August 4, 2023

Abbott Laboratories
Neha Vatsyayan
Regulatory Affairs Project Manager
4551 Great America Pkwy
Santa Clara, California 95054

Re: K220031
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
Dated: March 29, 2023
Received: March 31, 2023

Dear Neha Vatsyayan:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220031

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 System can be configured as:

- One standalone 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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Section 5: 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 Pkwy,
Santa Clara, CA 95054
Date Prepared: April 28, 2023

Contact:
Neha Vatsyayan
Regulatory Affairs Project Manager
Abbott Diagnostics Division
Phone: (408) 313 4401
E-Mail: neha.vatsyayan@abbott.com

II. Device Information

Trade name (proprietary name): Alinity h-series system

Common name (usual name): Automated Hematology Analyzer and Slide Maker Stainer

Classification Name: Automated Differential Cell Counter

III. Regulatory Information

Alinity hq (Analyzer)

Device Classification: Class II

Regulation Description: Automated Differential Cell Counter

Governing Regulation: 21 CFR 864.5220

Code: GKZ

Alinity hs (Slide maker stainer)

Device Classification: Class I

Regulation Description: Automated Slide Stainer

Governing Regulation: 21 CFR 864.3800

Code: KPA

IV. Predicate Device

Sysmex® XN-Series (XN-10, XN-20) Automated Hematology Analyzers (K112605)

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 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).

Principles of Operation

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

Two methods are used to introduce a specimen to the Alinity hq module:

- Closed-tube processing mode
- Open-tube processing mode

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.

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 standalone 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 K_2EDTA or K_3EDTA. The Alinity hq analyzer provides quantitative results for the following measurands: WBC, NEU, %N, LYM, %L, MONO, %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

Definitions of the reportable parameters are presented in Table 5-1.

Table 5-1

Peripheral Whole Blood Reportable Parameters

Abbreviation	Definition
White Blood Cell Parameters	
BASO	Basophil absolute concentration
%B	Basophil percentage of WBCs (%BASO)
EOS	Eosinophil absolute concentration
%E	Eosinophil percentage of WBCs (%EOS)
IG	Immature Granulocyte concentration
%IG	Immature Granulocyte percentage
LYM	Lymphocyte absolute concentration
%L	Lymphocyte percentage of WBCs (%LYM)
MONO	Monocyte absolute concentration
%M	Monocyte percentage of WBCs (%MON)
NEU	Neutrophil absolute concentration
%N	Neutrophil percentage of WBCs (%NEU)
WBC	White Blood Cell concentration

Abbreviation	Definition
Red Blood Cell Parameters	
HCT	Hematocrit
HGB	Hemoglobin concentration
IRF	Immature Reticulocyte Fraction
MCH	Mean Cell Hemoglobin
MCHC	Mean Cell Hemoglobin Concentration
MCHr	Mean cell hemoglobin of the reticulocyte
MCV	Mean Cell Volume
NRBC	Nucleated red blood cell absolute concentration
NR/W	NRBCs per 100 WBCs
RETIC	reticulocyte concentration (RETC)
RBC	Red Blood Cell concentration
RDW	red blood cell distribution width
%R	Reticulocyte percentage of RBCs (%RETC)

Platelet Parameters	
PLT	Platelet concentration
MPV	Mean Platelet Volume
%rP	Reticulated Platelet percentage

VI. Comparison of Technological Characteristics

The similarities and differences between the subject device and the predicate device are presented in the Device Similarities and Differences tables below.

Table 5-2
Device Similarities and Differences

Device Similarities		
Item	**Subject Device:** **Alinity h-series System**	**Predicate Device:** **Sysmex® XN-Series (XN-10, XN-20)**
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 standalone 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, MONO, %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.	The Sysmex XN-10 and XN-20 modules are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-Series modules classify and enumerate the following parameters for whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, NRBC%/#, IG%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IPF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF# parameters in cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K_2 or K_3EDTA anticoagulant and serous and synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.

Table 5-2, Continued
Device Similarities and Differences

Device Similarities (Continued)		
Item	**Subject Device: Alinity h-series System**	**Predicate Device: Sysmex® XN-Series (XN-10, XN-20)**
Test Principle	Performs hematology analyses according to flow cytometry method (using Hydro Dynamic Focusing) and absorption spectrophotometry method (using cyan-methemoglobin).	Performs hematology analyses according to flow cytometry method (using Hydro Dynamic Focusing), and absorption spectrophotometry method (using sodium lauryl sulphate (SLS))
Parameters [1]	Whole Blood Mode: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, MPV, IRF, NEU, %N, LYM, %L, MONO, %M, EOS, %E, BASO, %B, NRBC, NR/W, IG, %IG, RETIC, %R, RDW, MCHr, %rP	Whole Blood Mode: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, MPV, IRF, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, NRBC%/#, IG%/#, RET%/#, RDW-CV, RDW-SD, RET-He#, IPF
Specimen Type	Whole blood	Whole blood
Use of Controls/ Calibrators	Yes	Yes
IPU	Multi-Module connect	Multi-Module connect
Sample Aspiration/ Fluidic Pathway	Single aspiration pathway	Single aspiration pathway
Software/Hardware	Rules based rerun / reflex	Rules-based rerun / reflex

[1] Different names/formats of equivalent parameters are used between the Alinity h-series System and Sysmex® XN-series; therefore, equivalent parameters are listed in the same row.

