1.1	1.7	1.7	1.8	3.6

Table 2b: Level 2 Summary Statistics

	Ly%	Ly#	Mo%	Mo#	Ne%	Ne#	Eo%	Eo#	Ba%	Ba#	NRBC%	NRBC#
Lot 1 (Red data series)												
Mean	11.6	2.47	16.1	3.4	67.1	14.4	5.2	1.1	0.0	0	7.8	1.68
SD	0.46	0.10	0.57	0.13	0.67	0.20	0.31	0.07	0.02	0.00	0.35	0.07
%CV	4.0	4.1	3.5	3.7	1.0	1.4	6.0	6.2	57.0	57.1	4.4	4.2
Lot 2 (Yellow data series)												
Mean	11.6	2.49	15.9	3.4	66.9	14.3	5.4	1.2	0.0	0	7.6	1.62
SD	0.52	0.12	0.53	0.11	0.57	0.19	0.32	0.07	0.02	0.00	0.32	0.07
%CV	4.5	4.7	3.4	3.3	0.8	1.3	5.9	6.2	60.5	60.4	4.2	4.1
Lot 3 (Green data series)												
Mean	11.3	2.47	16.1	3.5	67.2	14.7	5.4	1.2	0.0	0	7.4	1.61
SD	0.45	0.10	0.49	0.12	0.71	0.24	0.35	0.08	0.02	0.01	0.32	0.07
%CV	4.0	4.1	3.0	3.3	1.1	1.6	6.4	6.6	61.6	61.8	4.3	4.2

Table 3a: Level 3 Summary Statistics

	WBC	RBC	Hgb	HCT	MCV	MCH	MCHC	RDW	RDW-SD	PLT	MPV
Lot 1 (Red data series)											
Mean	8.1	5.40	16.8	49.0	90.6	31.1	34.3	14.7	49.7	234	9.9
SD	0.15	0.06	0.16	0.61	1.31	0.23	0.52	0.56	2.54	3.98	0.37
%CV	1.9	1.1	1.0	1.2	1.4	0.7	1.5	3.8	5.1	1.7	3.7
Lot 2 (Yellow data series)											
Mean	8.2	5.39	16.4	47.5	88.1	30.4	34.4	14.8	48.6	235	9.9
SD	0.14	0.04	0.14	0.45	0.83	0.17	0.40	0.28	1.32	3.72	0.37
%CV	1.7	0.8	0.9	1.0	0.9	0.6	1.2	1.9	2.7	1.6	3.7
Lot 3 (Green data series)											
Mean	8.3	5.16	15.5	45.0	87.2	30.0	34.4	14.8	47.9	234	9.8
SD	0.12	0.05	0.16	0.47	0.94	0.20	0.47	0.25	1.17	3.96	0.37
%CV	1.4	0.9	1.0	1.0	1.1	0.7	1.4	1.7	2.4	1.7	3.8

Table 3b: Level 3 Summary Statistics

	Ly%	Ly#	Mo%	Mo#	Ne%	Ne#	Eo%	Eo#	Ba%	Ba#	NRBC%	NRBC#
Lot 1 (Red data series)												
Mean	25.4	2.07	8.3	0.7	58.4	4.7	7.8	0.6	0.0	0	17.0	1.38
SD	0.67	0.07	0.43	0.04	0.85	0.10	0.46	0.04	0.02	0.00	0.56	0.04
%CV	2.7	3.6	5.2	5.6	1.5	2.0	5.8	6.5	66.2	66.4	3.3	3.1
Lot 2 (Yellow data series)												
Mean	25.1	2.05	8.5	0.7	59.0	4.8	7.4	0.6	0.0	0	16.4	1.34
SD	0.66	0.06	0.46	0.04	0.70	0.10	0.33	0.03	0.02	0.00	0.66	0.05
%CV	2.6	3.0	5.5	5.6	1.2	2.1	4.5	4.8	57.9	57.9	4.0	3.5
Lot 3 (Green data series)												
Mean	25.0	2.07	8.4	0.7	58.7	4.9	7.9	0.7	0.0	0	15.9	1.32
SD	0.54	0.05	0.49	0.04	0.69	0.09	0.40	0.03	0.02	0.00	0.61	0.05
%CV	2.2	2.6	5.8	6.0	1.2	1.9	5.1	5.3	57.8	57.9	3.8	3.8

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.

6C Cell Control Level 1 does not contain any NRBC analog particles, thus assigned values are not generated for each lot. Instead, fixed acceptable upper limits for NRBC% and NRBC# were developed by the bio-statisticians. As part of product release testing, recovery within these limits is verified for each lot manufactured.

Open and Closed stability (tested on the UniCel® DxH 800 analyzer): Three lots of each level were evaluated throughout the product's shelf life (conducted at the beginning, middle, and end). The open vial claim for this product is 18 events within 16 days. The material was tested until at least 18 aspirations per tube (2 tubes) were taken and the open container date reached at least 16 calendar days. Storage temperature for products tested was 2-8°C. Closed vial stability is 95 days. To capture instrument variability, the testing was conducted on one to four instruments. The recovered values were compared to assay values established at the beginning of the test interval and the expected ranges to assess the product's stability.

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:

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 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.