# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY

## I Background Information:

### A 510(k) Number

K220031

### B Applicant

Abbott Laboratories

### C Proprietary and Established Names

Alinity h-series System

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| GKZ | Class II | 21 CFR 864.5220 - Automated Differential Cell Counter | HE - Hematology |

## II Submission/Device Overview:

### A Purpose for Submission:

New device

### B Measurand:

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

### C Type of Test:

Complete blood count and 6-part white blood cell differential

## III Intended Use/Indications for Use:

### A Intended Use(s):

See Indications for Use below.

### B Indication(s) for Use:

The Alinity h-series System is an integrated hematology analyzer (Alinity hq) and slide maker stainer (Alinity hs) intended for use in 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 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, %NEU, LYM, %LYM, MONO, %MONO, EOS, %EOS, BASO, %BASO, IG, %IG, RBC, HCT, HGB, MCV, MCH, MCHC, MCHr, RDW, NRBC, NR/W, RETIC, %RETIC, IRF, PLT, MPV, %rP.

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

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

For *in-vitro* diagnostic use.

### C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

## IV Device/System Characteristics:

### A Device Description:

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

The Alinity hq is a quantitative, multi-parameter, automated hematology analyzer designed for in vitro diagnostic use in counting and characterizing blood cells using a multi-angle polarized scattered separation (MAPSS) method to detect and count red blood cells (RBC), platelets (PLT), and white blood cells (WBC), and to perform WBC differentials (DIFF) in whole blood.

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

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

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

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

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

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

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

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

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

## B Principle of Operation:

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

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

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

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

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

## C Instrument Description Information:

1. Instrument Name:

   Alinity h-series System

2. Specimen Identification:

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

3. Specimen Sampling and Handling:

   Two methods are used to introduce a specimen to the Alinity hq module. These are closed-tube processing and open-tube processing.
   - In the closed-tube processing mode, capped specimen tubes are introduced to the Alinity hq module from 10-tube closed-tube racks that are inserted in the loading area. The module automatically mixes the specimens and moves the tubes to the aspiration position.
   - In the open-tube processing mode, the operator pre-mixes a specimen tube and removes the cap. The tube is placed in an open-tube sample rack and is inserted in the loading area. The sample handler robot within the Alinity hq module moves the open-tube rack that contains the specimen to the open-tube sampling position.

4. Calibration:
   Calibration of an Alinity hq module must be scheduled to conform to the guidelines that are established by regulatory and accrediting agencies.
   Calibration is performed using materials with assigned values that are traceable to standard reference methods. It is recommended that the laboratory calibrate using Alinity h-series HemCal, which is a commercial whole blood calibrator.

5. Quality Control:
   The Alinity h-series requires a commercial whole blood control and patient controls to monitor system performance.
   Commercial whole blood control - Alinity h-series Control 29P

## V Substantial Equivalence Information:

### A Predicate Device Name(s):
Sysmex XN-series

### B Predicate 510(k) Number(s):
K112605

### C Comparison with Predicate(s):

| **Device & Predicate Device(s):** | | |
|---|---|---|
| Device Trade Name | Alinity h-series System | Sysmex® XN-Series (XN-10, XN-20) |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | The Alinity h-series System is an integrated hematology analyzer (Alinity hq) and slide maker stainer (Alinity hs) intended for use in screening patient populations found in clinical laboratories by qualified health care professionals. The Alinity h-series System can be configured as:<br>• One standalone automated hematology analyzer system<br>• A multimodule system that includes at least one Alinity hq analyzer module and may include one Alinity hs slide maker stainer module.<br>The Alinity hq analyzer provides a 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 | 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.<br>The XN-Series modules classify and enumerate the following parameters for whole blood:<br>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.<br>The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF# parameters in |

| | | |
|---|---|---|
| | Analyzer provides quantitative results for the following measurands:<br>WBC, NEU, %NEU, LYM, %LYM, MONO, %MONO, EOS, %EOS, BASO, %BASO, IG, %IG, RBC, HCT, HGB, MCV, MCH, MCHC, MCHr, RDW, NRBC, NR/W, RETIC, %RETIC, IRF, PLT, MPV, %rP<br>The Alinity hq analyzer module is indicated to identify patients with hematologic parameters within and outside of established reference ranges.<br>Alinity hs slide maker stainer module automates whole blood film preparation and staining and stains externally prepared whole blood smears.<br>For *in-vitro* diagnostic use. | cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K2 or K3EDTA anticoagulant and serous and synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended. |
| 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:<br>WBC, RBC, HGB, HCT,<br>MCV, MCH, MCHC, PLT,<br>MPV, IRF,<br>NEU, %NEU,<br>LYM, %LYM,<br>MONO, %MONO,<br>EOS, %EOS,<br>BASO, %BASO,<br>NRBC, NR/W,<br>IG, %IG,<br>RETIC, %RETIC,<br>RDW-CV, RDW-SD,<br>MCHr,<br>%rP | Whole Blood Mode:<br>WBC, RBC, HGB, HCT,<br>MCV, MCH, MCHC, PLT,<br>MPV, IRF,<br>NEUT%/#,<br>LYMPH%/#,<br>MONO%/#,<br>EO%/#,<br>BASO%/#,<br>NRBC%/#,<br>IG%/#,<br>RET%/#,<br>RDW-CV, RDW-SD,<br>RET-He#,<br>IPF |
| Specimen Type | Whole blood | Whole blood |

