510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K243283

B Applicant

Abbott Laboratories

C Proprietary and Established Names

Alinity h-series System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GKZ	Class II	21 CFR 864.5220 - Automated Differential Cell Counter	HE - Hematology
KPA	Class I	21 CFR 864.3800 Automated slide stainer	Pathology

II Submission/Device Overview:

A Purpose for Submission:

Clearance of software modification (Version 5.8) to correct overestimation of basophil counts and basophil% results

B Measurand:

WBC, NEU, %NEU, LYM, %LYM, MONO, %MONO, EOS, %EOS, BASO, %BASO, IG, %IG, RBC, HCT, HGB, MCV, MCH, MCHC, MCHr, RDW, NRBC, NR/W, RETIC, %RETIC, IRF, PLT, MPV, %rP (reticulated platelet percent)

C Type of Test:

Complete blood count and 6-part white blood cell differential

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Alinity h-series System is an integrated hematology analyzer (Alinity hq) and slide maker stainer (Alinity hs) intended for screening patient populations found in clinical laboratories by qualified health care professionals. The Alinity h-series can be configured as:

- One stand-alone automated hematology analyzer system.
- A multimodule system that includes at least one Alinity hq analyzer module and may include one Alinity hs slide maker stainer module.

The Alinity hq analyzer module provides complete blood count and a 6-part white blood cell differential for normal and abnormal cells in capillary and venous whole blood collected in K2EDTA or K3EDTA. The Alinity hq analyzer provides quantitative results for the following measurands: WBC, NEU, %N, LYM, %L, MON, %M, EOS, %E, BASO, %B, IG, %IG, RBC, HCT, HGB, MCV, MCH, MCHC, MCHr, RDW, NRBC, NR/W, RETIC, %R, IRF, PLT, MPV, %rP.

The Alinity hq analyzer module is indicated to identify patients with hematologic parameters within and outside of established reference ranges.

The Alinity hs slide maker stainer module automates whole blood film preparation and staining and stains externally prepared whole blood smears.

For *in vitro* diagnostic use.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Alinity hq analyzer

IV Device/System Characteristics:

A Device Description:

The Alinity h-series System is a multimodule system that consists of different combinations of one or more of the following modules: a quantitative multi-parameter automated hematology analyzer (Alinity hq) and an automated slide maker stainer (Alinity hs).

The Alinity hq is a quantitative, multi-parameter, automated hematology analyzer designed for in vitro diagnostic use in counting and characterizing blood cells using a multi-angle polarized

scattered separation (MAPSS) method to detect and count red blood cells (RBC), platelets (PLT), and white blood cells (WBC), and to perform WBC differentials (DIFF) in whole blood.

There is also an option to choose whether to detect reticulocytes at the same time. The options of the selections are:

- CBC+DIFF: Complete blood count with differential
- CBC+DIFF+RETIC: Complete blood count with differential and reticulocyte

The Alinity h-series of instruments has a scalable design to provide full integration of multiple automated hematology analyzers that can include the integration of an automated blood film preparation and staining module, all of which are controlled by one user interface. The modules are designed to fit together. Each module has an internal conveyor that enables racks of specimen tubes to be transported between modules. The system can move racks between modules to perform different tests on a given specimen (e.g., make slide smears on the Alinity hs).

An Alinity h-series system can be configured as follows:

- Configuration 1: 1 (Alinity hq) + 0 (Alinity hs) = 1+0
- Configuration 2: 1 (Alinity hq) + 1 (Alinity hs) = 1+1
- Configuration 3: 2 (Alinity hq) + 0 (Alinity hs) = 2+0
- Configuration 4: 2 (Alinity hq) + 1 (Alinity hs) = 2+1

The Laboratory Automation System (LAS) is an optional automated track system that connects to the Alinity h-series through an interface module. The LAS, also known as the Total Lab Automation (cleared under K121012) is a third-party system used by high-volume laboratories to manage specimen tubes. It is an externally-manufactured system designed to interface with the Alinity h-series system.

The following configurations are configurable with the Laboratory Automation System (LAS) module:

- Configuration 1: 1 (Alinity hq) + 0 (Alinity hs) = 1+0
- Configuration 4: 2 (Alinity hq) + 1 (Alinity hs) = 2+1

The LAS system consists of a command center (coordinates what tests need to run on which instrument for a sample), track (transports specimen tubes from one instrument to another as needed), and an interface module (IM).

