



February 20, 2025

Abbott Laboratories
Saloni Shah
Senior Regulatory Affairs Specialist
4551 Great America Parkway
Santa Clara, California 95054

Re: K243283

Trade/Device Name: Alinity h-series System
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ, KPA
Dated: November 22, 2024
Received: November 22, 2024

Dear Saloni Shah:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu - 

Min Wu, Ph.D.

Branch Chief

Division of Immunology and Hematology Devices

OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K243283

Device Name
Alinity h-series System

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Applicant Name

Abbott Laboratories
4551 Great America Parkway
Santa Clara, CA 95054
Date Prepared: November 22, 2024

Contact:
Saloni Shah
Senior Regulatory Affairs Specialist
Abbott Core Diagnostics
Phone: (510) 449-1818
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II. Device Information

Trade name (proprietary name): Alinity h-series System
Common name (usual name): Automated Hematology Analyzer
Classification Name: Automated Differential Cell Counter

III. Regulatory Information

Alinity hq
Device Classification: Class II
Regulation Description: Automated Differential Cell Counter
Governing Regulation: 21 CFR 864.5220
Code: GKZ

Alinity hs
Device Classification: Class I
Regulation Description: Automated Slide Stainer
Governing Regulation: 21 CFR 864.3800
Code: KPA

IV. Predicate Device

Alinity h-series System (K220031)

V. 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), nucleated red blood cells (NRBC), 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 (RETIC) 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

Principles of Operation

The Alinity hq 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, non-flowing 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, DIFF, RBC, NRBC, RETIC, and PLT. Absorption spectrophotometry is used to measure the HGB concentration (HGB).

The Alinity hs 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 Wright-Giemsa stain.

Intended 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.

Definitions of Reportable Parameters

The definitions of the reportable parameters are presented in Table 39.1.

Table 39.1. Peripheral Whole Blood Reportable Parameters

Abbreviation	Definition
White Blood Cell Parameters	
WBC	White Blood Cell Concentration
NEU	Neutrophil Absolute Concentration
%N	Neutrophil Percentage of WBCs (%NEU)
LYM	Lymphocyte Absolute Concentration
%L	Lymphocyte Percentage of WBCs (%LYM)

MON	Monocyte Absolute Concentration (MONO)
%M	Monocyte Percentage of WBCs (%MON)
EOS	Eosinophil Absolute Concentration
%E	Eosinophil Percentage of WBCs (%EOS)
BASO	Basophil Absolute Concentration
%B	Basophil Percentage of WBCs (%BASO)
IG	Immature Granulocyte Concentration
%IG	Immature Granulocyte Percentage
Red Blood Cell Parameters	
RBC	Red Blood Cell Concentration
HGB	Hemoglobin Concentration
HCT	Hematocrit (Percentage)
MCV	Mean Cell Volume
MCH	Mean Cell Hemoglobin
MCHC	Mean Cell Hemoglobin Concentration
RDW	Red Blood Cell Distribution Width
NRBC	Nucleated Red Blood Cell Absolute Concentration
NR/W	NRBCs per 100 WBCs
MCHr	Mean Cell Hemoglobin of the Reticulocyte
RETIC	Reticulocyte Concentration (RETC)
%R	Reticulocyte Percentage of RBCs (%RETC)
IRF	Immature Reticulocyte Fraction
Platelet Parameters	
PLT	Platelet Concentration
MPV	Mean Platelet Volume
%rP	Reticulated Platelet Percentage

VI. Reason for Traditional 510(k) Submission

The Alinity h-series System software algorithm was modified to reduce overestimation of basophil counts 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).

The algorithm implements modified logic for counting basophils when the basophil cell population is not clearly defined in whole blood samples – which is predominantly due to the overlap of lymphocyte and basophil cell populations in select scatterplots. This modification reduces falsely increased basophil measurements (*i.e.*, BASO and %BASO) and the potential of incorrect results for these affected samples. The modification does not impact other modules or interfaces of the Alinity h-series System.

VII. Comparison of Device Characteristics

The similarities and difference in the intended use, indications for use, and technological characteristics between the subject device and the predicate device are presented in [Table 39.2](#).