| | | |
|---|---|---|
| Use of Controls/ Calibrators | Yes | Yes |
| Information Processing Unit (IPU) | Multi-Module connect | Same |
| Sample Aspiration/ Fluidic Pathway | Single aspiration pathway | Same |
| Software/Hardware | Rules based rerun / reflex | Same |
| **General Device Characteristic Differences** | | |
| 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 | No Body Fluid Mode | Body Fluid Mode:<br>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<br>• HGB Reagent<br>• WBC Reagent<br>• Retic Reagent | CELLPACKTM DCL (Diluent)<br>CELLPACKTM DFL (Diluent)<br>LYSERCELL WNR (Lyse)<br>LYSERCELL WDF (Lyse)<br>LYSERCELL WPC (Lyse)<br>FLUOROCELL WNR (Stain)<br>FLUOROCELL WDF (Stain)<br>FLUOROCELL RET (Stain)<br>FLUOROCELL PLT (Stain)<br>FLUOROCELL WPC (Stain)<br>SULFOLYSER® (Lyse) |
| Controls/ Calibrators | Whole Blood:<br>• Calibrator – Alinity h-series HemCal<br>• Control – Alinity h-series Control 29P<br>No Body Fluids Mode on Alinity hq. | Whole Blood:<br>• XN-Check - 3 Levels<br>• XN CAL (XN-10/X-20 Calibrator)<br>• XN CAL PF (Platelet F Calibrator)<br>• Body Fluid:<br>• XN Check BF – 2 Levels |

| | | |
|---|---|---|
| Measuring Channels/ Methods Selection | • CBC+Diff (for RBC, WBC, and PLT)<br>• CBC+Diff+Retic (for RBC, WBC, PLT and Retic) | • RET/PLT<br>• WNR, WDF, WNR, WPC (Not available in XN-10)<br>• PLT-F |
| Modules Connected to the Analyzer | Required:<br>• Water Purification System<br>• System Control Center Computer (SCC)<br>Optional:<br>• Laboratory Automation System (LAS) for automatic sample loading | • IPU (Information processing unit)<br>• Pneumatic Unit |
| Data Transfer Mode | USB, Internet, and Intranet | USB, CD-R, Internet, and Intranet |

[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.

## VI Standards/Guidance Documents Referenced:

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

- CLSI LIS02-A2, Standard Specification for Transfer Information Between Clinical Instruments and Computer Systems; Approved Standard - Second Edition [13-17];
- ISO 15223-1 Third Edition, Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied [5-117]

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:

**Repeatability**

*20-Day Within-Laboratory Precision*

Three levels of Alinity h-series Control 29P (low, normal, and high) were tested in 2 replicates in CBC+Diff+Retic test selection, 2 times per day (separated by a minimum of 2 hours), on 21 days, for a total of 84 measurements on one instrument in the 2+1 configuration using 1 reagent lot and 1 control lot. Between-run SD and %CV, and between-day SD and %CV were calculated for each sample by instrument and reagent lot. The within-laboratory SD and %CV were estimated using the summation of the within-run, between-run, and between-day variance components. The within-laboratory SD or %CV point estimates were evaluated against the evaluation criteria. Overall, the Alinity h-series System demonstrated acceptable long-term precision.

| Measurand | Level | N | Mean | Within-Run | | Between-Run | | Between-Day | | Within-Laboratory | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | SD[a] | %CV | SD[a] | %CV | SD[a] | %CV | SD[a] | %CV |
| WBC ($x10^3/\mu L$) | High | 84 | 15.82 | 0.165 | 1.04 | 0.093 | 0.59 | 0.000 | 0.00 | 0.190 | 1.20 |
| | Normal | 84 | 6.85 | 0.078 | 1.13 | 0.034 | 0.49 | 0.000 | 0.00 | 0.085 | 1.23 |
| | Low | 84 | 2.93 | 0.061 | 2.10 | 0.033 | 1.13 | 0.000 | 0.00 | 0.070 | 2.38 |
| NEU ($x10^3/\mu L$) | High | 84 | 7.83 | 0.149 | 1.90 | 0.000 | 0.00 | 0.043 | 0.55 | 0.155 | 1.98 |
| | Normal | 84 | 3.22 | 0.068 | 2.12 | 0.000 | 0.00 | 0.000 | 0.00 | 0.068 | 2.12 |
| | Low | 84 | 1.30 | 0.041 | 3.17 | 0.019 | 1.47 | 0.000 | 0.00 | 0.046 | 3.49 |
| LYM ($x10^3/\mu L$) | High | 84 | 3.45 | 0.065 | 1.87 | 0.035 | 1.01 | 0.000 | 0.00 | 0.074 | 2.13 |
| | Normal | 84 | 1.78 | 0.055 | 3.07 | 0.000 | 0.00 | 0.016 | 0.89 | 0.057 | 3.19 |
| | Low | 84 | 0.89 | 0.037 | 4.17 | 0.000 | 0.00 | 0.000 | 0.00 | 0.037 | 4.17 |
| MONO ($x10^3/\mu L$) | High | 84 | 1.84 | 0.092 | 5.00 | 0.027 | 1.47 | 0.032 | 1.76 | 0.101 | 5.49 |
| | Normal | 84 | 0.74 | 0.045 | 6.06 | 0.000 | 0.00 | 0.002 | 0.28 | 0.045 | 6.07 |
| | Low | 84 | 0.31 | 0.024 | 7.59 | 0.000 | 0.00 | 0.008 | 2.57 | 0.025 | 8.01 |
| EOS ($x10^3/\mu L$) | High | 84 | 0.49 | 0.027 | 5.40 | 0.000 | 0.00 | 0.007 | 1.38 | 0.027 | 5.57 |
| | Normal | 84 | 0.20 | 0.016 | 8.36 | 0.008 | 3.90 | 0.000 | 0.00 | 0.018 | 9.23 |
| | Low | 84 | 0.07 | 0.010 | 13.78 | 0.000 | 0.00 | 0.003 | 4.06 | 0.010 | 14.37 |
| BASO ($x10^3/\mu L$) | High | 84 | 0.15 | 0.017 | 11.87 | 0.006 | 3.82 | 0.003 | 1.87 | 0.019 | 12.61 |
| | Normal | 84 | 0.06 | 0.011 | 18.04 | 0.000 | 0.00 | 0.000 | 0.76 | 0.011 | 18.05 |
| | Low | 84 | 0.03 | 0.008 | 26.28 | 0.000 | 0.00 | 0.003 | 9.41 | 0.008 | 27.92 |