Table 5-2, Continued
Device Similarities and Differences

Device Differences		
Item	**Subject Device: Alinity h-series System**	**Predicate Device: Sysmex® XN-Series (XN-10, XN-20)**
Test Principle	The Alinity h-series System uses flow cytometry method with Hydro Dynamic Focusing to analyze whole blood samples including RBC and PLT.	Sysmex XN-Series uses Hydro Dynamic Focusing (Direct Current Detection) for RBC and PLT.
Parameters	Not Applicable - Body Fluid test selection is not included in this submission.	Body Fluid Mode: WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-BF#
Specimen Type	Not Applicable - Body Fluid is not included in this submission.	Body Fluids [i.e., cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids]
Reagents	• Diluent • HGB Reagent • WBC Reagent • Retic Reagent	CELLPACKTM DCL (Diluent) CELLPACKTM DFL (Diluent) LYSERCELL WNR (Lyse) LYSERCELL WDF (Lyse) LYSERCELL WPC (Lyse) FLUOROCELL WNR (Stain) FLUOROCELL WDF (Stain) FLUOROCELL RET (Stain) FLUOROCELL PLT (Stain) FLUOROCELL WPC (Stain) SULFOLYSER® (Lyse)
Controls/ Calibrators	Whole Blood: • Calibrator - Alinity h-series HemCal • Control - Alinity h-series Control 29P No Body Fluids Mode on Alinity hq.	Whole Blood: • XN-Check - 3 Levels • XN CAL (XN-10/X-20 Calibrator) • XN CAL PF (Platelet F Calibrator) Body Fluid: • XN Check BF – 2 Levels
Measuring Channels/ Methods Selection	• CBC+Diff (for RBC, WBC, and PLT) • CBC+Diff+Retic (for RBC, WBC, PLT and Retic)	• RET/PLT • WNR, WDF, WNR, WPC (Not available in XN-10) • PLT-F

Table 5-2, Continued
Device Similarities and Differences

Device Differences (Continued)		
Item	**Subject Device: Alinity h-series System**	**Predicate Device: Sysmex® XN-Series (XN-10, XN-20)**
Modules Connected to the Analyzer	Required Water Purification System System Control Center Computer (SCC) Optional Laboratory Automation System (LAS) for automatic sample loading	IPU (Information processing unit) Pneumatic Unit
Data Transfer Mode	USB, Internet, and Intranet	USB, CD-R, Internet, and Intranet

VII. Performance Characteristics:

A. Analytical Performance:

1. Method Comparison

The method comparison study was conducted based on guidance from the Clinical and Laboratory Standards Institute CLSI EP09c, 3rd edition[2] to assess the performance of the Alinity hq when compared to the predicate device, Sysmex (XN-10, XN-20) (K112605). A total of 2,194 unique venous and/or capillary specimens collected in K_2EDTA 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. For each measurand, each specimen was tested within 8 hours from the time of collection in 1 replicate using either the Closed or Open tube processing mode in the CBC+Diff+Retic test selection on the Alinity h-series System and in 1 replicate on the Sysmex (XN-10, XN-20) System.

Passing-Bablok and Deming regression analyses were performed with the investigational method as the dependent variable (y) and the predicate method as the independent variable (x).

Bias at the critical points (the upper and lower limits of the reference ranges and relevant medical decision levels) were also evaluated for each site individually and for all sites combined. All results were within the predefined acceptance criteria and found to be acceptable. The method comparison results are shown in the table below.

[2] Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. CLSI Document EP09-A3. Wayne, PA: CLSI; 2013.

All Sites Combined - Regression Analysis

Measurand	N	Sample Range	r (95% CI)	Slope (95% CI)	Intercept (95% CI)
WBC (X 10^3/µL)	2002	0.07 - 436.00	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.01 (0.00, 0.03)
%N (%)	1551	7.56 - 98.30	0.99 (0.99, 1.00)	1.00 (1.00, 1.01)	0.22 (-0.10, 0.50)
%L (%)	1640	0.34 - 84.60	1.00 (1.00, 1.00)	1.00 (0.99, 1.00)	0.08 (0.00, 0.16)
%M (%)	1646	0.03 - 49.20	0.98 (0.97, 0.98)	0.99 (0.98, 1.00)	-0.03 (-0.13, 0.06)
%E (%)	1712	0.00 - 37.50	0.99 (0.99, 0.99)	1.02 (1.01, 1.03)	0.02 (0.01, 0.03)
%B (%)	1854	0.00 - 8.37	0.45 (0.41, 0.49)	1.53 (1.47, 1.59)	-0.14 (-0.17, -0.11)
%IG (%)[a]	1545	0.00 - 12.50	0.59 (0.56, 0.62)	0.59 (0.45, 0.73)	-0.30 (-0.44, -0.15)
NR/W[a]	1949	0.00 - 228.00	0.99 (0.99, 0.99)	0.97 (0.93, 1.02)	-0.07 (-0.13, -0.01)
RBC (X 10^6/µL)	1993	0.60 - 8.03	1.00 (0.99, 1.00)	0.99 (0.99, 0.99)	0.04 (0.03, 0.06)
HGB (g/dL)	2006	1.64 - 23.30	1.00 (1.00, 1.00)	0.99 (0.99, 0.99)	0.24 (0.21, 0.28)
HCT (%)	1999	4.92 - 86.00	0.99 (0.99, 0.99)	1.02 (1.01, 1.02)	-0.49 (-0.68, -0.29)
MCV (fL)	2001	51.40 - 131.00	0.95 (0.94, 0.95)	1.05 (1.03, 1.07)	-4.56 (-6.06, -3.12)
MCH (pg)	1993	15.30 - 47.00	0.98 (0.97, 0.98)	0.97 (0.96, 0.98)	1.25 (0.94, 1.52)
MCHC (g/dL)	1993	25.00 - 39.30	0.66 (0.63, 0.68)	0.97 (0.92, 1.00)	1.51 (0.40, 2.90)
%R (%)	1942	0.12 - 20.80	0.97 (0.96, 0.97)	1.06 (1.04, 1.07)	0.01 (-0.01, 0.03)
IRF	1935	0.00 - 0.70	0.89 (0.88, 0.90)	0.94 (0.92, 0.96)	-0.01 (-0.01, -0.01)
PLT (X 10^3/µL)	1933	1.21 - 5144.00	0.99 (0.99, 0.99)	0.97 (0.97, 0.98)	0.27 (-0.41, 1.08)

[a]A summary of the Deming regression model is presented for NRBC, NR/W, IG, and %IG. A summary of the Passing-Bablok regression model is presented for all other measurands.