Table 39.2. Device Similarities & Difference

General Device Characteristics	Cleared Predicate Device (K220031)	Subject Device (K243283)
	Alinity hq of the Alinity h-series System (K220031) (Cleared Using Alinity h-series Software Version 5.0)	Alinity hq of the Alinity h-series System (Using Alinity h-series Software Version 5.8)
General Device Characteristic Similarities		
Intended Use & Indications for Use of the Alinity h-series System	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>For <i>in vitro</i> diagnostic use.</p>	Same

Table 39.2. Device Similarities & Difference (Continued)

General Device Characteristics	Cleared Predicate Device (K220031)	Subject Device (K243283)
	Alinity hq of the Alinity h-series System (K220031) (Cleared Using Alinity h-series Software Version 5.0)	Alinity hq of the Alinity h-series System (Using Alinity h-series Software Version 5.8)
General Device Characteristic Similarities (Continued)		
Test Principle	Performs hematology analyses according to flow cytometry method (using hydrodynamic focusing) and absorption spectrophotometry method (using a cyanide-free ligand)	Same
Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, MPV, IRF, NEU, %N, LYM, %L, MON, %M, EOS, %E, BASO, %B, NRBC, NR/W, IG, %IG, RETIC, %R, RDW, MCHr, %rP	Same
Specimen Type	Whole blood	Same
Information Processing Unit (IPU)	Multi-module connect	Same
Sample Aspiration/ Fluidic Pathway	Single aspiration pathway	Same
Software/Hardware	Rules based rerun/reflex	Same
Controls/Calibrators	<ul style="list-style-type: none"> • Calibrator: Alinity h-series HemCal • Control: Alinity h-series Control 29P 	Same
Reagents	<ul style="list-style-type: none"> • Diluent • HGB Reagent • WBC Reagent • Retic Reagent • AutoClean Solution 	Same
Measuring Channels/ Methods Selection	<ul style="list-style-type: none"> • CBC+Diff (for RBC, WBC, and PLT) • CBC+Diff+Retic (for RBC, WBC, PLT, and Retic) 	Same
Modules Connected to the Analyzer	<u>Required</u> <ul style="list-style-type: none"> • Water Purification System (WPS) • System Control Center Computer (SCC) <u>Optional</u> <ul style="list-style-type: none"> • Laboratory Automation System (LAS) for automatic sample loading 	Same

Table 39.2. Device Similarities & Difference (Continued)

General Device Characteristics	Cleared Predicate Device (K220031)	Subject Device (K243283)
	Alinity hq of the Alinity h-series System (K220031) (Cleared Using Alinity h-series Software Version 5.0)	Alinity hq of the Alinity h-series System (Using Alinity h-series Software Version 5.8)
General Device Characteristic Similarities (Continued)		
Data Transfer Mode	<ul style="list-style-type: none"> • USB • Internet • Intranet 	Same
General Device Characteristic Difference		
Software (SW) of the Alinity h-series System	Alinity h-series Software Version 5.0	Alinity h-series Software Version 5.8 [includes algorithm modification to reduce overestimation of basophil counts that may occur for some whole blood samples tested on the Alinity hq of the Alinity h-series System (K220031)]

VIII. Performance Characteristics:

A. Analytical Performance:

1. Precision/Repeatability:

20-Day Within-Laboratory Precision

Refer to 510(k) submission K220031.

Precision Study – Normal Samples

In 510(k) submission K220031, whole blood samples were collected from 20 unique healthy donors in K₂EDTA blood collection tubes and tested on the Alinity hq using both CBC+Diff and CBC+Diff+Retic test selections. Three Alinity hq in the 1+0 system configuration and two Alinity hq in the 2+1 system configuration were used. Alinity hq testing was performed using 1 set of reagent lots and 1 control lot. Four samples were tested on each of the 3 Alinity hq in the 1+0 system configuration, and 2

samples were tested on each of the 2 Alinity hq in the 2+1 system configuration using both CBC+Diff and CBC+Diff+Retic test selections for a minimum of 32 required measurements ([4 samples x 3 instruments] + [2 samples x 2 instruments]) x 2 test selections = 32). Each sample was tested in 1 run with at least 32 replicates. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. The mean value, standard deviation (SD), coefficient of variation (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. Results for measurands potentially impacted by the algorithm modification incorporated in the subject device are displayed in Table 39.3. Results for these measurands with acceptance criteria are shaded in Table 39.3. Refer to 510(k) submission K220031 for all other measurands.

The maximum SD/%CV reflects the worst or largest imprecision across all the whole blood samples for each measurand tested for short-term imprecision. 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.

Table 39.3. Precision of Normal Samples

Test Selection	Measurand	N	Results Range	Max SD/%CV
CBC+Diff	BASO ($\times 10^3/\mu\text{L}$)	20	0.01 to 0.12	0.021 SD
	%BASO (%)	20	0.13 to 2.20	0.352 SD 41.04 %CV
	LYM ($\times 10^3/\mu\text{L}$)	13	1.10 to 2.01	0.068 SD
			1.94 to 3.05	3.09 %CV
	%LYM (%)	20	13.80 to 57.80	1.239 SD 3.34 %CV
	WBC ($\times 10^3/\mu\text{L}$)	1	3.72 to 4.06	0.068 SD
			19	3.92 to 10.60
CBC+Diff+Retic	BASO ($\times 10^3/\mu\text{L}$)	19	0.01 to 0.11	0.025 SD
	%BASO (%)	19	0.13 to 2.00	0.455 SD 41.08 %CV
	LYM ($\times 10^3/\mu\text{L}$)	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
	WBC ($\times 10^3/\mu\text{L}$)	1	3.72 to 4.04	0.085 SD
		18	3.93 to 10.40	2.22 %CV