| Measurand | Level | N | Mean | Within-Run | | Between-Run | | Between-Day | | Within-Laboratory | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | SD[a] | %CV | SD[a] | %CV | SD[a] | %CV | SD[a] | %CV |
| IG ($x10^3/\mu L$) | High | 84 | 2.05 | 0.065 | 3.17 | 0.029 | 1.39 | 0.000 | 0.00 | 0.071 | 3.46 |
| | Normal | 84 | 0.85 | 0.036 | 4.21 | 0.016 | 1.88 | 0.019 | 2.26 | 0.044 | 5.13 |
| | Low | 84 | 0.33 | 0.020 | 5.99 | 0.011 | 3.21 | 0.000 | 0.00 | 0.022 | 6.79 |
| NRBC ($x10^3/\mu L$) | High | 84 | 2.23 | 0.057 | 2.58 | 0.000 | 0.00 | 0.005 | 0.24 | 0.058 | 2.59 |
| | Normal | 84 | 0.00 | 0.000 | NA | 0.000 | NA | 0.000 | NA | 0.000 | NA |
| | Low | 84 | 0.00 | 0.000 | NA | 0.000 | NA | 0.000 | NA | 0.000 | NA |
| RBC ($x10^6/\mu L$) | High | 84 | 5.08 | 0.037 | 0.72 | 0.022 | 0.44 | 0.029 | 0.58 | 0.052 | 1.02 |
| | Normal | 84 | 4.03 | 0.014 | 0.35 | 0.023 | 0.56 | 0.007 | 0.17 | 0.027 | 0.68 |
| | Low | 84 | 2.71 | 0.012 | 0.43 | 0.009 | 0.32 | 0.007 | 0.24 | 0.016 | 0.59 |
| HCT (%) | High | 84 | 47.32 | 0.342 | 0.72 | 0.222 | 0.47 | 0.451 | 0.95 | 0.608 | 1.29 |
| | Normal | 84 | 34.92 | 0.138 | 0.39 | 0.176 | 0.50 | 0.237 | 0.68 | 0.326 | 0.93 |
| | Low | 84 | 23.23 | 0.103 | 0.44 | 0.070 | 0.30 | 0.180 | 0.78 | 0.219 | 0.94 |
| MCV (fL) | High | 84 | 93.06 | 0.179 | 0.19 | 0.068 | 0.07 | 0.375 | 0.40 | 0.421 | 0.45 |
| | Normal | 84 | 86.66 | 0.148 | 0.17 | 0.162 | 0.19 | 0.360 | 0.42 | 0.422 | 0.49 |
| | Low | 84 | 85.63 | 0.086 | 0.10 | 0.160 | 0.19 | 0.420 | 0.49 | 0.458 | 0.53 |
| RDW (%) | High | 84 | 13.25 | 0.057 | 0.43 | 0.016 | 0.12 | 0.000 | 0.00 | 0.059 | 0.45 |
| | Normal | 84 | 14.08 | 0.048 | 0.34 | 0.011 | 0.08 | 0.034 | 0.24 | 0.059 | 0.42 |
| | Low | 84 | 13.90 | 0.053 | 0.38 | 0.033 | 0.24 | 0.054 | 0.39 | 0.083 | 0.59 |
| HGB (g/dL) | High | 84 | 15.70 | 0.058 | 0.37 | 0.000 | 0.00 | 0.037 | 0.24 | 0.069 | 0.44 |
| | Normal | 84 | 11.40 | 0.055 | 0.48 | 0.000 | 0.00 | 0.017 | 0.15 | 0.057 | 0.50 |
| | Low | 84 | 7.48 | 0.032 | 0.42 | 0.027 | 0.36 | 0.005 | 0.07 | 0.042 | 0.56 |
| MCH (pg) | High | 84 | 30.89 | 0.274 | 0.89 | 0.073 | 0.24 | 0.179 | 0.58 | 0.335 | 1.08 |
| | Normal | 84 | 28.30 | 0.153 | 0.54 | 0.129 | 0.45 | 0.122 | 0.43 | 0.234 | 0.83 |
| | Low | 84 | 27.58 | 0.185 | 0.67 | 0.092 | 0.33 | 0.031 | 0.11 | 0.209 | 0.76 |
| MCHC (g/dL) | High | 84 | 33.19 | 0.274 | 0.83 | 0.129 | 0.39 | 0.294 | 0.89 | 0.422 | 1.27 |
| | Normal | 84 | 32.66 | 0.192 | 0.59 | 0.140 | 0.43 | 0.218 | 0.67 | 0.322 | 0.99 |
| | Low | 84 | 32.20 | 0.221 | 0.69 | 0.098 | 0.30 | 0.212 | 0.66 | 0.321 | 1.00 |
| RETIC ($x10^3/\mu L$) | High | 84 | 110.12 | 3.251 | 2.95 | 0.000 | 0.00 | 2.029 | 1.84 | 3.833 | 3.48 |
| | Normal | 84 | 143.45 | 3.200 | 2.23 | 1.985 | 1.38 | 0.499 | 0.35 | 3.798 | 2.65 |
| | Low | 84 | 214.15 | 2.999 | 1.40 | 0.000 | 0.00 | 1.086 | 0.51 | 3.190 | 1.49 |
| IRF | High | 84 | 0.17 | 0.006 | 3.65 | 0.003 | 1.81 | 0.004 | 2.52 | 0.008 | 4.79 |
| | Normal | 84 | 0.25 | 0.008 | 3.29 | 0.006 | 2.55 | 0.005 | 1.93 | 0.012 | 4.59 |
| | Low | 84 | 0.29 | 0.008 | 2.74 | 0.012 | 4.04 | 0.012 | 4.03 | 0.018 | 6.33 |
| MCHr (pg) | High | 84 | 29.76 | 0.303 | 1.02 | 0.157 | 0.53 | 0.281 | 0.94 | 0.442 | 1.48 |
| | Normal | 84 | 24.07 | 0.213 | 0.88 | 0.252 | 1.05 | 0.020 | 0.08 | 0.330 | 1.37 |
| | Low | 84 | 19.80 | 0.140 | 0.71 | 0.185 | 0.93 | 0.162 | 0.82 | 0.282 | 1.43 |
| PLT ($x10^3/\mu L$) | High | 84 | 470.73 | 8.791 | 1.87 | 0.000 | 0.00 | 2.555 | 0.54 | 9.155 | 1.94 |
| | Normal | 84 | 213.65 | 3.609 | 1.69 | 0.000 | 0.00 | 0.000 | 0.00 | 3.609 | 1.69 |
| | Low | 84 | 68.38 | 1.595 | 2.33 | 0.219 | 0.32 | 0.000 | 0.00 | 1.610 | 2.35 |
| MPV (fL) | High | 84 | 9.63 | 0.026 | 0.27 | 0.012 | 0.12 | 0.007 | 0.07 | 0.029 | 0.31 |
| | Normal | 84 | 9.58 | 0.043 | 0.45 | 0.000 | 0.00 | 0.008 | 0.08 | 0.044 | 0.46 |
| | Low | 84 | 9.67 | 0.068 | 0.71 | 0.000 | 0.00 | 0.000 | 0.00 | 0.068 | 0.71 |