All Sites Combined - Regression Analysis (Continued)

Measurand	N	Sample Range	r (95% CI)	Slope (95% CI)	Intercept (95% CI)
MPV (fL)	1723	8.04 - 13.30	0.73 (0.71, 0.75)	0.94 (0.91, 0.99)	0.29 (-0.14, 0.65)
%rP (%)[b]	1910	0.55 - 42.10	0.82 (0.81, 0.84)	0.78 (0.76, 0.80)	0.62 (0.55, 0.69)
MCHr (pg)	1933	6.89 - 45.80	0.84 (0.82, 0.85)	1.09 (1.06, 1.12)	-1.28 (-2.27, -0.29)
NEU (X 10^3/µL)	1551	0.10 - 55.00	1.00 (1.00, 1.00)	1.01 (1.01, 1.01)	0.00 (-0.02, 0.02)
LYM (X 10^3/µL)	1640	0.05 - 27.20	0.99 (0.99, 1.00)	0.99 (0.99, 1.00)	0.02 (0.01, 0.03)
MONO (X 10^3/µL)	1646	0.00 - 8.84	0.99 (0.99, 0.99)	1.02 (1.01, 1.03)	-0.02 (-0.03, -0.01)
EOS (X 10^3/µL)	1712	0.00 - 4.19	0.99 (0.99, 0.99)	1.02 (1.01, 1.03)	0.00 (0.00, 0.00)
BASO (X 10^3/µL)	1854	0.00 - 8.11	0.22 (0.18, 0.26)	1.31 (1.27, 1.37)	0.00 (-0.01, 0.00)
IG (X 10^3/µL)[a]	1545	0.00 - 3.15	0.81 (0.80, 0.83)	1.01 (0.85, 1.18)	-0.07 (-0.09, -0.05)
NRBC (X 10^3/µL)[a]	1945	0.00 - 17.70	0.91 (0.90, 0.92)	0.88 (0.70, 1.07)	0.01 (0.00, 0.02)
RDW (%)	2003	10.10 - 32.30	0.94 (0.93, 0.94)	0.86 (0.84, 0.87)	2.23 (2.06, 2.45)
RETIC (X 10^3/µL)	1935	1.96 - 614.00	0.96 (0.96, 0.97)	1.05 (1.04, 1.06)	0.79 (0.02, 1.64)

[a] A summary of the Deming regression model is presented for NRBC, NR/W, IG, and %IG. A summary of the Passing-Bablok regression model is presented for all other measurands.
[b] %rP (%) on Alinity h-series System is equivalent to the Sysmex XN-10 IPF measurand.

All Sites Combined - Estimated Bias at Critical Points

Measurand	Critical Points	Bias		%Bias	
		Estimate	95% CI	Estimate	95% CI
HGB (g/dL)	8.00	0.17	0.16, 0.20	2.18	2.03, 2.48
	12.0	0.14	0.13, 0.17	1.17	1.09, 1.43
	16.2	0.11	0.09, 0.15	0.65	0.53, 0.90
HCT (%)	14.0	-0.25	-0.37, -0.11	-1.75	-2.61, -0.81
	35.4	0.13	0.06, 0.20	0.38	0.18, 0.57
	46.4	0.33	0.22, 0.45	0.71	0.46, 0.97
	70.0	0.75	0.51, 1.00	1.07	0.72, 1.42
MCV (fL)	80.0	-0.47	-0.70, -0.29	-0.58	-0.88, -0.36
	100	0.55	0.31, 0.82	0.55	0.31, 0.82
RDW (%)	11.6	0.57	0.54, 0.63	4.93	4.64, 5.42
	14.0	0.23	0.20, 0.27	1.63	1.46, 1.93
WBC (X 10^3/µL)	1.00	0.01	0.00, 0.02	1.09	0.03, 2.40
	3.54	0.01	0.00, 0.02	0.29	0.02, 0.54
	9.06	0.01	-0.01, 0.02	0.10	-0.10, 0.21
	30.0	0.00	-0.08, 0.04	0.01	-0.26, 0.13
%N (%)	40.0	0.39	0.25, 0.60	0.99	0.62, 1.50
	70.0	0.52	0.40, 0.60	0.74	0.57, 0.86
%L (%)	20.0	0.02	-0.03, 0.10	0.09	-0.14, 0.50
	50.0	-0.08	-0.23, 0.10	-0.15	-0.46, 0.20
%M (%)	4.00	-0.05	-0.11, -0.01	-1.34	-2.79, -0.25
	8.00	-0.08	-0.12, -0.05	-1.00	-1.53, -0.68
%E (%)	0.00	0.02	0.01, 0.03	NA	NA
	6.00	0.16	0.11, 0.21	2.67	1.81, 3.42
%B (%)	0.00	-0.14	-0.18, -0.11	NA	NA
	2.00	0.91	0.80, 1.01	45.57	40.05, 50.73
NEU (X 10^3/µL)	0.50	0.01	-0.01, 0.02	1.17	-1.99, 4.10
	1.42	0.01	0.00, 0.03	0.97	0.03, 1.85
	6.34	0.06	0.04, 0.07	0.89	0.66, 1.12
	25.0	0.22	0.13, 0.30	0.88	0.53, 1.19
LYM (X 10^3/µL)	1.00	0.01	0.00, 0.01	0.77	0.27, 1.28
	4.00	-0.02	-0.04, 0.00	-0.47	-0.89, 0.05

NA = Not applicable since the critical point is zero.