Repeatability - Pathological Samples and Medical Decision Levels

In 510(k) submission K220031, abnormal whole blood samples were collected from a minimum of 16 donors per measurand and range. A minimum of 4 repeatability samples (2 samples using the CBC+Diff test selection and 2 samples using the CBC+Diff+Retic test selection) per measurand and range were tested on each of 3 standalone Alinity hq (1+0 system configuration) in the closed tube processing mode. A minimum of 4 repeatability samples per measurand and range were tested on one Alinity h-series System in the 2+1 system configuration (2 samples using the CBC+Diff test selection on an Alinity hq and 2 samples using the CBC+Diff+Retic mode on the other Alinity hq). Each sample was tested in a minimum of 10 replicates. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. The mean, SD, CV, and 95% CI were calculated for each measurand. The SD or %CV point estimates were evaluated against the evaluation criteria. All results met the predefined acceptance criteria, demonstrating acceptable short-term precision when testing pathological samples at medical decision levels. A summary of the maximum %CV or SD, across samples by range, for measurands potentially impacted by the algorithm modification incorporated in the subject device is presented in Table 39.4. Refer to 510(k) submission K220031 for all other measurands.

Table 39.4. Precision of Pathological Samples and Medical Decision Levels

Target Range	Recommended Target Values	Measurand	N	Results Range	Max SD/%CV
Low	$0.06 - 2.00 \times 10^3/\mu\text{L}$	WBC ($\times 10^3/\mu\text{L}$)	16	0.06 to 2.01	0.083 SD
High	$50.0 - 400.0 \times 10^3/\mu\text{L}$	WBC ($\times 10^3/\mu\text{L}$)	17	41.40 to 209.00	1.88 %CV
Low WBC Related	Not Applicable	BASO ($\times 10^3/\mu\text{L}$)	18	0.00 to 0.04	0.010 SD
Low WBC Related	Not Applicable	LYM ($\times 10^3/\mu\text{L}$)	11	0.12 to 0.74	0.040 SD

2. Precision/Reproducibility:

Refer to 510(k) submission K220031.

3. Linearity:

In 510(k) submission K220031, linearity for RBC, HGB, and NRBC was determined using whole blood samples that span the analytical measuring range of each measurand. Linearity for WBC, PLT, and RETIC was determined using commercially available linearity kits. A minimum of 9 levels were prepared for each measurand. The levels were tested in a minimum of 4 replicates on each of 3 Alinity hq using 1 set of reagent lots. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. Results for the measurand potentially impacted by the algorithm modification incorporated in the subject device is displayed in Table 39.5. Refer to 510(k) submission K220031 for all other measurands. All results met the predefined acceptance criteria and were determined to be acceptable.

Table 39.5. Linearity Results

Measurand	Overall Linearity Range
WBC	(0.00 to 448.58) x 10 ³ /μL

4. Analytical Specificity/Interference:

Refer to 510(k) submission K220031.

5. Reportable Range:

The reportable range is unchanged from 510(k) submission K220031 and is provided in Table 39.6.

Table 39.6. Alinity h-series System Reportable Range

Parameter	Analytical Measuring Range
WBC	(0.04 to 447.) x 10 ³ /μL
RBC	(0.01 to 8.08) x 10 ⁶ /μL
HCT	4.92% to 86.0%
MCV	51.4 fL to 131. fL
HGB	0.15 g/dL to 24.1 g/dL
RETIC	(0.05 to 644.) x 10 ³ /μL
%R	0.12% to 20.8%

IRF	0.00 to 0.70
NRBC	(0.00 to 20.0) x 10 ³ /μL
PLT	(0.46 to 5325) x 10 ³ /μL
MPV	8.04 fL to 13.3 fL

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

Specimen Stability

In 510(k) submission K220031, sample stability studies were conducted to evaluate the stability of specimens – venous and capillary whole blood specimens collected in K₂EDTA or K₃EDTA blood collection tubes – when stored under various conditions (*i.e.*, room temperature and refrigerated). The results from these studies were used to support the information provided in the system labeling for the Alinity h-series System when venous and capillary whole blood specimens collected in either K₂EDTA or K₃EDTA blood collection tubes are stored for either of the following:

- Up to 48 hours at refrigerated temperature (2 to 8°C)
- Up to 24 hours at controlled room temperature (18 to 26°C)

Refrigerated K₂EDTA Venous & Capillary Whole Blood Specimen Stability

In 510(k) submission K220031, a study was conducted to evaluate the stability of K₂EDTA venous and capillary whole blood specimens when stored at refrigerated storage temperature (2 to 8°C) and then tested on the Alinity hq. A total of 14 unique native venous whole blood specimens from apparently healthy donors and 30 unique native capillary whole blood specimens from apparently healthy donors were collected in K₂EDTA blood collection tubes. The samples were tested to evaluate the below-mentioned test condition and time points in this study.