B Principle of Operation:

The Alinity hq module uses optical and fluorescence flow cytometry, hydrodynamic focusing, and absorption spectrophotometry technologies to measure, count, and calculate hematological parameters in samples.

- Optical and fluorescence flow cytometry is a process used to count and measure the properties of cells or particles as they are carried by fluid through a sensing zone. The physical and chemical characteristics of cells or particles are measured via light scatter, polarization, and/or fluorescence response from a laser.
- The Alinity hq uses hydrodynamic focusing to align cells into a single-file passage through the sensing zone. A cell-free liquid sheath surrounds the diluted sample and

moves with it in a laminar flow. The laminar flow prevents any mixing between the liquid sheath and the diluted sample.

- Absorption spectrophotometry is based on the linear relationship between the amount of light that a well-mixed, nonflowing sample absorbs at a particular absorption band and the concentration of an absorbing entity in the sample (Beer's Law). To perform absorption spectrophotometry, the system uses the hemoglobin dilution as the sample and a hemoglobin complex as the light-absorbing entity.

Flow cytometry technologies are used to analyze whole blood samples for WBC, RBC, NRBC, RETIC, and PLT. Absorption spectrophotometry is used to measure the HGB concentration.

The Alinity hs module creates and stains smears from whole blood samples in addition to staining externally prepared smears for morphologic review. The operator selects and may configure staining protocols as needed by the laboratory. The Alinity hs module is configured with the May-Grünwald-Giemsa stain or the Wright-Giemsa stain.

Modification

The Alinity h-series System software algorithm (Software Version 5.8) was modified to reduce overestimation of basophil counts due to potential misclassification of lymphocytes to basophils that may occur for some whole blood samples (hereafter, referred to as "affected samples") tested on the Alinity hq of the Alinity h-series System (K220031). This modification reduces falsely increased basophil measurements (i.e., BASO and %BASO) and the potential of incorrect results for these affected samples. The modification only impacts how the algorithm evaluates whole blood samples and does not affect how quality control (QC) materials are evaluated. The modification does not impact other modules or interfaces of the Alinity h-series System.

C Instrument Description Information:

1. Instrument Name:

   Alinity h-series System

2. Specimen Identification:

   The system supports the use of a bar-coded Sample Identification (SID) on a specimen tube to provide specimen identification. Specimens are also identified alphanumerically by rack and tube position number. A bar code reader on the sample handler robot reads the rack ID bar code to identify the rack number. The rack ID bar code also provides information to identify the tube position on the rack.

3. Specimen Sampling and Handling:

   Two methods are used to introduce a specimen to the Alinity hq module. These are closed-tube processing and open-tube processing.

   - In the closed-tube processing mode, capped specimen tubes are introduced to the Alinity hq module from 10-tube closed-tube racks that are inserted in the loading

area. The module automatically mixes the specimens and moves the tubes to the aspiration position.

- In the open-tube processing mode, the operator pre-mixes a specimen tube and removes the cap. The tube is placed in an open-tube sample rack and is inserted in the loading area. The sample handler robot within the Alinity hq module moves the open-tube rack that contains the specimen to the open-tube sampling position.

4. Calibration:

   Calibration is performed using materials with assigned values that are traceable to standard reference methods. It is recommended that the laboratory calibrate using Alinity h-series HemCal, which is a commercial whole blood calibrator.

5. Quality Control:

   The Alinity h-series requires a commercial whole blood control (Alinity h-series Control 29P) and patient controls to monitor system performance.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Alinity h-series System

B Predicate 510(k) Number(s):
K220031

C Comparison with Predicate(s):

Device & Predicate Device(s):	K243283	K220031
Device Trade Name	Alinity h-series System	Alinity h-series System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Alinity h-series System is an integrated hematology analyzer (Alinity hq) and slide maker stainer (Alinity hs) intended for screening patient populations found in clinical laboratories by qualified health care professionals. The Alinity h-series can be configured as: • One stand-alone automated hematology analyzer system.	Same