All Sites Combined - Estimated Bias at Critical Points (Continued)

Measurand	Critical Points	Bias		%Bias	
		Estimate	95% CI	Estimate	95% CI
MONO (X 10^3/µL)	0.20	-0.01	-0.02, -0.01	-7.49	-10.18, -5.56
	1.00	0.00	0.00, 0.01	0.39	-0.24, 0.95
EOS (X 10^3/µL)	0.00	0.0	0.00, 0.00	NA	NA
	0.40	0.01	0.01, 0.01	2.72	1.96, 3.50
	1.50	0.04	0.02, 0.05	2.38	1.56, 3.21
BASO (X 10^3/µL)	0.00	0.00	-0.01, 0.00	NA	NA
	0.20	0.06	0.05, 0.07	29.22	24.67, 34.63
	1.00	0.31	0.26, 0.37	30.73	25.66, 36.94
%IG (%)	0.00	-0.30	-0.44, -0.15	NA	NA
	1.00	-0.71	-0.74, -0.68	-70.96	-73.67, -68.25
	2.00	-1.12	-1.26, -0.99	-56.13	-62.86, -49.39
NR/W	0.00	-0.07	-0.13, -0.01	NA	NA
	1.00	-0.10	-0.15, -0.04	-9.54	-15.36, -3.72
RBC (X 10^6/µL)	4.00	0.00	0.00, 0.01	0.10	-0.03, 0.26
	5.60	-0.01	-0.02, 0.00	-0.22	-0.42, -0.02
MCH (pg)	26.7	0.47	0.43, 0.51	1.76	1.60, 1.89
	31.9	0.32	0.27, 0.37	1.00	0.85, 1.15
MCHC (g/dL)	32.3	0.43	0.39, 0.50	1.33	1.20, 1.55
	35.9	0.31	0.18, 0.40	0.86	0.49, 1.11
RETIC (X 10^3/µL)	32.0	2.38	1.86, 2.97	7.43	5.80, 9.29
	129	7.18	6.09, 8.21	5.57	4.72, 6.36
%R (%)	0.80	0.05	0.04, 0.07	6.29	4.79, 8.68
	2.30	0.13	0.12, 0.15	5.82	5.24, 6.68
IRF	0.04	-0.01	-0.01, -0.01	-25.91	-30.19, -20.67
	0.37	-0.03	-0.04, -0.02	-8.01	-9.72, -6.41
PLT (X 10^3/µL)	10.0	-0.02	-0.75, 0.85	-0.24	-7.51, 8.53
	165	-4.58	-5.06, -3.93	-2.78	-3.06, -2.38
	415	-11.94	-13.55, -10.31	-2.88	-3.27, -2.48
	1000	-29.14	-33.97, -24.59	-2.91	-3.40, -2.46

NA = Not applicable since the critical point is zero.

All Sites Combined - Estimated Bias at Critical Points (Continued)

Measurand	Critical Points	Bias		%Bias	
		Estimate	95% CI	Estimate	95% CI
MPV (fL)	6.40	-0.07	-0.23, 0.06	-1.16	-3.61, 0.93
	11.0	-0.34	-0.38, -0.30	-3.06	-3.44, -2.68
%rP (%)	1.00	0.40	0.35, 0.45	39.80	34.65, 45.18
	7.00	-0.92	-1.03, -0.80	-13.17	-14.70, -11.50
MCHr (pg)	29.0	1.30	1.11, 1.46	4.47	3.83, 5.04
	34.5	1.78	1.62, 1.95	5.17	4.70, 5.64

NA = Not applicable since the critical point is zero.

2. Sensitivity and Specificity

The Sensitivity and Specificity study was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document CLSI H20-A2[3].

Sensitivity and specificity performance of the Alinity h-series System was assessed by identifying distributional abnormalities and morphological flags using blood films from venous and capillary specimens collected in K_2EDTA tubes.

For this analysis, separate 2x2 tables were constructed in order to determine sensitivity for both morphological and distributional abnormalities. The sample size (N) and numbers of true positives (TP), false positives (FP), true negatives (TN), false negatives (FN), sensitivity, specificity, and efficiency are presented in the table below. All results were within the predefined acceptance criteria and found to be acceptable.

All Sites Combined – Sensitivity and Specificity

	N	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)	Efficiency (95% CI)
Any Morphological Flags and/or Distributional Abnormalities	674	255	84	63	272	80.19% (75.38%, 84.43%)	76.40% (71.64%, 80.72%)	78.19% (74.88%, 81.25%)

[3] Clinical and Laboratory Standards Institute (CLSI). *Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition*. CLSI Document H20-A2. Wayne, PA: CLSI; 2007.

3. Precision (Repeatability)

Precision was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document H26-A2[4]. Samples from 32 unique donors (16 normal and 16 pathological around medical decision points) were collected in K_2EDTA tubes and tested in a minimum of 32 consecutive replicates for normal samples and a minimum of 10 consecutive replicates for pathological samples. The mean, standard deviation (SD), coefficient of variation (CV), and 95% CI were calculated for each parameter. All results met the predefined acceptance criteria and were determined to be acceptable.

4. System Reproducibility

Reproducibility was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A3[5].