Table 39.7. Refrigerated K₂EDTA Venous & Capillary Whole Blood Specimen Stability Evaluation Conditions

Condition	Time Points (Time from Specimen Collection)
Baseline (Control Condition)	≥ 20 Minutes to < 4 Hours
2 to 8°C (Refrigerated Test Storage Condition)	≥ 48 Hours to < 50 Hours at 2 to 8°C
	≥ 50 Hours to < 52 Hours at 2 to 8°C

Baseline testing was performed within 4 hours of specimen collection. Aliquots of each venous and capillary whole blood specimen were stored refrigerated at 2 to 8°C. Before each test time point (≥ 48 Hours to < 50 Hours at 2 to 8°C and ≥ 50 Hours to < 52 Hours at 2 to 8°C), aliquots of the venous and capillary whole blood specimens were equilibrated to instrument room temperature – as recommended by the Alinity h-series Operations Manual.

Alinity hq testing was performed using a minimum of 1 set of reagent lots and 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal calibrator. Each venous whole blood specimen was tested at all time points in a minimum of 2 replicates on the Alinity hq using the CBC+Diff+Retic test selection. If volume permitted, each capillary whole blood specimen was tested at baseline and all test time points. Due to volume constraints, each capillary whole blood specimen was tested at the time points in a minimum of 1 replicate on the Alinity hq using the CBC+Diff+Retic test selection. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. The analysis was performed separately for each specimen, test time point, and measurand. For each specimen and measurand, the difference between each test time point and the corresponding baseline was calculated.

Overall, this specimen stability study supports the system labeling claim for the stability of venous and capillary whole blood specimens collected in K₂EDTA blood collection tubes when stored for up to 48 hours at refrigerated storage temperature (2 to 8°C).

Controlled Room Temperature K₂EDTA Venous & Capillary Whole Blood Specimen Stability

In 510(k) submission K220031, a study was conducted to evaluate the stability of K₂EDTA venous and capillary whole blood specimens when stored at controlled room temperature (18 to 26°C) and then tested on the Alinity hq. The study included 10 K₂EDTA venous samples from healthy donors, 10 abnormal de-identified leftover K₂EDTA venous samples, and 20 normal K₂EDTA capillary samples from healthy

donors. The samples were tested to evaluate the below-mentioned test condition and time points in this study.

Table 39.8. Room Temperature K₂EDTA Venous & Capillary Whole Blood Specimen Stability Evaluation Conditions

Condition	Time Points (Time from Specimen Collection)
Baseline (Control Condition)	≥ 20 Minutes to < 4 Hours
18 to 26°C (Controlled Room Temperature)	≥ 24 Hours to < 26 Hours
	≥ 26 Hours to < 28 Hours

Baseline testing was performed within 4 hours of specimen collection. Aliquots of each venous and capillary whole blood specimen were either stored in incubators at the extreme ends of room temperature (18°C and 26°C) or at controlled room temperature (18 to 26°C).

Alinity hq testing was performed using a minimum of 1 set of reagent lots and 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal calibrator. Each venous whole blood specimen was tested at all time points in a minimum of 2 replicates on the Alinity hq using the CBC+Diff+Retic test selection. If volume permitted, each capillary whole blood specimen was tested at baseline and all test time points. Due to volume constraints, each capillary whole blood specimen was tested at the time points in a minimum of 1 replicate on the Alinity hq using the CBC+Diff+Retic test selection. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. The analysis was performed separately for each specimen, test time point, and measurand. For each specimen and measurand, the difference between each test time point and the corresponding baseline was calculated.

Overall, this specimen stability study supports the system labeling claim for the stability of venous and capillary whole blood specimens collected in K₂EDTA blood collection tubes when stored for up to 24 hours at controlled room temperature (18 to 26°C).

Refrigerated and Room Temperature K₃EDTA Venous Whole Blood Specimen Stability

In 510(k) submission K220031, a study was conducted to evaluate the stability of venous whole blood specimens collected in K₃EDTA blood collection tubes when stored at refrigerated storage temperature (2 to 8°C) and at controlled room temperature (18 to 26°C) and then tested on the Alinity hq. A total of 14 unique, native venous whole blood specimens collected from apparently healthy donors in K₃EDTA blood collection tubes were tested to evaluate the below-mentioned test conditions and time points in this study.

