

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k111534

B. Purpose for Submission:

New device

C. Manufacturer and Instrument Name:

Diatron US Inc., Abacus 3CP

D. Type of Test or Tests Performed:

Quantitative test for WBC, LYM%, LYM#, MID%, MID#, GRA%, GRA#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, and MPV parameters.

E. System Descriptions:

1. Device Description:

The Abacus 3 Cap Piercer (Abacus 3CP) is a fully automated, bench top hematology cell counter. It uses the impedance-method for counting cells passing through a small aperture, and measures the hemoglobin content of red blood cells using a photometric method.

The analyzer features a color graphical LCD display module and a foil keypad of 29 keys including 6 software buttons (with icons), 6 function keys (above LCD) and has a START button. The Abacus 3CP instrument requires 100 uL of K₃EDTA anti-coagulated venous whole blood sample and can process 60 samples per hour. The Abacus 3CP hematology analyzer is composed of a Fluidic System, Data Processing System and a Control Panel.

2. Principles of Operation:

It uses the impedance-method for counting cells passing through a small aperture, and measures the hemoglobin content of red blood cells using a photometric method. The Diatron Abacus 3CP System uses electronic sizing to determine three distinct white cell subpopulations. Cells correlating to lymphocytes are included in the small cell subpopulation. Cells correlating to granulocytes are included in the large cell population. The remaining cells correlating to monocytes, basophils, eosinophils, blasts, and other precursor white cells are included in the mid-size cell population. The MCV and RDW values are derived from statistical analysis of the RBC histogram. The HCT, MCH, and MCHC are calculated values. The MPV value is derived from statistical analysis of the PLT histogram.

3. Modes of Operation:

The Abacus 3CP operates in both open and closed sample tube mode.

4. Specimen Identification:
The sample ID can be entered by the operator from a keyboard or hand held barcode reader for a manually processed specimen. For automatically processed specimens, the sample ID can be read from a sample tube barcode or entered into a list for one of the automatic processing list modes.
5. Specimen Sampling and Handling:
Manually presented whole blood K₃EDTA sample tubes must be mixed properly prior to specimen analysis. Sample tubes are placed into a tube adapter inserted on the sample rotor for closed vial or open vial single tube manual sample processing.
6. Calibration:
The Abacus 3CP analyzer calibration is calibrated using a commercial calibrator. The known calibrator parameter values and measured values are used to calculate calibration factors. Diatron recommends performing calibration at installation, when indicated by quality control, after major maintenance or service, and at periodic time intervals as directed by laboratory regulatory agencies.
7. Quality Control:
Diatron recommends the use of CBC-3D controls from R&D Systems to verify performance of the Abacus 3CP. Quality control is performed at intervals established by the laboratory or as required by laboratory accreditation, licensing, or regulatory agencies.
8. Software:
FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:
Yes or No

F. Regulatory Information:

1. Regulation section:
21 CFR § 864.5220, Automated differential cell counter
2. Classification:
Class II
3. Product code:
GKZ, Counter, differential cell
4. Panel:

Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

The Diatron Abacus 3CP System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro-diagnostic use in clinical laboratories for enumeration of the following parameters: WBC, LYM%, LYM#, MID%, MID#, GRA%, GRA#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV in K₃EDTA anti-coagulated venous whole blood samples. The Diatron Abacus 3CP is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.

2. Special Conditions for Use Statement(s):

For Prescription Use Only

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

Abbott CELL-DYN 1800 (k030513)

2. Comparison with Predicate Device:

Similarities		
Item	Device Abacus 3CP	Predicate CELL-DYN 1800
Intended Use	The Diatron Abacus 3CP System is a quantitative multi-parameter automated hematology analyzer designed for in vitro diagnostic use in clinical laboratories for enumeration of the following parameters WBC, LYM%, LYM#, MID%, MID#, GRA%, GRA#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV in K ₃ EDTA anticoagulated venous whole blood samples. Diatron Abacus 3CP is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.	The CELL-DYN 1800 System is an automated, multiparameter hematology analyzer designed to report sixteen parameters relating to the cells of EDTA-anticoagulated blood.
IVD Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYMPH%/#, MID%/#, GRA%/#, RDW, MPV	Same