The reproducibility study was performed at three clinical sites using a single lot of Alinity h-series 29P Control (low, normal, high). Each control level was tested for 5 days with 3 runs per day and in a minimum of 2 replicates per run. The within-laboratory %CV or SD for each control level were calculated and presented in the table below. All results met the predefined acceptance criteria and were determined to be acceptable.

[4] Clinical and Laboratory Standards Institute (CLSI). *Validation, Verification, And Quality Assurance Of Automated Hematology Analyzers; Approved Standard - Second Edition*. CLSI Document H26-A2. Wayne, PA: CLSI; 2010.

[5] Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

All Sites Combined – Reproducibility Study

Measurand	Level	N	Mean	Repeatability		Between-Run		Between-Day		Within-Laboratory[a]		Between-Device		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC (X 10^3/µL)	Low	84	3.04	0.068	2.22	0.000	0.00	0.028	0.93	0.073	2.41	0.027	0.87	0.078	2.56
	Normal	84	7.18	0.138	1.92	0.000	0.00	0.000	0.00	0.138	1.92	0.045	0.63	0.145	2.02
	High	84	16.12	0.185	1.15	0.000	0.00	0.000	0.00	0.185	1.15	0.000	0.00	0.185	1.15
NEU (X 10^3/µL)	Low	84	1.40	0.052	3.73	0.014	0.98	0.000	0.00	0.054	3.86	0.034	2.46	0.064	4.58
	Normal	84	3.45	0.097	2.80	0.015	0.42	0.000	0.00	0.098	2.83	0.060	1.72	0.115	3.32
	High	84	8.15	0.187	2.29	0.000	0.00	0.000	0.00	0.187	2.29	0.102	1.25	0.213	2.61
LYM (X 10^3/µL)	Low	84	0.88	0.035	4.02	0.000	0.00	0.008	0.93	0.036	4.13	0.012	1.35	0.038	4.34
	Normal	84	1.84	0.054	2.92	0.000	0.00	0.000	0.00	0.054	2.92	0.000	0.00	0.054	2.92
	High	84	3.57	0.082	2.29	0.000	0.00	0.000	0.00	0.082	2.29	0.000	0.00	0.082	2.29
MONO (X 10^3/µL)	Low	84	0.33	0.024	7.18	0.000	0.00	0.005	1.65	0.024	7.36	0.007	2.15	0.025	7.67
	Normal	84	0.80	0.051	6.35	0.000	0.00	0.000	0.00	0.051	6.35	0.000	0.00	0.051	6.35
	High	84	1.84	0.073	4.00	0.047	2.57	0.000	0.00	0.087	4.75	0.000	0.00	0.087	4.75
EOS (X 10^3/µL)	Low	84	0.07	0.010	13.91	0.000	0.00	0.002	2.76	0.010	14.18	0.000	0.00	0.010	14.18
	Normal	84	0.20	0.014	7.20	0.006	2.77	0.000	0.00	0.015	7.72	0.000	0.00	0.015	7.72
	High	84	0.49	0.025	5.16	0.010	2.13	0.000	0.00	0.027	5.59	0.003	0.55	0.027	5.61

NA=Not Applicable; %CVs are not meaningful when measurand result approaches zero.

[a] Reproducibility contains repeatability, between-run, between-day, and between-device variance components.

All Sites Combined – Reproducibility Study (Continued)

Measurand	Level	N	Mean	Repeatability		Between-Run		Between-Day		Within-Laboratory[a]		Between-Device		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
BASO (X 10^3/µL)	Low	84	0.03	0.008	24.23	0.005	14.55	0.001	2.04	0.009	28.34	0.000	0.00	0.009	28.34
	Normal	84	0.06	0.012	18.37	0.000	0.00	0.000	0.00	0.012	18.37	0.000	0.00	0.012	18.37
	High	84	0.15	0.017	10.71	0.007	4.57	0.000	0.00	0.018	11.64	0.003	2.14	0.018	11.84
IG (X 10^3/µL)	Low	84	0.33	0.024	7.40	0.000	0.00	0.000	0.00	0.024	7.40	0.010	2.96	0.026	7.97
	Normal	84	0.82	0.047	5.71	0.000	0.00	0.013	1.62	0.049	5.94	0.017	2.06	0.052	6.29
	High	84	1.92	0.079	4.09	0.061	3.16	0.000	0.00	0.099	5.17	0.059	3.08	0.116	6.02
NRBC (X 10^3/µL)	Low	84	0.00	0.000	NA	0.000	NA	0.000	NA	0.000	NA	0.000	NA	0.000	NA
	Normal	84	0.00	0.000	NA	0.000	NA	0.000	NA	0.000	NA	0.000	NA	0.000	NA
	High	84	2.34	0.062	2.64	0.000	0.00	0.000	0.00	0.062	2.64	0.016	0.69	0.064	2.73
RBC (X 10^6/µL)	Low	84	2.67	0.018	0.69	0.000	0.00	0.006	0.23	0.019	0.73	0.000	0.00	0.019	0.73
	Normal	84	4.13	0.028	0.68	0.000	0.00	0.000	0.00	0.028	0.68	0.019	0.46	0.034	0.82
	High	84	5.16	0.047	0.92	0.000	0.00	0.008	0.15	0.048	0.93	0.085	1.65	0.098	1.90
HGB (g/dL)	Low	84	7.11	0.041	0.57	0.017	0.25	0.000	0.00	0.044	0.62	0.048	0.68	0.065	0.92
	Normal	84	11.34	0.066	0.58	0.000	0.00	0.000	0.00	0.066	0.58	0.048	0.42	0.082	0.72
	High	84	16.37	0.094	0.57	0.017	0.11	0.020	0.12	0.097	0.60	0.000	0.00	0.097	0.60

NA=Not Applicable; %CVs are not meaningful when measurand result approaches zero.