Table 39.9. Refrigerated & Room Temperature K₃EDTA Venous Whole Blood Specimen Stability Evaluation Conditions

Condition	Time Points (Time from Specimen Collection)
Baseline (Control Condition)	≥ 20 Minutes to < 4 Hours
2 to 8°C (Refrigerated Test Storage Condition)	≥ 48 Hours to < 50 Hours at 2 to 8°C
	≥ 50 Hours to < 52 Hours at 2 to 8°C
At 18°C (Controlled Room Temperature Test Storage Condition)	≥ 24 Hours to < 26 Hours at 18°C
	≥ 26 Hours to < 28 Hours at 18°C
At 26°C (Controlled Room Temperature Test Storage Condition)	≥ 24 Hours to < 26 Hours at 26°C
	≥ 26 Hours to < 28 Hours at 26°C

Baseline testing was performed within 4 hours of specimen collection. Aliquots of each venous whole blood specimen were stored refrigerated at 2 to 8°C and in incubators at the extreme ends of room temperature (18°C and 26°C). Before each test time point, aliquots of the venous whole blood specimens were equilibrated to instrument room temperature – as recommended by the Alinity h-series Operations Manual.

Alinity hq testing was performed using a minimum of 1 set of reagent lots and 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal calibrator. Each venous whole blood specimen was tested at all time points in a minimum of 2 replicates on one Alinity hq using the CBC+Diff+Retic test selection.

In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. The analysis was performed separately for each specimen, test time point, storage condition, and measurand. For each storage condition, specimen, and measurand, the difference between each test time point and the corresponding baseline was calculated.

The results of this specimen stability study support the system labeling claim for the stability of venous whole blood venous specimens collected in K₃EDTA blood collection tubes when stored for up to 48 hours at refrigerated storage temperature (2 to 8°C) and up to 24 hours at controlled room temperature (18 to 26°C).

Refrigerated and Room Temperature K₃EDTA Capillary Whole Blood Specimen Stability

In 510(k) submission K220031, a study was conducted to evaluate the stability of capillary whole blood specimens collected in K₃EDTA blood collection tubes when stored at refrigerated storage temperature (2 to 8°C) and at controlled room temperature (18 to 26°C) and then tested on the Alinity hq. A total of 94 unique, native capillary whole blood specimens collected from apparently healthy donors in K₃EDTA blood collection tubes were tested to evaluate the below-mentioned test conditions and time points in this study.

Table 39.10. Refrigerated & Room Temperature K₃EDTA Capillary Whole Blood Specimen Stability Evaluation Conditions

Condition	Time Points (Time from Specimen Collection)
Baseline (Control Condition)	≥ 20 Minutes to < 4 Hours
2 to 8°C (Refrigerated Test Storage Condition)	≥ 48 Hours to < 50 Hours at 2 to 8°C
	≥ 50 Hours to < 52 Hours at 2 to 8°C
At 18°C (Controlled Room Temperature Test Storage Condition)	≥ 24 Hours to < 26 Hours at 18°C
	≥ 26 Hours to < 28 Hours at 18°C
At 26°C (Controlled Room Temperature Test Storage Condition)	≥ 24 Hours to < 26 Hours at 26°C
	≥ 26 Hours to < 28 Hours at 26°C

Baseline testing was performed within 4 hours of specimen collection. Aliquots of each capillary whole blood specimen were stored refrigerated at 2 to 8°C and/or in

incubators at the extreme ends of room temperature (18°C or 26°C). Before each test time point, aliquots of the capillary whole blood specimens were equilibrated to instrument room temperature – as recommended by the Alinity h-series Operations Manual.

Alinity hq testing was performed using a minimum of 1 set of reagent lots and 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal calibrator. If volume permitted, each capillary whole blood specimen was tested at baseline and all test time points for the storage conditions. Due to volume constraints, each capillary whole blood specimen was tested at the time points in a minimum of 1 replicate on the Alinity hq using the CBC+Diff+Retic test selection. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. The analysis was performed separately for each specimen, test time point, storage condition, and measurand. For each storage condition, specimen, and measurand, the difference between each test time point and the corresponding baseline was calculated.

The results of this specimen stability study support the system labeling claim for the stability of capillary whole blood specimens collected in K₃EDTA blood collection tubes when stored for up to 48 hours at refrigerated storage temperature (2 to 8°C) and up to 24 hours at controlled room temperature (18 to 26°C).

7. Detection Limit:

In 510(k) submission K220031, limits of blank, detection, and quantitation were established for WBC, RBC, HGB and PLT. Testing was conducted on the Alinity hq 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 2 sets of reagent lots. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values

are displayed in Table 39.11. All results met the predefined acceptance criteria and were determined to be acceptable.