| Measurand | Level | N | Mean | Within-Run | | Between-Run | | Between-Day | | Within-Laboratory | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | SD[a] | %CV | SD[a] | %CV | SD[a] | %CV | SD[a] | %CV |
| %rP (%) | High | 84 | 9.10 | 0.143 | 1.57 | 0.000 | 0.00 | 0.057 | 0.63 | 0.154 | 1.69 |
| | Normal | 84 | 8.91 | 0.179 | 2.01 | 0.000 | 0.00 | 0.000 | 0.00 | 0.179 | 2.01 |
| | Low | 84 | 9.90 | 0.464 | 4.69 | 0.011 | 0.11 | 0.191 | 1.93 | 0.502 | 5.07 |
| %IG (%) | High | 84 | 12.99 | 0.382 | 2.94 | 0.167 | 1.29 | 0.000 | 0.00 | 0.417 | 3.21 |
| | Normal | 84 | 12.47 | 0.529 | 4.24 | 0.188 | 1.51 | 0.257 | 2.06 | 0.618 | 4.95 |
| | Low | 84 | 11.27 | 0.647 | 5.74 | 0.267 | 2.37 | 0.205 | 1.82 | 0.730 | 6.47 |
| NR/W (%) | High | 84 | 14.10 | 0.366 | 2.59 | 0.000 | 0.00 | 0.098 | 0.69 | 0.379 | 2.69 |
| | Normal | 84 | 0.00 | 0.000 | NA | 0.000 | NA | 0.000 | NA | 0.000 | NA |
| | Low | 84 | 0.00 | 0.000 | NA | 0.000 | NA | 0.000 | NA | 0.000 | NA |
| %RETIC (%) | High | 84 | 2.17 | 0.066 | 3.04 | 0.000 | 0.00 | 0.039 | 1.81 | 0.077 | 3.54 |
| | Normal | 84 | 3.56 | 0.078 | 2.20 | 0.039 | 1.10 | 0.029 | 0.81 | 0.092 | 2.59 |
| | Low | 84 | 7.89 | 0.110 | 1.39 | 0.000 | 0.00 | 0.052 | 0.65 | 0.121 | 1.54 |
| %NEU (%) | High | 84 | 49.51 | 0.805 | 1.63 | 0.109 | 0.22 | 0.000 | 0.00 | 0.813 | 1.64 |
| | Normal | 84 | 46.98 | 0.901 | 1.92 | 0.107 | 0.23 | 0.064 | 0.14 | 0.910 | 1.94 |
| | Low | 84 | 44.53 | 1.087 | 2.44 | 0.000 | 0.00 | 0.380 | 0.85 | 1.152 | 2.59 |
| %LYM (%) | High | 84 | 21.83 | 0.365 | 1.67 | 0.180 | 0.83 | 0.064 | 0.29 | 0.412 | 1.89 |
| | Normal | 84 | 26.00 | 0.668 | 2.57 | 0.000 | 0.00 | 0.219 | 0.84 | 0.703 | 2.70 |
| | Low | 84 | 30.22 | 1.004 | 3.32 | 0.000 | 0.00 | 0.000 | 0.00 | 1.004 | 3.32 |
| %MONO (%) | High | 84 | 11.65 | 0.581 | 4.99 | 0.108 | 0.93 | 0.190 | 1.63 | 0.621 | 5.33 |
| | Normal | 84 | 10.77 | 0.644 | 5.97 | 0.000 | 0.00 | 0.000 | 0.00 | 0.644 | 5.97 |
| | Low | 84 | 10.61 | 0.817 | 7.70 | 0.000 | 0.00 | 0.092 | 0.87 | 0.822 | 7.75 |
| %EOS (%) | High | 84 | 3.11 | 0.165 | 5.30 | 0.000 | 0.00 | 0.032 | 1.03 | 0.168 | 5.39 |
| | Normal | 84 | 2.86 | 0.241 | 8.42 | 0.105 | 3.66 | 0.000 | 0.00 | 0.262 | 9.18 |
| | Low | 84 | 2.40 | 0.323 | 13.45 | 0.000 | 0.00 | 0.096 | 4.01 | 0.337 | 14.04 |
| %BASO (%) | High | 84 | 0.93 | 0.108 | 11.63 | 0.035 | 3.73 | 0.023 | 2.46 | 0.116 | 12.46 |
| | Normal | 84 | 0.92 | 0.167 | 18.07 | 0.000 | 0.00 | 0.014 | 1.56 | 0.167 | 18.14 |
| | Low | 84 | 0.98 | 0.253 | 25.93 | 0.000 | 0.00 | 0.094 | 9.64 | 0.270 | 27.66 |

[a] SDs that are 0.000 may not signify that the results were zero but may be due to rounding.
NA = Not Applicable: %CVs are not meaningful when measurand result approaches zero.

*Precision Study – Normal Samples*

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

%CV or SD values across donors by range was reported. The SD or %CV point estimates were evaluated against the evaluation criteria.