[a] Reproducibility contains repeatability, between-run, between-day, and between-device variance components.

All Sites Combined – Reproducibility Study (Continued)

Measurand	Level	N	Mean	Repeatability		Between-Run		Between-Day		Within-Laboratory[a]		Between-Device		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
HCT (%)	Low	84	22.64	0.179	0.79	0.000	0.00	0.107	0.47	0.209	0.92	0.062	0.27	0.218	0.96
	Normal	84	35.88	0.269	0.75	0.000	0.00	0.038	0.11	0.272	0.76	0.244	0.68	0.366	1.02
	High	84	49.80	0.468	0.94	0.000	0.00	0.155	0.31	0.493	0.99	0.897	1.80	1.023	2.05
MCV (fL)	Low	84	84.68	0.120	0.14	0.185	0.22	0.248	0.29	0.332	0.39	0.320	0.38	0.461	0.54
	Normal	84	86.93	0.212	0.24	0.153	0.18	0.173	0.20	0.313	0.36	0.247	0.28	0.399	0.46
	High	84	96.48	0.092	0.10	0.116	0.12	0.270	0.28	0.308	0.32	0.201	0.21	0.368	0.38
MCH (pg)	Low	84	26.58	0.231	0.87	0.076	0.29	0.069	0.26	0.253	0.95	0.154	0.58	0.296	1.11
	Normal	84	27.48	0.240	0.88	0.000	0.00	0.000	0.00	0.240	0.88	0.041	0.15	0.244	0.89
	High	84	31.72	0.344	1.08	0.000	0.00	0.075	0.24	0.352	1.11	0.495	1.56	0.607	1.92
MCHC (g/dL)	Low	84	31.39	0.292	0.93	0.000	0.00	0.154	0.49	0.330	1.05	0.251	0.80	0.415	1.32
	Normal	84	31.61	0.310	0.98	0.000	0.00	0.000	0.00	0.310	0.98	0.150	0.47	0.344	1.09
	High	84	32.88	0.363	1.10	0.000	0.00	0.112	0.34	0.380	1.16	0.563	1.71	0.679	2.07
RDW (%)	Low	84	13.26	0.084	0.63	0.000	0.00	0.033	0.25	0.090	0.68	0.670	5.05	0.676	5.10
	Normal	84	13.32	0.096	0.72	0.000	0.00	0.021	0.16	0.098	0.74	0.705	5.29	0.711	5.34
	High	84	12.37	0.049	0.39	0.031	0.25	0.035	0.29	0.068	0.55	0.621	5.02	0.625	5.05

NA=Not Applicable; %CVs are not meaningful when measurand result approaches zero.

[a] Reproducibility contains repeatability, between-run, between-day, and between-device variance components.

All Sites Combined – Reproducibility Study (Continued)

Measurand	Level	N	Mean	Repeatability		Between-Run		Between-Day		Within-Laboratory[a]		Between-Device		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
RETIC (X 10^3/µL)	Low	84	216.24	3.142	1.45	0.000	0.00	1.132	0.52	3.340	1.54	4.535	2.10	5.632	2.60
	Normal	84	153.55	3.478	2.26	0.805	0.52	1.374	0.89	3.825	2.49	7.441	4.85	8.367	5.45
	High	84	132.30	4.172	3.15	0.000	0.00	0.000	0.00	4.172	3.15	10.734	8.11	11.517	8.71
IRF	Low	84	0.33	0.011	3.30	0.000	0.00	0.008	2.52	0.014	4.15	0.050	15.31	0.052	15.86
	Normal	84	0.27	0.011	4.23	0.000	0.00	0.005	2.02	0.013	4.69	0.028	10.30	0.031	11.32
	High	84	0.19	0.009	4.56	0.003	1.48	0.000	0.00	0.009	4.80	0.004	2.28	0.010	5.31
PLT (X 10^3/µL)	Low	84	73.78	1.977	2.68	0.000	0.00	0.508	0.69	2.041	2.77	1.317	1.79	2.429	3.29
	Normal	84	225.19	3.454	1.53	1.380	0.61	0.216	0.10	3.726	1.65	1.257	0.56	3.932	1.75
	High	84	478.12	7.653	1.60	0.000	0.00	2.889	0.60	8.180	1.71	3.997	0.84	9.105	1.90
MPV (fL)	Low	84	9.55	0.070	0.73	0.000	0.00	0.000	0.00	0.070	0.73	0.022	0.23	0.073	0.77
	Normal	84	9.59	0.041	0.43	0.000	0.00	0.008	0.08	0.042	0.44	0.022	0.23	0.047	0.49
	High	84	9.60	0.031	0.32	0.021	0.22	0.000	0.00	0.037	0.39	0.005	0.05	0.038	0.39
%rP (%)	Low	84	9.77	0.439	4.49	0.000	0.00	0.030	0.31	0.440	4.50	0.000	0.00	0.440	4.50
	Normal	84	8.82	0.140	1.59	0.095	1.08	0.017	0.20	0.170	1.93	0.000	0.00	0.170	1.93
	High	84	9.00	0.105	1.16	0.000	0.00	0.055	0.62	0.119	1.32	0.000	0.00	0.119	1.32

NA=Not Applicable; %CVs are not meaningful when measurand result approaches zero.

[a] Reproducibility contains repeatability, between-run, between-day, and between-device variance components.