Table 39.11. Detection Limits

Measurand	Results		
	LoB	LoD	LoQ
WBC (x 10 ³ /μL)	0.01	0.02	0.03
RBC (x 10 ⁶ /μL)	0.00	0.01	0.01
HGB (g/dL)	0.03	0.05	0.05
PLT (x 10 ³ /μL)	0.12	0.29	0.29

8. Assay Cut-Off:

Not Applicable

9. Accuracy (Instrument):

Not Applicable

10. Carryover:

Alinity hq susceptibility to potential carryover was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document H26-A2. The results in this 510(k) submission demonstrate acceptable performance.

B. Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was conducted to assess the performance of the Alinity hq using the algorithm of the subject device when compared to the predicate device for this 510(k) submission [Alinity hq of the Alinity h-series System (K220031)] as well as the predicate device for 510(k) submission K220031 [Sysmex XN-Series (XN-10) Automated Hematology Analyzer (K112605)].

In 510(k) submission K220031, a total of 2,194 unique venous and/or capillary specimens collected in K₂EDTA blood collection tubes from pediatric (≤ 21 years) and adult (> 21 years) 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 blood collection 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 and 244 specimens collected from subjects without any medical conditions. Study sites aimed to cover the reportable ranges for the measurands. A maximum of 10% samples per measurand were permitted to be contrived to cover the reportable range.

Each specimen was tested within 8 hours from the time of collection in 1 replicate using the CBC+Diff+Retic test selection and either the closed or open tube processing mode on the Alinity hq and in 1 replicate on the Sysmex XN-Series (XN-10) Automated Hematology Analyzer. Specimens were tested on the Alinity hq and the Sysmex XN-Series (XN-10) Automated Hematology Analyzer within 2 hours of each other. The Alinity hq was in a 1+0 system configuration (5 standalone Alinity hq) at 5 of the 7 sites. The Alinity hq was in a 2+1 system configuration (2 Alinity hq that are configured as part of the Alinity h-series System) at 1 site. One site tested the Alinity hq in both the 1+0 and 2+1 system configurations. Alinity hq testing was performed using a minimum of 1 set of reagent lots and 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal calibrator. The Sysmex XN-Series (XN-10) Automated Hematology Analyzer was calibrated using its recommended commercial calibrators at each site. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device.

Passing-Bablok regression analyses was performed with the investigational method [Alinity hq using the algorithm of the subject device] as the dependent variable (y) and the predicate method [Alinity hq of the Alinity h-series System (K220031) and

Sysmex XN-Series (XN-10) Automated Hematology Analyzer (K112605)] as the independent variable (x). Deming regression analyses were used in place of Passing-Bablok analysis for measurands with very low numeric values. Bias at medical decision points was also evaluated for each site individually and for all sites combined. All results were within the predefined acceptance criteria and found to be acceptable when compared to the predicate device from this 510(k) submission [Alinity hq of Alinity h-series System (K220031)] as well as the predicate device for 510(k) submission K220031 [Sysmex XN-Series (XN-10) Automated Hematology Analyzer (K112605)]. Results for measurands potentially impacted by the algorithm modification incorporated in the subject device are in [Table 39.12](#) and [Table 39.13](#). Results for potentially impacted measurands with acceptance criteria are shaded in [Table 39.12](#) and [Table 39.13](#). Refer to 510(k) submission K220031 for all other measurands.

The 67 affected samples in this study were further analyzed. Results for potentially impacted measurands are provided in [Table 39.14](#). The shaded results demonstrate reduction of falsely increased basophil measurements (*i.e.*, BASO and %BASO) when using the Alinity hq with the algorithm of the subject device as compared to the predicate device for affected samples. There were no notable differences in the results for all other measurands – including %LYM, LYM, and WBC – reported by the Alinity hq.

Overall, the Alinity hq – when using the algorithm of the subject device – demonstrates comparable performance to the predicate device from this 510(k) submission [Alinity hq of the Alinity h-series System (K220031)] as well as the predicate device for 510(k) submission K220031 [Sysmex XN-Series (XN-10) Automated Hematology Analyzer (K112605)] in a clinical laboratory setting. Additionally, the results demonstrate that the algorithm modification incorporated in subject device reduces overestimation of basophil counts and, hereby, reduces falsely increased basophil measurements (*i.e.*, BASO and %BASO) and the potential of incorrect results for affected samples.