	• A multimodule system that includes at least one Alinity hq analyzer module and may include one Alinity hs slide maker stainer module. The Alinity hq analyzer module provides complete blood count and a 6-part white blood cell differential for normal and abnormal cells in capillary and venous whole blood collected in K2EDTA or K3EDTA. The Alinity hq analyzer provides quantitative results for the following measurands: WBC, NEU, %N, LYM, %L, MON, %M, EOS, %E, BASO, %B, IG, %IG, RBC, HCT, HGB, MCV, MCH, MCHC, MCHr, RDW, NRBC, NR/W, RETIC, %R, IRF, PLT, MPV, %rP. The Alinity hq analyzer module is indicated to identify patients with hematologic parameters within and outside of established reference ranges. The Alinity hs slide maker stainer module automates whole blood film preparation and staining and stains externally prepared whole blood smears. For in vitro diagnostic use.	
Test Principle	Performs hematology analyses according to flow cytometry method (using Hydro Dynamic Focusing) and absorption spectrophotometry method (using cyanide-free ligand).	Same

Parameters	Whole Blood Mode: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, MPV, IRF, NEU, %NEU, LYM, %LYM, MONO, %MONO, EOS, %EOS, BASO, %BASO, NRBC, NR/W, IG, %IG, RETIC, %RETIC, RDW-CV, RDW-SD, MCHr, %rP	Same
Specimen Type	Whole Blood	Same
Use of Controls/ Calibrators	Yes	Same
Measuring Channels/ Methods Selection	• CBC+Diff (for RBC, WBC, and PLT) • CBC+Diff+Retic (for RBC, WBC, PLT, and Retic)	Same
Information Processing Unit (IPU)	Multi-Module connect	Same
Modules Connected to the Analyzer	Required • Water Purification System (WPS) • System Control Center Computer (SCC) Optional • Laboratory Automation System (LAS) for automatic sample loading	Same
Data Transfer Mode	• USB • Internet • Intranet	Same
Sample Aspiration/ Fluidic Pathway	Single aspiration pathway	Same
Reagents	• Diluent • HGB Reagent • WBC Reagent • Retic Reagent	Same
Controls/ Calibrators	Whole Blood: • Calibrator – Alinity h-series HemCal • Control – Alinity h-	Same

	series Control 29P	
General Device Characteristic Differences		
Software Version	5.8 [includes algorithm modification to resolve overestimation of basophil counts]	5.0

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition
- CLSI EP06, Evaluation of the Linearity of Quantitative Measurement Procedures – Second Edition
- CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition.
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
- CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition
- CLSI EP35, Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures [7-298] – First Edition
- CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry– First Edition
- CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard – Second Edition;
- CLSI H26-A2 Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Proposed Standard - Second Edit [7-210];
- IEC 60825-1:2014 Edition 3.0, Safety of laser products - Part 1: Equipment Classification and Requirements [12-273];
- ISO 14971 Third Edition 2019-12, Medical devices - Applications of risk management to medical devices [5-125];
- IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [19-8];
- CLSI LIS01-A2, Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems [13-29];
- CLSI LIS02-A2, Standard Specification for Transfer Information Between Clinical Instruments and Computer Systems; Approved Standard - Second Edition [13-17];
- ISO 15223-1 Third Edition, Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied [5-117]

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

In this 510(k) submission, raw signal data files from 510(k) submission K220031 were analyzed using the modified algorithm for the subject device.

1. Precision:

   a) 20-Day Within-Laboratory Precision

   Please refer to K220031.

   b) Repeatability (Normal samples):

   Samples were collected from 20 healthy donors in K2EDTA and tested using both CBC+Diff and CBC+Diff+Retic test selections. Three Alinity h-series system instruments of 1+0 configuration and two Alinity h-series system instruments of 2+1 configurations were used. Four (4) samples were tested on each of the three (3) instruments in the 1+0 configuration and two (2) samples on each of the two instruments in the 2+1 configuration using both CBC+Diff and CBC+Diff+Retic test selections. Each sample was tested in one (1) run with at least 32 replicates using 1 reagent lot and 1 control lot. The mean value, SD, %CV, minimum and maximum values, and the two-sided 95% Confidence Intervals (CI) around the SD and %CV were calculated for each measurand and test selection (CBC+Diff and CBC+Diff+Retic). The maximum %CV or SD values across donors by range was reported. The SD or %CV point estimates were evaluated against the evaluation criteria.