All Sites Combined – Reproducibility Study (Continued)

Measurand	Level	N	Mean	Repeatability		Between-Run		Between-Day		Within-Laboratory[a]		Between-Device		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
%B (%)	Low	84	1.04	0.251	24.03	0.154	14.79	0.032	3.03	0.296	28.38	0.000	0.00	0.296	28.38
	Normal	84	0.90	0.164	18.32	0.000	0.00	0.000	0.00	0.164	18.32	0.000	0.00	0.164	18.32
	High	84	0.96	0.100	10.39	0.049	5.09	0.000	0.00	0.111	11.57	0.020	2.06	0.113	11.75
%IG (%)	Low	84	10.78	0.780	7.24	0.000	0.00	0.000	0.00	0.780	7.24	0.450	4.17	0.900	8.35
	Normal	84	11.46	0.572	4.99	0.175	1.53	0.078	0.68	0.603	5.26	0.322	2.81	0.684	5.97
	High	84	11.92	0.465	3.90	0.378	3.17	0.000	0.00	0.599	5.03	0.379	3.18	0.709	5.95
NR/W	Low	84	0.00	0.000	NA	0.000	NA	0.000	NA	0.000	NA	0.000	NA	0.000	NA
	Normal	84	0.00	0.000	NA	0.000	NA	0.000	NA	0.000	NA	0.000	NA	0.000	NA
	High	84	14.53	0.384	2.64	0.000	0.00	0.035	0.24	0.385	2.65	0.093	0.64	0.396	2.73
%R (%)	Low	84	8.09	0.120	1.49	0.000	0.00	0.000	0.00	0.120	1.49	0.173	2.14	0.211	2.60
	Normal	84	3.72	0.078	2.10	0.027	0.73	0.026	0.70	0.087	2.33	0.198	5.32	0.216	5.81
	High	84	2.57	0.084	3.28	0.000	0.00	0.000	0.00	0.084	3.28	0.254	9.90	0.268	10.43

NA=Not Applicable; %CVs are not meaningful when measurand result approaches zero.

[a] Reproducibility contains repeatability, between-run, between-day, and between-device variance components.

5. Linearity

Linearity was evaluated based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP06 2nd edition[6].

Linearity for RBC, HGB, and NRBC was determined using whole blood to span the analytical measuring interval of each measurand. Linearity for WBC, PLT, and RETIC was determined using commercially available linearity kits. For each measurand, the testing minimally included:

- 9 levels
- 4 replicates of each level
- 1 instrument
- 1 set of reagent lots

A weighted linear regression analysis was used to assess linearity for each measurand. Results are presented in the table below. All results met the predefined acceptance criteria and were determined to be acceptable.

Measurand	Linear Range
RBC	0.00 – 8.08 x 10^6/µL
HGB	0.04 – 24.14 g/dL
NRBC	0.00 – 26.10 x 10^3/µL
WBC	0.00 – 449. x 10^3/µL
PLT	0.06 – 5325 x 10^3/µL
RETIC	0.05 – 644. x 10^3/µL

[6] Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures. 2nd edition.* CLSI Document EP06. Wayne, PA: CLSI; 2020.

6. Carryover

Alinity hq susceptibility to potential carryover was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document H26-A2.[7] Venous whole blood specimens were collected in K_2EDTA tubes. For each measurand, a minimum of 4 carryover runs was completed at each of 4 testing sites for a minimum of 16 total carryover runs per measurand, where each run consisted of testing a high target specimen in 3 replicates followed by testing a low target specimen in 3 replicates. All results met the predefined acceptance criteria and were determined to be acceptable.

7. Potentially Interfering Substances Study

The susceptibility of the Alinity h-series System to interference in the presence of hemoglobin, triglycerides, bilirubin, cholesterol, elevated WBCs, elevated RBCs, elevated PLTs, and microcytic RBCs was tested in samples collected in K_2EDTA tubes. Results are presented in the table below. All results met the predefined acceptance criteria and were determined to be acceptable.

Interferent	Result Level	Measurand Impacted
Hemoglobin	1.0 g/dL	WBC, RBC, MCV, PLT, RETIC
Triglyceride	1.15 g/dL	WBC, RBC, HGB, MCV, RETIC
	0.63 g/dL	PLT
Bilirubin - unconjugated	0.080 g/dL	WBC, RBC, HGB, PLT, RETIC
	0.040 g/dL	MCV
Bilirubin - conjugated	0.080 g/dL	WBC, RBC, HGB, MCV, PLT, RETIC
Cholesterol	0.40 g/dL	WBC, RBC, HGB, MCV, RETIC
	0.50 g/dL	PLT
Elevated WBCs	99.0 x 10^3 cells/µL	RBC, PLT, HGB, MPV
Elevated RBCs	No interference was observed across the measuring range	
Elevated PLTs	2840 x 10^3 cells/µL	WBC, RBC, HGB, MPV
Microcytic RBCs	Microcytosis (MCV < 57 fL)	PLT

[7] Clinical and Laboratory Standards Institute (CLSI). *Validation, Verification, And Quality Assurance Of Automated Hematology Analyzers; Approved Standard - Second Edition*. CLSI Document H26-A2. Wayne, PA: CLSI; 2010.

VIII. Other Supportive Instrument Performance Data

1. Limits of Blank, Detection, and Quantitation (LoB, LoD, and LoQ)

Limits of Blank, Detection, and Quantitation were established for the measurands WBC, RBC, HGB, and PLT based on guidance from the Clinical and Laboratory Standards Institute (CLSI) documents EP17-A2[8] and H26-A2[9].

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

Limits of Blank, Detection, and Quantitation (LoB, LoD, and LoQ)

Measurand	Results		
	LoB	LoD	LoQ
WBC ($x10^3/\mu L$)	0.01	0.02	0.03
RBC ($x10^6/\mu L$)	0.00	0.01	0.01
HGB (g/dL)	0.08	0.11	0.05
PLT ($x10^3/\mu L$)	0.15	0.38	0.29

[8] Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.