Table 39.12. Regression Analysis of Alinity hq using Algorithm of the Subject Device (SW5.8) Compared to the Sysmex XN-Series (XN-10) Automated Hematology Analyzer

Measurand	N	Sample Range	r (95% CI)	Slope (95% CI)	Intercept (95% CI)
BASO (x 10 ³ /μL)	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)
LYM (x 10 ³ /μL)	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)
WBC (x 10 ³ /μL)	1958	0.07 - 436.00	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)

Table 39.13. Regression Analysis of Alinity hq using Algorithm of the Subject Device (SW5.8) Compared to the Predicate Device (SW5.0)

Measurand	N	Sample Range	r (95% CI)	Slope (95% CI)	Intercept (95% CI)
BASO (x 10 ³ /μL)	1801	0.00 - 2.41	0.75 (0.73, 0.77)	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)
%BASO (%)	1801	0.00 - 8.37	0.92 (0.91, 0.92)	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)
LYM (x 10 ³ /μL)	1589	0.05 - 8.34	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)
%LYM (%)	1589	0.34 - 84.60	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)
WBC (x 10 ³ /μL)	1948	0.07 - 436.00	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)

Table 39.14. Regression Analyses Comparing Alinity hq using Algorithm of the Subject Device (SW5.8) and Predicate Device (SW5.0) for Affected Samples

Measurand	Device	N	Sample Range	r (95% CI)	Slope (95% CI)	Intercept (95% CI)
BASO (x 10 ³ /μL)	Predicate Device (K220031)	67	0.03 - 8.11	0.93 (0.90, 0.96)	2.22 (1.64, 2.80)	-0.01 (-0.05, 0.02)
	Alinity hq using Algorithm of the Subject Device	67	0.00 - 1.69	0.84 (0.75, 0.90)	1.17 (1.00, 1.32)	0.00 (-0.01, 0.01)
%BASO (%)	Predicate Device (K220031)	67	2.00 - 4.49	0.33 (0.10, 0.53)	0.54 (0.31, 0.83)	1.83 (1.45, 2.05)
	Alinity hq using Algorithm of the Subject Device	67	0.00 - 4.33	0.61 (0.44, 0.75)	1.22 (0.98, 1.52)	-0.08 (-0.39, 0.19)
LYM (x 10 ³ /μL)	Predicate Device (K220031)	53	0.37 - 6.26	0.99 (0.99, 1.00)	0.93 (0.90, 0.98)	0.06 (-0.01, 0.12)
	Alinity hq using Algorithm of the Subject Device	53	0.38 - 6.47	0.99 (0.98, 0.99)	0.98 (0.95, 1.01)	0.04 (-0.02, 0.11)
%LYM (%)	Predicate Device (K220031)	53	6.31 - 60.50	0.99 (0.98, 0.99)	0.99 (0.95, 1.03)	-0.50 (-1.78, 0.72)
	Alinity hq using Algorithm of the Subject Device	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 /μL)	Predicate Device (K220031)	65	1.22 - 205.00	1.00 (1.00, 1.00)	0.99 (0.98, 1.01)	0.02 (-0.05, 0.12)
	Alinity hq using Algorithm of the Subject Device	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:

Anticoagulants Comparability – K₃EDTA versus K₂EDTA

In 510(k) submission K220031, anticoagulant comparability (K₃EDTA versus K₂EDTA) was evaluated at 3 sites (1 internal site and 2 external clinical sites) based on guidance from CLSI EP35. A total of 190 venous whole blood samples (normal and abnormal) collected from unique donors in the evaluation tube type (K₃EDTA) and in the control tube type (K₂EDTA) were included in the study. The K₃EDTA and K₂EDTA whole blood samples from 1 donor constituted 1 donor set. The clinical sites aimed to enroll donor sets that covered all relevant medical decision points and were representative of the analytical measuring ranges of the Alinity hq. The samples were tested on the Alinity hq using a minimum of 1 set of reagent lots and 1 control lot and a minimum of 1 lot of Alinity h-series HemCal calibrator. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. Comparability between the anticoagulants was

assessed for all measurands based on the mean difference or % difference. All results met the predefined bias acceptance criteria.

Matrix Comparability – Capillary versus Venous

In 510(k) submission K220031, a study was conducted to evaluate the comparability of matrices (capillary versus venous) using whole blood specimens tested on the Alinity hq. Paired venous and capillary samples (normal and abnormal) were obtained from unique donors in Microtainer Microtube for Automated Process (MAP) Microtubes (K093972) (capillary, test condition) and standard K₂EDTA blood collection tubes (K981013) (venous, control condition). The blood collection tubes from 1 donor constituted 1 donor set. The samples were tested on the Alinity hq (1+0 system configuration and 2+1 system configuration) in a minimum of 2 replicates using the CBC+Diff+Retic test selection. Alinity hq testing was performed using a minimum of 1 set of reagent lots and 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal calibrator. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. Comparability between the matrices was assessed for all measurands based on the mean difference or % difference. All results met the predefined bias acceptance criteria.

Microtainer Capillary versus Microtube for Automated Process (MAP)

In 510(k) submission K220031, comparability between the K₂EDTA Microtainer Capillary tube versus K₂EDTA Microtainer Microtube for Automated Process (MAP) was evaluated. A total of 44 unique normal specimens were collected in the K₂EDTA Microtainer Microtube for Automated Process (MAP, K093972) and K₂EDTA Microtainer Capillary (K182078) blood collection tube types and tested in 1 replicate on the Alinity hq in the open or closed tube processing mode. Alinity hq testing was performed using a minimum of 1 set of reagent lots and 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal calibrator.