Item	Device Abacus 3CP	Predicate CELL-DYN 1800
Principle of Measurement	Uses the impedance method for counting White Blood Cell (WBC) including Lymphocytes, Monocytes and Neutrophil granulocytes, Red Blood Cell (RBC), and platelet (PLT) passing through a small aperture and uses the photometric method to measure the hemoglobin content of red blood cells. The instrument analyzes whole blood samples from open vials and can be upgraded with a vial piercing option to be used with closed vials.	Same
Sample types	Whole Blood (K ₃ EDTA)	Same
Sample Container	Open and Closed	Same
Sample System	Manual	Same
Samples/hour	60	Same
Sampling Mechanisms	Manual sampling (open tube mode) Closed vial mode Autosampler cap piercing	Same
Sample ID	Manual and barcode	Same
Methodology	WBC Differential-Optical RBC, PLT- Impedance HGB – Photometric MCV- Derived	Same
Aperture Diameter (µm)	WBC 100µm RBC/PLT 80µm	Same
QC data	Maintains QC files; generated Levy-Jennings charts	Same

Differences		
Item	Device Abacus 3CP	Predicate CELL-DYN 1800
Sample Volume (µL)	Open Vial Mode – 100 µL Closed Vial Mode - 100 µL	Open Vial Mode – 30 µL Closed Vial Mode - 450 µL
Calibrator	CBC-Cal Plus Calibrator (k003991)	CELL-DYN 18 Plus Calibrator
Quality Control	R&D CBC 3D Cell Control (k843962)	CELL-DYN 18 Plus Controls
Reagents	Diatro•Dil-DIFF (diluent) Diatro•Lyse-DIFF(lysing reagent) Diatro•Cleaner (cleaner)	CN-Free Diff Lyse, detergent and lysing reagents

I. Special Control/Guidance Document Referenced (if applicable):

CLSI EP05-A2 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition

CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP09-A2, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition

CLSI EP17-A Protocols for the Determination of Limits of Detection and Limits of Quantitation; 1st Edition

CLSI H26-A2 Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; 2nd Edition

CLSI C28-A3 Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; 3rd Edition

CLSI EP07-A2 Interference Testing in Clinical Chemistry; Second Edition

J. Performance Characteristics:

1. Analytical Performance:

a. *Accuracy:*

Each parameter of the Abacus 3CP was compared to the predicate analyzer, Cell-Dyn 1800. A total of 656 samples were analyzed at three (3) sites in the U.S. Patient demographics include age range from >2 to >80 years of age. Fifty-seven percent (n = 367) samples were normal and 36% (n = 277) had one or more abnormal conditions. In addition, 37.4% were male and 62.6% were female. The correlation analysis was performed using the first replicate of the Abacus 3CP against the first replicate of the Cell-Dyn 1800. Accuracy summary data analysis is provided in the tables below:

Regression Results

(n = 656)			Intercept 95% CI			Slope 95% CI		Acceptance Criteria	
Parameter	Range	(r)	Intercept	Lower	Upper	Slope	Lower		Upper
WBC	0.4 - 77.1	0.9987	-0.0285	-0.1300	0.0731	0.9866	0.9731	1.0000	0.30 or 6%
GRA%	7.9 - 96.7	0.9137	1.5956	-0.7747	3.9658	0.9749	0.9388	1.0109	3.00 or 10%
LYM%	1.4 - 77.7	0.9352	-1.3378	-2.5059	-0.1696	1.0523	1.0069	1.0977	3.00 or 10%
MID%	2.2 - 37.8	0.8515	-1.0994	-1.7549	-0.4439	1.0849	1.0181	1.1518	3.00 or 10%
RBC	0.5 - 7.8	0.9965	-0.1007	-0.1246	-0.0769	1.0304	1.0240	1.0367	0.15 or 6%
HGB	1.3 - 23.4	0.9982	0.1915	0.1414	0.2415	0.9869	0.9826	0.9911	0.30 or 6%
MCV	65.6 - 114	0.9866	1.6424	0.5211	2.7637	0.9845	0.9721	0.9969	1.00 or 6%
RDW	11.8-25.3	0.9126	0.3061	-0.4101	1.0223	0.9737	0.9242	1.0233	0.50 or 6%
PLT	15 - 1168	0.9920	-1.4551	-5.1098	2.1996	1.0348	1.0185	1.0511	15 or 8%
MPV	7.3 - 18.2	0.8805	-0.0438	-0.5992	0.5117	1.0085	0.9543	1.0628	0.50 or 10%

Conclusion: The absolute value of the calculated predictive bias of all clinical decision points and range points were below the predictive bias goals for the points determined

from the acceptance criteria for all parameters. Therefore, the method comparison evaluation is considered to meet its acceptance criteria and all the requirements of the data collection and its evaluation.