   The maximum SD/%CV reflects the worst or largest imprecision across all the samples for each measurand tested for short-term imprecision with whole blood. If the maximum SD or %CV meets the acceptance criteria for a given measurand, then all the samples tested for short-term imprecision had SDs/%CVs that also meet the acceptance criteria for that measurand. All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements.

Test Mode	Measurand	N	Result Range	Max SD/%CV
CBC+Diff	WBC ($x10^3/\mu L$)	1	3.72 to 4.06	0.068 SD
		19	3.92 to 10.60	2.71 %CV
	LYM ($x10^3/\mu L$)	13	1.10 to 2.01	0.068 SD
		7	1.94 to 3.05	3.09 %CV
	LYM (%)	20	13.80 to 57.80	1.239 SD
				3.34 %CV
	BASO (x $10^3/\mu L$)	20	0.01 to 0.12	0.021 SD
	BASO (%)	20	0.13 to 2.20	0.352 SD
				41.04 %CV

Test Mode	Measurand	N	Result Range	Max SD/%CV
CBC+Diff+Retic	WBC ($x10^3/\mu L$)	1	3.72 to 4.04	0.085 SD
		18	3.93 to 10.40	2.22 %CV
	LYM ($x10^3/\mu L$)	13	1.10 to 2.01	0.063 SD
		6	1.91 to 3.07	3.17 %CV
	LYM (%)	19	13.40 to 58.10	1.193 SD
				3.63 %CV
	BASO ($x10^3/\mu L$)	19	0.01 to 0.11	0.025 SD
	BASO (%)	19	0.13 to 2.00	0.455 SD
				41.08 %CV

For other reported parameters, please refer to K220031.

c) Repeatability (Pathological &MDL samples):

Abnormal samples were collected from a minimum of 16 donors per measurand and range. A minimum of 4 repeatability samples (2 samples using CBC+Diff mode and 2 samples using CBC+Diff+Retic mode) per measurand and range were tested on each of three 1+0 Alinity hq analyzers in closed-tube processing mode. A minimum of 4 repeatability samples per measurand and range were tested on one 2+1 Alinity h-series System (2 samples using CBC+Diff mode on one Alinity hq module and 2 samples using CBC+Diff+Retic mode on the other Alinity hq module). Each sample was tested in a minimum of 10 replicates. The mean, standard deviation (SD), coefficient of variation (CV), and 95% CI were calculated for each parameter. The SD or %CV point estimates were evaluated against the evaluation criteria. All results met the predefined acceptance criteria. A summary table showing the maximum %CV or SD, across samples by range, for applicable measurand(s) is presented below.

Target Range	Recommended Target Values	Measurand	N	Result Range	Max SD / %CV[a]
Low	0.06 – 2.00 $x10^3/\mu L$	WBC ($x10^3/\mu L$)	16	0.06 to 2.01	0.083 SD
High	50.0 – 400.0 $x10^3/\mu L$	WBC ($x10^3/\mu L$)	17	41.40 to 209.00	1.88 %CV
Low WBC related	NA	LYM ($x10^3/\mu L$)	11	0.12 to 0.74	0.040 SD
Low WBC related	NA	BASO ($x10^3/\mu L$)	18	0.00 to 0.04	0.010 SD

[a]Indicate the maximum SD or %CV comparing to the acceptance criteria

For other reported parameters, please refer to K220031.

d) Reproducibility

Please refer to K220031.

2. Linearity:

   Please refer to K220031.

3. Analytical Specificity/Interference:

   Please refer to K220031.

4. Assay Reportable Range:

   Please refer to K220031.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Please refer to K220031.

6. Detection Limit:

   Limits of Blank, Detection, and Quantitation were conducted over a minimum of 3 days using 2 unique samples per day on each of 2 test selections (CBC+Diff and CBC+Diff+Retic) in 5 replicates on each of the two reagent lots. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below. All results met the predefined acceptance criteria and were determined to be acceptable.

Measurand	Results		
	LoB	LoD	LoQ
WBC ($x10^3/\mu L$)	0.01	0.02	0.03

   For other reported parameters, please refer to K220031

7. Assay Cut-Off:

   Not applicable

8. Accuracy (Instrument):

   See Method Comparison Study Section

9. Carry-Over:

   Please refer to K220031.