Two assessments were performed:

- MAP (open tube processing mode; test condition) vs. MAP (closed tube processing mode; control condition)
- Microtainer Capillary (open tube processing mode; test condition) vs. MAP (open tube processing mode; control condition)

In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. Comparability between the sample tube types was assessed for all measurands based on the mean difference or % difference. All results met the predefined bias acceptance criteria.

Sample/Tube Processing Mode Comparability – Closed Mode versus Open Mode

In 510(k) submission K220031, sample processing mode comparability was evaluated. Venous whole blood specimens (normal and abnormal) were collected from unique donors in K₂EDTA blood collection tubes at 3 clinical sites. The samples were tested on the Alinity hq in a minimum of 2 replicates in the closed tube processing mode (control condition) and in the open tube processing mode (test condition) using the CBC+Diff+Retic test selection. The samples were tested in the 1+0 system configuration or 2+1 system configuration. Alinity hq testing was performed using a minimum of 1 set of reagent lots and 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal calibrator. In this 510(k) submission, raw data files

from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. Comparability between the sample processing modes was assessed for all measurands based on the mean difference or % difference. All results met the predefined bias acceptance criteria.

C. Clinical Studies:

1. Clinical Sensitivity:

In 510(k) submission K220031, sensitivity and specificity performance of the Alinity hq were assessed for accuracy of identifying distributional abnormalities and morphological flags (PLT Clumps, RBC Fragments) by comparing to a 400-cell differential derived from 2 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 whole blood specimens collected in K₂EDTA blood collection tubes for the method comparison study were included in this study. Testing was performed at each of 6 clinical sites. Three blood films were prepared for each sample. Each sample was tested in 1 replicate on the Alinity hq using the open or closed tube processing mode and the CBC+Diff+Retic test selection. Alinity hq testing was performed using a minimum of 1 set of reagent lots and 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal calibrator. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device.

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 microscopic 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 by microscopy or Alinity hq testing were considered abnormal (positive). Specimens were classified as morphologically abnormal (morphological positive) based on predefined criteria for blast, left shift, variant lymphocytes, PLT clumps, and 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 microscopy results. For this analysis, separate 2x2 tables were constructed in order to determine sensitivity and specificity for both morphological and distributional abnormalities. Results potentially impacted by the algorithm modification incorporated in the subject device are displayed in [Table 39.15](#). The sensitivity and specificity for both morphological and distributional abnormalities (shaded in [Table 39.15](#)) met predefined acceptance criteria. Additionally, the results demonstrate a reduction in the number of false positive sample %BASO classifications in affected samples when using the modified algorithm of the subject device as compared to the predicate device.

Table 39.15. Morphological and Distributional Abnormalities Summary

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%)

^aSensitivity = 100* TP / (TP + FN)

^bSpecificity = 100* TN / (TN + FP)

^cEfficiency = 100* (TN + TP) / (TP + FN + FP + TN)

2. Clinical Specificity:

See Clinical Sensitivity

D. Clinical Cut-Off:

Not Applicable

E. Expected Values/Reference Range:

In 510(k) submission K220031, reference range studies were performed based on guidance from the CLSI document EP28-A3 to establish adult (> 21 years old) reference ranges for male and female populations and to establish reference ranges for pediatric subgroups (neonate [birth to 1 month], infant [> 1 month to 2 years old], child [> 2 to 12 years old], and adolescent [> 12 to 21 years old]) by evaluating venous or capillary whole blood specimens collected in K2EDTA blood collection tubes from apparently healthy subjects. Alinity hq testing was performed using a minimum of 1 set of reagent lots and 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal calibrator. In this 510(k) submission, raw data files from 510(k) submission K220031 were replayed using the modified algorithm for the subject device. For each patient population and measurand, verification of reference ranges was considered acceptable if the upper bound of the two-sided 95% CI for the percentage of replayed results that were within the reference ranges of the predicate device was $\geq 95\%$. Since this predefined acceptance criteria was

met for all measurands, the reference ranges are unchanged from 510(k) submission K220031. Refer to 510(k) submission K220031 for the reference ranges.

IX. Conclusion:

The results presented in this 510(k) Pre-market Notification demonstrate that the performance of the subject device [Alinity hq of the Alinity h-series System (using Alinity h-series Software Version 5.8)] is substantially equivalent to the predicate device [Alinity hq of the Alinity h-series System (K220031, which was cleared using Alinity h-series Software Version 5.0)].

The results also demonstrate that the algorithm modification reduces overestimation of basophil counts and, hereby, reduces falsely increased basophil measurements (*i.e.*, BASO and %BASO) and the potential of incorrect results for affected samples. The submitted information is complete and supports the safety and effectiveness of the device.