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

| Test Selection | Measurand | N | Result Range[a] | Max SD/%CV | Result Against Acceptance |
|---|---|---|---|---|---|
| CBC+Diff | WBC ($x10^3/\mu L$) | 1 | 3.72 to 4.06 | 0.068 | SD |
| CBC+Diff | WBC ($x10^3/\mu L$) | 19 | 3.92 to 10.60 | 2.71 | %CV |
| CBC+Diff | NEU ($x10^3/\mu L$) | 2 | 1.17 to 1.98 | 0.052 | SD |
| CBC+Diff | NEU ($x10^3/\mu L$) | 18 | 2.13 to 8.33 | 3.07 | %CV |
| CBC+Diff | LYM ($x10^3/\mu L$) | 13 | 1.10 to 2.01 | 0.068 | SD |
| CBC+Diff | LYM ($x10^3/\mu L$) | 7 | 1.94 to 3.05 | 3.37 | %CV |
| CBC+Diff | MONO ($x10^3/\mu L$) | 15 | 0.22 to 0.60 | 0.035 | SD |
| CBC+Diff | MONO ($x10^3/\mu L$) | 5 | 0.52 to 0.98 | 6.28 | %CV |
| CBC+Diff | EOS ($x10^3/\mu L$) | 20 | 0.04 to 0.41 | 0.025 | SD |
| CBC+Diff | BASO ($x10^3/\mu L$) | 20 | 0.01 to 0.26 | 0.042 | SD |
| CBC+Diff | RBC ($x10^6/\mu L$) | 20 | 4.46 to 5.64 | 0.75 | %CV |
| CBC+Diff | HGB (g/dL) | 20 | 13.4 to 16.8 | 0.78 | %CV |
| CBC+Diff | HCT (%) | 8 | 40.0 to 45.5 | 0.360 | SD |
| CBC+Diff | HCT (%) | 12 | 44.8 to 50.5 | 0.73 | %CV |
| CBC+Diff | MCV (fL) | 20 | 86.0 to 99.1 | 0.30 | %CV |
| CBC+Diff | MCH (pg) | 20 | 27.7 to 32.4 | 0.99 | %CV |
| CBC+Diff | MCHC (g/dL) | 20 | 31.3 to 34.6 | 1.02 | %CV |
| CBC+Diff | RDW (%) | 20 | 12.1 to 14.6 | 0.52 | %CV |
| CBC+Diff | PLT ($x10^3/\mu L$) | 20 | 155.0 to 361.0 | 2.26 | %CV |
| CBC+Diff | MPV (fL) | 8 | 9.20 to 10.1 | 0.065 | SD |
| CBC+Diff | MPV (fL) | 12 | 10.3 to 12.4 | 1.38 | %CV |

| Test Selection | Measurand | N | Range Tested | Max SD/%CV | Result against Acceptance |
|---|---|---|---|---|---|
| CBC+Diff+Retic | WBC ($x10^3/\mu L$) | 1 | 3.72 to 4.04 | 0.085 | SD |
| CBC+Diff+Retic | WBC ($x10^3/\mu L$) | 18 | 3.93 to 10.4 | 2.22 | %CV |
| CBC+Diff+Retic | NEU ($x10^3/\mu L$) | 2 | 1.19 to 1.98 | 0.058 | SD |
| CBC+Diff+Retic | NEU ($x10^3/\mu L$) | 17 | 2.11 to 8.17 | 2.89 | %CV |
| CBC+Diff+Retic | LYM ($x10^3/\mu L$) | 13 | 1.10 to 2.01 | 0.063 | SD |
| CBC+Diff+Retic | LYM ($x10^3/\mu L$) | 6 | 1.87 to 3.07 | 3.20 | %CV |
| CBC+Diff+Retic | MONO ($x10^3/\mu L$) | 15 | 0.22 to 0.61 | 0.039 | SD |
| CBC+Diff+Retic | MONO ($x10^3/\mu L$) | 4 | 0.54 to 0.91 | 8.99 | %CV |
| CBC+Diff+Retic | EOS ($x10^3/\mu L$) | 19 | 0.03 to 0.38 | 0.024 | SD |
| CBC+Diff+Retic | BASO ($x10^3/\mu L$) | 19 | 0.01 to 0.24 | 0.048 | SD |
| CBC+Diff+Retic | RBC ($x10^6/\mu L$) | 19 | 4.44 to 5.63 | 0.56 | %CV |

| Test Selection | Measurand | N | Range Tested | Max SD/%CV | Result against Acceptance |
|---|---|---|---|---|---|
| CBC+Diff+Retic | HGB (g/dL) | 19 | 12.8 to 16.8 | 1.05 | %CV |
| CBC+Diff+Retic | HCT (%) | 10 | 39.7 to 45.5 | 0.285 | SD |
| CBC+Diff+Retic | HCT (%) | 9 | 45.2 to 49.9 | 0.64 | %CV |
| CBC+Diff+Retic | MCV (fL) | 19 | 85.8 to 99.1 | 0.36 | %CV |
| CBC+Diff+Retic | MCH (pg) | 19 | 28.3 to 32.6 | 1.24 | %CV |
| CBC+Diff+Retic | MCHC (g/dL) | 19 | 31.5 to 34.5 | 1.24 | %CV |
| CBC+Diff+Retic | RDW (%) | 19 | 12.1 to 14.7 | 0.47 | %CV |
| CBC+Diff+Retic | RETIC ($x10^3/\mu L$) | 19 | 51.0 to 126.0 | 4.037 | SD |
| CBC+Diff+Retic | IRF | 19 | 0.04 to 0.14 | 0.012 | SD |
| CBC+Diff+Retic | PLT ($x10^3/\mu L$) | 19 | 159.0 to 367.0 | 1.74 | %CV |
| CBC+Diff+Retic | MPV (fL) | 8 | 9.21 to 10.0 | 0.055 | SD |
| CBC+Diff+Retic | MPV (fL) | 11 | 10.3 to 12.4 | 0.89 | %CV |
| CBC+Diff+Retic | %rP (%) | 19 | 1.04 to 9.33 | 0.622 | SD |
| CBC+Diff+Retic | MCHr (pg) | 19 | 33.8 to 40.3 | 2.23 | %CV |

[a] The result ranges may overlap for certain measurands as these reflect the individual replicate values. The samples are grouped based on their mean values.