B Comparison Studies:

1. Method Comparison:

A method comparison study was conducted to assess the performance of the Alinity hq with software version 5.8 compared to the predicate device, Sysmex XN-10 (K112605). A total of 2,194 unique venous and/or capillary specimens collected in K2EDTA from pediatric (≤21 years) and adult subjects including a wide variety of disease states (clinical conditions) were tested across 7 clinical sites.

Venous and/or capillary whole blood leftover specimens were collected in K2EDTA tubes from a wide range of demographics (age and sex) and disease states (clinical conditions). In total, there were 1,528 specimens collected from subjects with one or more medical conditions while there were 244 specimens without any medical conditions. Study sites aimed to cover the target assay reportable range for the measurands. A maximum of 10% samples per measurand were permitted to be contrived to cover the entire target assay reportable range.

Each specimen was tested within 8 hours from the time of collection in one replicate using either the Closed or Open tube processing mode in the CBC+Diff+Retic test selection on the Alinity h-series System and one replicate on the Sysmex XN-10 System. Specimens were tested on the Alinity hq and the Sysmex XN-10 within 2 hours of each other. At five of the seven sites, the Alinity hq configuration was 1+0 (five stand-alone Alinity hq analyzers), at one site the configuration was 2+1 (2 Alinity hq modules that are configured as part of the Alinity h-series System), and at one site both 1+0 and 2+1 configurations were tested.

Alinity hq testing was performed using a minimum of 1 reagent lot, 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal commercial calibrator. The Sysmex XN-10/20 was calibrated using its recommended commercial calibrators at each site. A Passing-Bablok regression analysis was performed but Deming regression analysis was used in place of Passing-Bablok analysis where there are very low numeric values. All results were within the predefined acceptance criteria and found to be acceptable.

All Sites Combined – Regression Analysis Results
Candidate (Ver. 5.8) vs. Sysmex XN-10:

Measurand	N	Alinity h Result Range	r (95% CI)	Slope (95% CI)	Intercept (95% CI)
WBC ($x10^3/\mu L$)	1958	0.07 – 436.00	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.01 (0.00, 0.03)
LYM ($x10^3/\mu L$)	1598	0.05 – 8.34	0.99 (0.99, 0.99)	0.99 (0.99, 1.00)	0.02 (0.01, 0.02)
LYM (%)	1598	0.34 – 84.60	1.00 (1.00, 1.00)	1.00 (0.99, 1.00)	0.04 (0.04, 0.15)
BASO ($x10^3/\mu L$)	1812	0.00 – 2.41	0.26 (0.22, 0.30)	1.25 (1.20, 1.30)	0.00 (0.00, 0.00)
BASO (%)	1812	0.00 – 8.37	0.44 (0.40, 0.48)	1.44 (1.39, 1.50)	-0.12 (-0.14, -0.09)

Within the 2,194 samples tested, there were 67 whole blood samples that are impacted by basophil count overestimation due to basophil misclassification. A subgroup analysis was conducted by comparing the performance of the subject device (software version 5.8), the predicate device (software version 5.0) to Sysmex XN-10 for the 67 samples.

Alinity version 5.0 vs. Sysmex

Measurand	N	Result Range	r (95% CI)	Slope (95% CI)	Intercept (95% CI)
BASO ($x10^3/\mu L$)	67	0.03 – 8.11	0.93 (0.90, 0.96)	2.22 (1.64, 2.80)	-0.01 (-0.05, 0.02)
BASO (%)	67	2.00 – 4.49	0.33 (0.10, 0.53)	0.54 (0.31, 0.83)	1.83 (1.45, 2.05)
LYM ($x10^3/\mu L$)	53	0.37 – 6.26	0.99 (0.99, 1.00)	0.93 (0.90, 0.98)	0.06 (-0.01, 0.12)
LYM (%)	53	6.31 – 60.50	0.99 (0.98, 0.99)	0.99 (0.95, 1.03)	-0.50 (-1.78, 0.72)
WBC ($x10^3/\mu L$)	65	1.22 – 205.00	1.00 (1.00, 1.00)	0.99 (0.98, 1.01)	0.02 (-0.05, 0.12)