Predictive Value of Abacus 3CP vs. Microscopy (Reference Method)

The ability of the Abacus 3CP to flag abnormal samples was evaluated per CLSI H20-A2 in comparison with the reference method (Manual Microscopy). A total of 212 samples were analyzed on the Abacus 3CP in combination with manual differential reviews. The WBC distributional flagging statistical analysis was performed 2 ways and the data are summarized in the tables below:

Binned manual differential analysis per CLSI H20-A2:

This approach counted the total number of monocytes, eosinophils, basophils, immature granulocytes and blast cells represented in a reference sample and determined whether this total value was outside of the expected reference range for “MID” cells. If that sample was outside the reference range for “MID” cells then it was considered in this analysis to be distributionally positive for the reference sample.

3-Part Diff Performance vs Manual Diff (binned manual diff data) per CLSI H20-A2		
	% Positive Agreement	% Negative Agreement
Overall	81.4%	96.6%
Lymph	86.1%	98.3%
Mid Cells	33.3%	97.3%
Grans	81.4%	97.6%

Unbinned manual differential analysis:

This approach counted each cell type, monos, eos, basos, immature grans and blasts, represented in a reference sample and determined whether the individual population was outside of the expected reference range for that particular population. If any individual cell type, monos, eos, basos, immature grans or blasts, was outside of its individual expected reference range, then it would be considered in this analysis to be distributionally positive for “MID” cells for the reference sample.

3-Part Diff Performance vs Manual Diff (unbinned manual diff data)		
	Sensitivity	Specificity
Overall	58.0%	97.4%
Lymph	86.1%	98.3%
Mid Cells	16.7%	99.1%
Grans	81.4%	97.6%

Conclusions: The results of the comparison of the predictive value of the Abacus 3CP versus the manual differential demonstrated performance expected for

instruments of this class (3-part differential). The overall sensitivity result is attributed to the effect of binning to a 3-part differential and was found to be comparable to other devices reporting a 3-part differential.

b. Precision/Reproducibility:

Repeatability

The Abacus 3CP repeatability evaluation was conducted using 23 human blood samples and three levels of control. The samples were selectively chosen to span the analytical measuring range and to be close to clinical decision points on two Abacus 3CP instruments. A minimum of 15 and a maximum of 21 replicates were run for each sample. All repeatability runs passed either their SD or CV criteria for all parameters for both instruments according to the acceptance criteria.

The following tables represent reproducibility and precision. Two replicates of a single lot of commercial low, normal, and high control samples were run twice per day at three different sites for 20 working days. The data from three instruments was analyzed to determine the overall mean and precision for between-site, between-day, within-day, and within-device. Within-day variation represents the variability between AM and PM runs pooled across the 20 days.

Low Control	WBC	LYM%	MID%	GRA%	RBC	HGB	MCV	RDW	PLT	MPV
Repeatability SD	0.058	2.194	1.658	2.387	0.05	0.087	0.299	0.024	3.283	0.285
Repeatability CV	1.54%	3.88%	15.9%	7.23%	1.97%	1.34%	0.39%	1.52%	4.94%	3.84%
Repeatability SD acceptance criteria	0.18	3.1	2.00	3.50	0.11	0.20	1.00	0.4	23	0.45
Repeatability CV Criteria	2.70%	8.0	17.0	8.0	1.70%	2.00%	1.70%	2.50%	6.00%	8.70%
Repeatability Pass/Fail	Pass									

Normal Control	WBC	LYM%	MID%	GRA%	RBC	HGB	MCV	RDW	PLT	MPV
Repeatability SD	0.127	0.74	0.438	0.805	0.09	0.159	0.373	0.25	6.344	0.19
Repeatability CV	1.64%	2.37%	5.08%	1.33%	1.85%	1.12 %	0.42%	1.69%	2.65%	2.58%
Repeatability SD acceptance criteria	0.18	3.1	2	3.5	0.11	0.20	1.00	0.40	23	0.45
Repeatability CV acceptance criteria	2.70%	8.0	17.0	8.0	1.70%	2.00%	1.70%	2.50%	6.00%	8.70%
Repeatability Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