*Repeatability - Pathological Samples and Medical Decision Levels*

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

| Target Range | Recommended Target Values | Measurand | N | Result Range | Max SD / %CV |
|---|---|---|---|---|---|
| Low | 0.06 – 2.00 $x10^3/\mu L$ | WBC ($x10^3/\mu L$) | 17 | 0.06 to 2.01 | 0.083 SD |
| Low | 0.01 – 3.00 $x10^6/\mu L$ | RBC ($x10^6/\mu L$) | 26 | 1.59 to 3.17 | 0.025 SD |
| Low | 6.00 – 10.0 g/dL | HGB (g/dL) | 27 | 5.42 to 10.4 | 0.154 SD |
| Low | 10.0 – 50.0 $x10^3/\mu L$ | PLT ($x10^3/\mu L$) | 20 | 8.57 to 44.5 | 2.029 SD |
| High | 50.0 – 400.0 $x10^3/\mu L$ | WBC ($x10^3/\mu L$) | 17 | 41.4 to 209 | 1.88 %CV |
| High | 6.00 – 8.00 $x10^6/\mu L$ | RBC ($x10^6/\mu L$) | 19 | 5.68 to 7.79 | 1.46 %CV |

| Target Range | Recommended Target Values | Measurand | N | Result Range | Max SD / %CV |
|---|---|---|---|---|---|
| High | 15.0 – 25.0 g/dL | HGB (g/dL) | 18 | 15.4 to 22.2 | 1.00 %CV |
| High | 500 – 5400 x$10^3$/µL | PLT (x$10^3$/µL) | 22 | 470. to 3217 | 2.05 %CV |
| Pathological | %IG>2.0% and WBC>5.00 x$10^3$/µL | IG (x$10^3$/µL) | 17 | 0.00 to 0.98 | 0.149 SD |
| Pathological | %IG>2.0% and WBC>5.00 x$10^3$/µL | IG (x$10^3$/µL) | 8 | 0.96 to 7.92 | 18.79 %CV |
| Pathological | NR/W>=1% and NRBC>0.10 x$10^3$/µL | NRBC (x$10^3$/µL) | 17 | 0.00 to 0.59 | 0.148 SD |
| Pathological | NR/W>=1% and NRBC>0.10 x$10^3$/µL | NRBC (x$10^3$/µL) | 5 | 0.77 to 6.37 | 14.76 %CV |
| Low WBC related | NA | NEU (x$10^3$/µL) | 11 | 0.00 to 1.56 | 0.059 SD |
| Low WBC related | NA | LYM (x$10^3$/µL) | 11 | 0.12 to 0.74 | 0.040 SD |
| Low WBC related | NA | MONO (x$10^3$/µL) | 11 | 0.00 to 0.52 | 0.032 SD |
| Low WBC related | NA | EOS (x$10^3$/µL) | 8 | 0.00 to 0.18 | 0.021 SD |
| Low WBC related | NA | BASO (x$10^3$/µL) | 19 | 0.00 to 0.05 | 0.010 SD |
| Low WBC related | NA | IG (x$10^3$/µL) | 8 | 0.00 to 0.00 | 0.000 SD |
| Low RBC/HGB related | NA | RBC (x$10^6$/µL) | 8 | 1.42 to 3.61 | 0.024 SD |

## Reproducibility

The reproducibility study was performed at three clinical sites using a single lot of Alinity h-series 29P Control (low, normal, high). Each site used a stand-alone (1+0 configuration) Alinity hq analyzer. Each control level was tested for 5 days with three runs per day and two replicates per run (one replicate each from the left and right incubation blocks). The within-run, between-run, between-day, within-laboratory, between-site, and reproducibility %CV or SD for each control level were calculated and presented in the table below. Overall, the Alinity h-series System demonstrated acceptable reproducibility for all sites combined using 3 levels of the Alinity h-series 29P Controls. All results met the predefined acceptance criteria.

*Reproducibility Results*

| Measurand[a] | Level | N | Mean | Repeatability | | Between-Run | | Between-Day | | Within-Laboratory[b] | | Between-Site | | Reproducibility[c] | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | 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 |

| Measurand[a] | Level | N | Mean | Repeatability | | Between-Run | | Between-Day | | Within-Laboratory[b] | | Between-Site | | Reproducibility[c] | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| LYM ($x10^3/\mu L$) | 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 ($x10^3/\mu L$) | 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 ($x10^3/\mu L$) | 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 |
| BASO ($x10^3/\mu L$) | 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 ($x10^3/\mu L$) | 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 ($x10^3/\mu L$) | 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 ($x10^6/\mu L$) | 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 |
| 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 |
| RETIC ($x10^3/\mu L$) | 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 |