Alinity version 5.8 vs. Sysmex

Measurand	N	Result Range	r (95% CI)	Slope (95% CI)	Intercept (95% CI)
BASO ($x10^3/\mu L$)	67	0.00 – 1.69	0.84 (0.75, 0.90)	1.17 (1.00, 1.32)	0.00 (-0.01, 0.01)
BASO (%)	67	0.00 – 4.33	0.61 (0.44, 0.75)	1.22 (0.98, 1.52)	-0.08 (-0.39, 0.19)
LYM ($x10^3/\mu L$)	53	0.38 – 6.47	0.99 (0.98, 0.99)	0.98 (0.95, 1.01)	0.04 (-0.02, 0.11)
LYM (%)	53	7.00 – 62.00	0.99 (0.99, 1.00)	1.01 (0.97, 1.04)	0.13 (-0.84, 0.83)
WBC ($x\ 10^3/\mu L$)	65	1.22 – 204.00	1.00 (1.00, 1.00)	0.99 (0.98, 1.01)	0.02 (-0.04, 0.12)

2. Matrix Comparison:

Please refer to K220031.

C Clinical Studies:

1. Clinical Sensitivity and Specificity:

Sensitivity and specificity performance with the Alinity h-series System were assessed for accuracy of identifying distributional abnormalities and morphological flags (PLT Clumps, RBC Fragments) by comparing to a 400-cell differential derived from two independent 200-cell microscopic reviews of a blood smear (reference method) from negative (normal) and positive (abnormal) specimens. A subset of 674 venous and capillary specimens collected in K2EDTA for the method comparison study were included in this study. Testing was

performed at six clinical sites. One (1) replicate of each specimen was analyzed using the CBC+Diff+Retic test selection in the Open or Closed tube processing mode on the Alinity hq. Three blood films were prepared for each sample.

The final WBC differential and WBC, RBC, and PLT morphology results were based on the 400-cell WBC differential counts derived from the average of 2 concurring 200-cell differential counts and concordant RBC and PLT morphology results with the exception of PLT clumps.

Sensitivity and specificity analysis were performed to compare the Alinity hq morphological flags, WBC 6-part differential, and NR/W against the results from microscopy analysis. Agreement between 2 readers was determined for %BASO, %EOS, %MONO, %NEU, %LYM, %IG, and NR/W for the assessment of distributional abnormalities, as well as for blasts, variant lymphocytes, band neutrophils, RBC fragments, and PLT clumps for the assessment of morphological abnormalities.

Results from all specimens tested in this study were evaluated against the respective reference ranges for each differential cell type. Results within the lower and upper limits of the reference ranges were considered normal (negative). Results not within the lower and upper limits of the respective reference ranges for Microscopy or Alinity hq were considered abnormal (positive). Specimens were classified as morphologically abnormal (morphological positive) based on predefined criteria for blast, left shift, variant lymphocytes, PLT clumps, RBC fragments/schistocytes. Distributional classification and morphological flagging were categorized as True Positive (TP), False Positive (FP), False Negative (FN), and True Negative (TN) per the following contingency table based on agreement between Alinity hq and Microscopic results.

Category of Abnormalities	N	TP	FP	FN	TN	Sensitivity (95% CI)[a]	Specificity (95% CI)[b]	Efficiency (95% CI)[c]
Any Morphological Flags	650	75	121	36	418	67.57% (58.03%, 76.15%)	77.55% (73.79%, 81.01%)	75.85% (72.37%, 79.09%)
Any Distributional Abnormalities	636	220	72	45	299	83.02% (77.95%, 87.34%)	80.59% (76.20%, 84.49%)	81.60% (78.37%, 84.54%)
Any Morphological Flags and/or Distributional Abnormalities	648	247	82	58	261	80.98% (76.12%, 85.23%)	76.09% (71.22%, 80.51%)	78.40% (75.02%, 81.51%)

[a] Sensitivity = 100* TP / (TP + FN)
[b] Specificity = 100* TN / (TN + FP)
[c] Efficiency = 100* (TN + TP) / (TP + FN + FP + TN)

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Please refer to K220031.

F Other Supportive Instrument Performance Characteristics Data:

Please refer to K220031.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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