High Control	WBC	LYM%	MID%	GRA%	RBC	HGB	MCV	RDW	PLT	MPV
Repeatability SD	3.48	0.672	0.347	0.656	0.107	0.259	0.345	0.189	11.028	0.134
Repeatability CV	1.74%	4.14%	4.87%	0.85%	1.85%	1.37%	0.35%	1.36%	2.31%	1.74%
Repeatability SD acceptance criteria	0.18	3.1	2.0	3.50	0.11	0.20	1.00	0.40	23.00	0.45
Repeatability CV acceptance criteria	2.70%	8.0%	17.0%	8.0%	1.70%	2.00%	1.70%	2.50%	6.00%	8.70%
Repeatability Pass/Fail	Pass	Pass								

Reproducibility

The following tables represent reproducibility. Two replicates of a single lot of commercial low, normal, and high control samples were run twice per day at three different sites for 20 working days. The data from three instruments was analyzed to determine the overall mean and precision for between-site, between-day, within-day, and within-device. Within-day variation represents the variability between AM and PM runs pooled across the 20 days. Acceptance criteria for each reproducibility study are represented under within-device CV or SD. Acceptance criteria were met for each parameter.

Low Control	WBC	LYM%	MID%	GRA%	RBC	HGB	MCV	RDW	PLT	MPV
Mean (n = 240)	2.019	56.601	10.375	32.991	2.533	6.453	77.15	15.78	66.438	7.418
Between-Site SD	0.103	0.703	0.293	1.058	0.034	0.018	0.637	0.046	1.535	0.309
Between-Site CV	5.10%	1.24%	2.82%	3.21%	1.34%	0.28%	0.83%	0.29%	2.31%	4.17%
Between-Day SD	0.064	0	0.303	0.417	0.005	0.07	0.548	0.031	2.586	0.152
Between-Day CV	3.17%	0.00%	2.92%	1.26%	0.20%	1.08%	0.71%	0.20%	3.89%	2.05%
Within-Day SD	0.031	0	0	0	0.023	0.047	0.211	0.044	2.659	0.07
Within-Day CV	1.54%	0.00%	0.00%	0.00%	0.91%	0.73%	0.27%	0.28%	0.28%	0.94%
Within-Device SD*	0.092	2.194	1.686	2.423	0.055	0.121	0.659	0.246	4.953	0.33
Within-Device CV	4.53%	3.88%	16.2%	7.34%	2.18%	1.88%	0.85%	1.56%	7.46%	4.45%
SD acceptance criteria	0.40	3.10	2.0	3.5	0.15	0.22	1.2	0.45	27	0.5
CV acceptance criteria	4.00%	8.00%	17.0%	8.0	2.50%	2.40%	2.00%	3.00%	7.00%	10.0%
Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Normal Control	WBC	LYM%	MID%	GRA%	RBC	HGB	MCV	RDW	PLT	MPV
Mean (n = 240)	7.745	31.247	8.614	60.139	4.859	14.169	87.829	14.811	239.168	7.363
Between-Site SD	0.148	0.321	0.256	0.55	0.058	0.149	0.34	0.11	3.714	0.231
Between-Site CV	1.91%	1.03%	2.97%	0.91%	1.19%	1.05%	0.39%	0.74%	1.55%	3.14%
Between-Day SD	0.085	0.361	0	0.492	0.051	0.127	0.385	0.083	4.601	0.086
Between-Day CV	1.10%	1.16%	0.00%	0.82%	1.05%	0.90%	0.44%	0.56%	1.92%	1.17%
Within-Day SD	0.104	0.046	0.071	0.188	0.016	0.108	0.186	0	3.731	0
Within-Day CV	1.34%	0.15%	0.82%	0.31%	0.33%	0.76%	0.21%	0.00%	1.56%	0.00%
Within-Device SD*	0.185	0.824	0.443	0.962	0.105	0.23	0.567	0.263	8.68	0.209
Within-Device CV	2.39%	2.64%	5.14%	1.60%	2.15%	1.62%	0.65%	1.78%	3.63%	2.84%
SD acceptance criteria	0.4	3.1	2	3.5	0.15	0.22	1.2	0.45	27	0.5
CV acceptance criteria	4.00%	8.0%	17.0%	8.0	2.50%	2.40%	2.00%	3.00%	7.00%	10.0%
Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