| Measurand[a] | Level | N | Mean | Repeatability | | Between-Run | | Between-Day | | Within-Laboratory[b] | | Between-Site | | Reproducibility[c] | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| 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 ($x10^3/\mu L$) | 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 |
| MCHr (pg) | Low | 84 | 21.16 | 0.133 | 0.63 | 0.169 | 0.80 | 0.147 | 0.69 | 0.260 | 1.23 | 0.780 | 3.69 | 0.823 | 3.89 |
| | Normal | 84 | 25.13 | 0.180 | 0.71 | 0.222 | 0.88 | 0.107 | 0.43 | 0.305 | 1.21 | 0.788 | 3.14 | 0.845 | 3.36 |
| | High | 84 | 32.40 | 0.360 | 1.11 | 0.140 | 0.43 | 0.000 | 0.00 | 0.387 | 1.19 | 1.416 | 4.37 | 1.467 | 4.53 |
| %NEU (%) | Low | 84 | 45.99 | 1.386 | 3.01 | 0.000 | 0.00 | 0.000 | 0.00 | 1.386 | 3.01 | 0.629 | 1.37 | 1.522 | 3.31 |
| | Normal | 84 | 48.12 | 0.865 | 1.80 | 0.461 | 0.96 | 0.000 | 0.00 | 0.980 | 2.04 | 0.491 | 1.02 | 1.096 | 2.28 |
| | High | 84 | 50.56 | 0.929 | 1.84 | 0.000 | 0.00 | 0.000 | 0.00 | 0.929 | 1.84 | 0.573 | 1.13 | 1.091 | 2.16 |
| %LYM (%) | Low | 84 | 28.97 | 0.915 | 3.16 | 0.000 | 0.00 | 0.000 | 0.00 | 0.915 | 3.16 | 0.000 | 0.00 | 0.915 | 3.16 |
| | Normal | 84 | 25.58 | 0.627 | 2.45 | 0.000 | 0.00 | 0.000 | 0.00 | 0.627 | 2.45 | 0.161 | 0.63 | 0.647 | 2.53 |
| | High | 84 | 22.15 | 0.453 | 2.04 | 0.000 | 0.00 | 0.000 | 0.00 | 0.453 | 2.04 | 0.046 | 0.21 | 0.455 | 2.05 |
| %MONO (%) | Low | 84 | 10.79 | 0.755 | 7.00 | 0.000 | 0.00 | 0.115 | 1.06 | 0.764 | 7.08 | 0.345 | 3.19 | 0.838 | 7.77 |
| | Normal | 84 | 11.16 | 0.662 | 5.93 | 0.228 | 2.04 | 0.061 | 0.55 | 0.703 | 6.30 | 0.000 | 0.00 | 0.703 | 6.30 |
| | High | 84 | 11.40 | 0.448 | 3.93 | 0.315 | 2.76 | 0.000 | 0.00 | 0.548 | 4.80 | 0.052 | 0.46 | 0.550 | 4.82 |
| %EOS (%) | Low | 84 | 2.43 | 0.332 | 13.68 | 0.000 | 0.00 | 0.047 | 1.92 | 0.335 | 13.81 | 0.000 | 0.00 | 0.335 | 13.81 |
| | Normal | 84 | 2.78 | 0.191 | 6.87 | 0.077 | 2.77 | 0.000 | 0.00 | 0.206 | 7.41 | 0.000 | 0.00 | 0.206 | 7.41 |
| | High | 84 | 3.02 | 0.142 | 4.72 | 0.078 | 2.60 | 0.000 | 0.00 | 0.162 | 5.39 | 0.026 | 0.86 | 0.165 | 5.46 |
| %BASO (%) | 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 |
| %RETIC (%) | 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] Each measurand level was evaluated based on SD for control level results below or equal to a threshold or based on %CV for control level results above a threshold

[b] Within-Laboratory variability contains repeatability, between-run, and between-day variance components.

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

2. Linearity:

Linearity for RBC, HGB, and NRBC was determined using whole blood samples that span the analytical measuring interval 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 and tested in a minimum of 4 replicates on 3 instruments using 1 reagent lot.

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 |

3. Analytical Specificity/Interference:

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 venous samples collected in K2EDTA tubes.

**Hemoglobin, Triglycerides, Bilirubin, and Cholesterol**

For the Hemoglobin, Triglycerides, Bilirubin, and Cholesterol studies, two interferent levels were tested with samples at the normal measurand levels and at the low measurand levels listed in the table below.

| **Measurand** | **Normal Level** | **Low Level** |
|---|---|---|
| WBC (x$10^3$/µL) | 3.54 – 9.06 | ≤ 3.00 |
| RBC (x$10^6$/µL) | 4.00 – 5.60 | ≤ 3.00 |
| PLT (x$10^3$/µL) | 165 – 415 | ≤ 150 |
| MCV (fL) | 80 – 96* | |
| RETIC (x$10^3$/µL) | 45 – 150 | |

* The MCV measurand is based on the size of the cells rather than the concentration and therefore, the normal and low levels are the same.

Each sample was tested in a minimum of 10 replicates in CBC+Diff+Retic test selection in closed tube processing mode. The following measurands were evaluated for each potential interferent:

| Measurands | Potential Interferent |
|---|---|
| WBC, RBC, HGB, MCV, PLT, Retic | Bilirubin, Conjugated |
| WBC, RBC, HGB, MCV, PLT, Retic | Bilirubin, Unconjugated |
| WBC, RBC, HGB, MCV, PLT, Retic | Cholesterol |
| WBC, RBC, PLT, MCV, Retic | Hemoglobin |
| WBC, RBC, HGB, MCV, Retic | Triglycerides |

The Alinity h-series System was considered not susceptible to interference from bilirubin (conjugated and unconjugated), cholesterol, hemoglobin, and triglycerides, if the absolute difference or % difference criteria were met for each measurand.

**Elevated WBC, RBC, and PLT**

A study was conducted to evaluate the susceptibility of the Alinity h-series System to interference from elevated WBC, RBC, and PLT measurands in native whole blood specimens. This study utilized a subset of samples tested in the method comparison study, where unique, native whole blood specimens with high WBCs (>30 x $10^3$/µL & ≤100 x $10^3$/µL), high RBCs (> 7.6 x $10^6$/µL), and/or high PLTs (>1000 x $10^3$/µL) collected in K2EDTA tubes were identified for interference analysis. A minimum of 10 specimens were evaluated per interferent.

The Alinity h-series System results for WBC, RBC, PLT, MPV, MCV, and HGB were considered not susceptible to interference from high WBCs, high RBCs, and high PLTs if the mean difference or mean % difference values for each measurand were within the total allowable error limits. The total allowable error was used for this analysis because the study compares the Alinity h-series System and another method (Sysmex XN-10) in specimens with the interfering condition. Overall, the Alinity h-series System demonstrated no interference in measuring WBC, RBC, PLT, MCV, and HGB from elevated WBC, RBC, and PLT measurands in native whole blood specimens.

**PLT with Microcytic RBCs**

A study was conducted to evaluate the susceptibility of the Alinity h-series System to interference from microcytic RBCs to the PLT measurand in native whole blood specimens with MCV of ≤ 70 fL. This study utilized a subset of samples tested in the method comparison study, where unique, native whole blood specimens with MCV of ≤ 70 fL collected in K2EDTA tubes were identified for interference analysis. A minimum of 10 specimens were evaluated per interferent.