[9] Clinical and Laboratory Standards Institute (CLSI). *Validation, Verification, And Quality Assurance Of Automated Hematology Analyzers; Approved Standard - Second Edition*. CLSI Document H26-A2. Wayne, PA: CLSI; 2010.

2. Specimen Stability

For venous specimen stability, a minimum of 10 abnormal and 10 normal venous whole blood specimens K_2EDTA and K_3EDTA tubes. Each specimen was tested in a minimum of 2 replicates. For capillary specimen stability, a minimum of 20 normal whole blood specimens were collected in K_2EDTA and K_3EDTA tubes. Each specimen was tested in a minimum of 1 replicate. All samples were tested within 4 hours (baseline) of specimen collection. Samples stored at Refrigerated Temperature (2-8ºC) were tested at up to 24 hours after specimen collection. Samples stored at Room Temperature (18-26ºC) were tested at up to 48 hours after specimen collection. The results were used to support the information provided in the system labeling for venous and capillary specimen stability.

3. Anticoagulant Comparability (K_3EDTA versus K_2EDTA)

Anticoagulant Comparability (K_3EDTA versus K_2EDTA) was evaluated based on guidance from CLSI EP35 1st ed[10]. A total of 199 unique adult and pediatric donor sets covering relevant medical decision levels and reference ranges and spanning the analytical measurement ranges to the extent possible were tested in 2 replicates for each measurand. The performance between the anticoagulant tube type (K_3EDTA) and anticoagulant tube type (K_2EDTA) was compared.

Comparability between the anticoagulants was assessed based on the mean difference or % difference and a regression analysis using either a Passing-Bablok or Deming regression model. All reportable parameters that were evaluated met their predefined bias acceptance criteria.

4. Microtainer Capillary versus Microtube for Automated Process (MAP)

Comparability between the K_2EDTA Microtainer Capillary tube versus K_2EDTA Microtainer Microtube for Automated Process (MAP) was evaluated

[10] Clinical and Laboratory Standards Institute (CLSI). *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures.* 1st ed. CLSI Guideline EP35-A. Wayne, PA: CLSI; 2019.

based on guidance from CLSI document EP35 1st ed[11]. A total of 44 unique donor sets (normal whole blood specimens) were collected in K_2EDTA Microtainer Capillary and Microtainer Microtube for Automated Process (MAP) blood collection tubes. Each specimen was tested in 1 replicate in the open-tube processing mode for each measurand.

Comparability between the capillary tube types was assessed based on the mean difference or % difference and a regression analysis using either a Passing-Bablok or Deming regression model. All reportable parameters that were evaluated met their predefined bias acceptance criteria.

5. Matrix Comparability (Capillary versus Venous)

Matrix Comparability (Capillary versus Venous) was evaluated based on guidance from CLSI EP35 1st ed.[12] A total of 76 unique venous and capillary donor sets (normal and abnormal whole blood specimens) were collected in Microtainer Microtube for Automated Process (MAP) Microtubes (capillary specimens) and standard K_2EDTA tubes (venous specimens). Each specimen was tested in 2 replicates for each measurand.

Comparability between capillary and venous matrices was assessed based on the mean difference or % difference and a regression analysis using either a Passing-Bablok or Deming regression model. All reportable parameters that were evaluated met their predefined bias acceptance criteria.

6. Sample/Tube Processing Mode Comparability (Open Mode versus Closed Mode)

Sample processing mode comparability was evaluated based on guidance from CLSI EP35 1st ed.[11] A total of 226 unique venous specimens covering relevant medical decision levels and reference ranges and spanning the analytical

[11] Clinical and Laboratory Standards Institute (CLSI). *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures.* 1st ed. CLSI Guideline EP35-A. Wayne, PA: CLSI; 2019.

[12] Clinical and Laboratory Standards Institute (CLSI). *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures.* 1st ed. CLSI Guideline EP35. Wayne, PA: CLSI; 2019.

measurement ranges to the extent possible were collected in K_2EDTA tubes. Each specimen was tested in 2 replicates in the closed-tube and open-tube processing modes for each measurand.

Comparability between the sample/tube processing modes was assessed based on the mean difference or % difference and a regression analysis using either a Passing-Bablok or Deming regression model. All reportable parameters that were evaluated met their predefined bias acceptance criteria.

7. Reference Intervals (Expected Values)

The study was performed based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP28-A3c[13] to establish adult (> 21 years old) reference intervals for male and female populations and pediatric (≤ 21 years old) reference intervals for all subgroups (neonate, infant, child, and adolescent). Reference intervals were established by evaluating venous or capillary whole blood specimens collected in K_2EDTA tubes from apparently healthy subjects.

A total of 261 unique venous and 1 capillary whole blood specimens collected from 126 male and 136 female adult subjects were tested in a minimum of 1 replicate to establish adult reference intervals. A total of 360 venous or capillary specimens from pediatric sub-populations: 61 neonates (birth to 1 month); 68 infant (> 1 month to 2 years old), 109 child (> 2 to 12 years old), and 122 adolescents (> 12 to 21 years old) were tested in 1 replicate to establish pediatric reference intervals for each measurand.

[13] Clinical and Laboratory Standards Institute (CLSI). *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory*, 3rd Ed CLSI Guideline EP28-A3c. Wayne, PA: CLSI; 2019.

IX. Conclusion

The results presented in this 510(k) Pre-market Notification demonstrate that the performance of the subject device, Alinity h-series System, is substantially equivalent to the predicate device, Sysmex® XN-Series (XN-10, XN-20).

The similarities and differences between the subject device and predicate device are presented in Section 5-VI.

There is no known potential adverse effect to the operator when using the subject device, Alinity h-series System according to its Operations Manual.