High Control	WBC	LYM%	MID%	GRA%	RBC	HGB	MCV	RDW	PLT	MPV
Mean (n = 240)	20.02	16.24	7.12	76.64	5.771	18.916	98.026	13.873	477.739	7.703
Between-Site SD	0.679	0.160	0.313	0.279	0.131	0.190	0.175	0.074	14.952	0.234
Between-Site CV	3.39%	0.99%	4.40%	0.36%	2.27%	1.00%	0.18%	0.53%	3.13%	3.04%
Between-Day SD	0.436	0.00	0.141	0.127	0.027	0.201	0.368	0.034	6.270	0.080
Between-Day CV	2.18%	0.00%	1.98%	0.17%	0.47%	1.06%	0.38%	0.25%	1.31%	1.04%
Within-Day SD	0.164	0.000	0.177	0.181	0.025	0.121	0.000	0.082	3.257	0.086
Within-Day CV	0.82%	0.00%	2.49%	0.24%	0.43%	0.64%	0.00%	0.59%	0.68%	1.12%
Within-Device SD*	0.582	0.672	0.414	0.692	0.113	0.35	0.504	0.209	13.098	0.178
Within-Device CV	2.91%	4.14%	5.81%	0.90%	1.96%	1.85%	0.51%	1.50%	2.74%	2.31%
SD acceptance criteria	0.4	3.1	2.00	3.5	0.15	0.22	1.2	0.45	27	0.5
CV acceptance criteria	4.00%	8.0%	17.0%	8.0%	2.50%	2.40%	2.00%	3.00%	7.00%	10.0%
Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

* As there is only one instrument per site, within-device precision is the same as within-site

c. *Linearity:*

The analytical measuring range (AMR) was established according to the protocol in CLSI EP6-A by analyzing dilutions made from manipulated whole human blood or from commercial linearity kit material. In order to demonstrate that each parameter is within the claimed performance, a minimum of 9 proportional dilutions spanning the reportable range were run in triplicate on two Abacus 3CP analyzers. All of the eight linearity runs produced coefficients of determination (r^2) >0.99 for each measurand. All linearity runs met their respective specifications.

Measurand	Units	AMR
WBC	10 ³ /μL	0.95 - 83.45
LYM%	%	0 - 100
MID%	%	0 - 40
GRA%	%	0 - 100
LYM	10 ³ /μL	0 - 85
MID	10 ³ /μL	0 - 34

Measurand	Units	AMR
GRA	10 ³ /μL	0 - 85
RBC	10 ⁶ /μL	0.44 - 7.74
HGB	g/dL	1.4 - 23.7
MCV	fl	50 - 120
PLT	10 ³ /μL	11 - 975
MPV	fl	5 - 30

d. *Carryover:*

Carryover was determined using three Abacus 3CP analyzers by running whole blood specimens with high target values (HTV) of WBC, RBC, HGB, and PLT. Each specimen was run in triplicate followed by three aspirations of whole blood specimens with low target values (LTV). Carryover % was calculated by using the following equation: % Carryover = (HTV1 – LTV3)/(HTV3 – LTV3) x 100. The maximum carryover for WBC, RBC, HGB, and PLT are 1.00%, 0.50%, 0.80%, and 1.00% respectively.

Abacus 3CP	Carryover			
	WBC	RBC	HGB	PLT
Analyzer #1	0.09%	-0.03%	-0.31%	0.03%
Analyzer #2	0.08%	-0.13%	0.34%	0.00%
Analyzer #3	0.12%	0.00%	0.11%	-0.01%

The carryover measurements for WBC, RBC, HGB and PLT were less than their respective criteria. The overall carryover evaluation is therefore considered passing.

e. *Interfering Substances:*

Test samples are created by adding interfering substances to normal samples such as bilirubin and lipids based on CLSI EP07-A2. Other evaluations were made by finding naturally occurring human blood samples with potential interferences such as high WBC, platelet abnormalities and NRBCs. A bias of 5% or more was considered clinically significant in the directly measured parameters. Measurands were not impacted by bilirubin up to 30 mg/dL. The following parameters were affected by interference from NRBC, PLT clumps/large PLT, increased WBC, and lipids (see table below):

Parameter	Interference
WBC	> 5 NRBCs/100 WBCs , PLT clumps/large PLTs
RBC	WBC Count > 50.0 x10 ³ /μL
MCV	WBC Count > 75.0 x10 ³ /μL
PLT	PLT clumps/large PLTs
Hemoglobin	WBC count > 50.0 x10 ³ /μL , Lipids > 270 mg/dL
Differential	> 5 NRBCs/100 WBCs , PLT clumps/large PLTs

f. Background Counts:

Daily start-up background counts were performed on the Abacus 3CP and were verified by each site against the specifications. Start-up background specifications were achieved before data collection. The Abacus 3CP background specifications are as follows:

Measurand	Background Concentration Limits
WBC	≤ 0.1 x 10 ³ cells/μL
RBC	≤ 0.01 x 10 ⁶ cells/μL
HGB	≤ 0.3 g/dL
PLT	≤ 10 x 10 ³ cells/μL

2. Other Supportive Instrument Performance Data Not Covered Above:

Studies were conducted to support claims and attributes for whole blood sampling and were designed to evaluate the following:

a. Sample stability:

The parameters selected for this evaluation are the directly measured parameters (WBC, RBC, HGB, PLT), the optically measured parameters (GRA%, LYM%, MID%) and the derived parameters (MCV, RDW, MPV). A total of 10 normal and six abnormal K₃ EDTA anticoagulated human whole blood samples were analyzed at 0.5 hours after venipuncture and at various time intervals thereafter. The averages of the parameters at each time point were compared to the baseline averages. The results support sample stability at room temperature (20 - 23°C) of 7 hours.

The acceptance criteria are found in the following table:

	WBC	LYM%	MID%	GRA%	RBC	HGB	MCV	RDW	PLT	MPV
Absolute	0.3	3.0	3.0	3.0	0.2	0.3	1.0	0.5	15.0	0.5
Percent	6%	10%	10%	10%	6%	6%	6%	6%	8%	10%

b. Comparison of open and closed vial sampling:

A total of 50 K₃EDTA anticoagulated human blood samples spanning the reportable range were used in the study. The specimens were run in closed vial cap pierce mode (selected as the reference as per CLSI H26-A2) and compared to

the open vial mode and to the Autosampler automatic processing mode, on two instruments. The absolute value of the calculated predictive bias at all range and clinical decision points for all parameters were less than the bias goals calculated from the absolute and percent criteria for the parameter. Therefore, the overall mode-to-mode evaluation is considered to meet its specifications.

The predictive bias acceptance criteria are found in the following table:

	WBC	LYM%	MID%	GRA%	RBC	HGB	MCV	RDW	PLT	MPV
Absolute	0.3	3.0	3.0	3.0	0.15	0.3	1.0	0.5	15.0	0.5
Percent	6%	10%	10%	10%	6%	6%	6%	6%	8%	10%

c. Reference ranges:

Evaluation of reference ranges for the Abacus 3CP instrument was conducted using a data set of 120 normal human whole blood samples collected at the US site. Of these 120 samples, 60 were from female patients and 60 were from male patients. The established reference ranges are represented in the table below.

Parameter	Units	Lower limit	Upper limit
WBC	10 ³ /μL	4.0	11.7
LYM	%	10.8	45.40
MID	%	1.8	17.0
GRA	%	44.0	80.9
LYM	10 ³ /μL	0.8	3.3
MID	10 ³ /μL	0.3	1.7
GRA	10 ³ /μL	2.3	8.8
RBC	10 ⁶ /μL	F-2.76 M-3.27	F-5.59 M-5.74
HGB	g/dL	F-8.8 M-10.1	F-15.5 M-16.5
HCT	%	F-26.1 M-30.6	F-47.4 M-49.6
MCV	fL	76.4	102.0
MCH	pg	23.3	36.1
MCHC	g/dL	29.7	36.8
RDW _{cv}	%	111.3	16.7
PLT	10 ³ /μL	97	390
MPV	fL	7.5	13.1

d. Determination of lower limits of detection and quantitation:

The lower limit of detection (LLoD) and the lower limit of quantitation (LLoQ) of WBC, PLT, RBC and HGB were quantified as per CLSI H26-A2 section 5.8. To determine LLoD, 12 blank runs were collected daily over five days (total 60 blank runs) on two instruments using alternating operators. The values of WBC, PLT, RBC and HGB for these blank runs are analyzed to determine the LLoD. Once

the LLoD is calculated, five low level specimens were run over a period of five days. One specimen was run each day using alternating operators. Twelve replicates per specimen were collected for a total of 60 replicates. The CVs of each dilution of WBC and PLT were analyzed to determine the LLoQ of each. Results were as follows:

Item	WBC	PLT	RBC	HGB
LLoD	0.0748	5.6138	0.000	0.3192
LLoQ	0.1645	7.3450	0.4016	0.3192

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.