This study utilizes specimens with elevated MCV measurand collected in the method comparison study. Therefore, the total allowable error was used for this analysis because this study compares the Alinity h-series System and another method (Sysmex XN-10) in specimens with the interfering condition. For each sample, the difference or % difference between the Sysmex XN-10 and Alinity h-series System result were compared to the pre-determined total allowable error limits.

The Alinity h-series System was considered not susceptible to interference from microcytic RBC if the mean difference was within the total allowable error limits. Overall, the Alinity h-series System demonstrated no interference from microcytic RBCs for the PLT measurand in native whole blood specimens with MCV of ≤ 70 fL.

The results of the interference studies met the predefined acceptance criteria and are summarized below.

| **Interferent** | **Level** | **Conclusion** |
|---|---|---|
| Hemoglobin | 1.0 g/dL | There was no significant hemolysis interference up to a free HGB concentration of 1.0 g/dL for the WBC, RBC, MCV, PLT, and Retic measurands. |
| Triglycerides | 1.15 g/dL | There was no significant triglyceride interference up to a concentration of 1.15 g/dL for the WBC, RBC, HGB, MCV, and Retic measurands. |
| | 0.63 g/dL | There was no significant triglycerides interference up to a concentration of 0.63 g/dL for the PLT measurand. |
| Bilirubin - unconjugated | 0.080 g/dL | There was no significant unconjugated bilirubin interference up to a concentration of 0.080 g/dL for the WBC, RBC, HGB, PLT, and Retic measurands. |
| | 0.040 g/dL | There was no significant Bilirubin (unconjugated) interference up to a concentration of 0.040 g/dL for the MCV measurand. |
| Bilirubin - conjugated | 0.080 g/dL | There was no significant conjugated bilirubin interference up to a concentration of 0.080 g/dL for the WBC, RBC, HGB, MCV, PLT, and Retic measurands. |
| Elevated WBCs | 99.0 x $10^3$ cells/µL | There was no significant WBC interference up to a concentration of 99.0 x $10^3$ cells/µL for the RBC, PLT, HGB, and MPV measurands. |
| Elevated RBCs | There was no interference in measuring WBC, RBC, PLT, MCV, and HGB from RBC levels across the measuring range. | |
| Elevated PLTs | 2840 x $10^3$ cells/µL | There was no significant PLT interference up to a concentration of 2840 x $10^3$ cells/µL for the WBC, RBC, HGB, and MPV measurands. |
| Microcytic RBCs | Microcytosis (MCV < 57 fL) | There was no significant interference from microcytic RBCs for the PLT measurand in native whole blood specimens with MCV of ≤ 70 fL. |

4. Reportable Range:

The reportable range was determined by the following studies:

- HCT, MCV, MPV, and %R: The upper and lower limits were determined by the method comparison study for the HCT, MCV, MPV, and %R measurands.

- RETIC and NRBC: The upper and lower limits were determined by the linearity studies for the RETIC, and NRBC measurands.

- WBC, RBC, HGB, and PLT:
  - The upper limits were determined by the linearity studies for the WBC, RBC, HGB, and PLT measurands.
  - The lower limits were determined by the LoQ studies for the WBC, RBC, HGB, and PLT measurands.

The resulting reportable range of each measurand is provided in Table below.

**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 |

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

**Specimen Stability**

Sample stability studies were conducted to evaluate the stability of specimens, venous and capillary whole blood samples collected in K2EDTA or K3EDTA, when stored under various conditions (e.g. 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 K2EDTA 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 and Capillary Whole Blood Specimen Stability*

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 conditions and time points in this study.

| 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. These venous and capillary whole blood specimens 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), the

whole blood specimens were equilibrated to instrument room temperature, as recommended by the Alinity h-series Operations Manual, for approximately 15 to 30 minutes.

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 all time points. For each time point and condition, the difference between each test time point and the corresponding baseline was calculated.

Overall, the above specimen stability studies support the proposed 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 and Capillary Whole Blood Sample Stability*

A study was conducted to evaluate the stability of K2EDTA venous and capillary whole blood samples when stored under controlled room temperature conditions (e.g. 18°C and 26°C). 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 time points and storage conditions tested are as summarized below.

| **Condition** | **Time Points (Time from Specimen Collection)** |
|---|---|
| Baseline (Control Condition) | ≥ 20 minutes to < 4 Hours |
| 18°C or 26°C (Controlled Room Temperature) | ≥ 8 Hours to < 10 Hours |
| | ≥ 10 Hours to < 12 Hours |
| | ≥ 24 Hours to < 26 Hours |
| | ≥ 26 Hours to < 28 Hours |

For this study, normal venous and capillary specimens were stored in an incubator at the intended temperature (at 18°C and at 26°C) and timepoints.

The analysis was performed separately for each specimen, time point, storage condition, and measurand. For each time point and condition, the results for each specimen were compared to its results at baseline.

*Refrigerated and Room Temperature K3EDTA Venous Whole Blood Specimen Stability*

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 h-series System.

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 conditions and time points in this study.

| 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, the aliquots of the venous whole blood specimens were equilibrated to instrument room temperature, as recommended by the Alinity h-series Operations Manual.

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. For each time point and condition, the results for each specimen were compared to its results at baseline.

The results of this specimen stability study support the proposed 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*

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 h-series System. 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 conditions and time points in this study.

| 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, the aliquots of the capillary whole blood specimens were equilibrated to instrument room temperature, as recommended by the Alinity h-series Operations Manual.

If volume permitted, each capillary whole blood specimen was tested at baseline and all test time points for the storage condition. 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.

For each storage condition, test time point, and measurand, the mean of the differences and % differences, along with the two-sided 95% confidence interval (CI), were calculated across samples. Of note, mean % difference was not calculated for a measurand if any sample had a baseline result of zero or near zero.

The results of this specimen stability study support the proposed system labeling claim for the stability of capillary 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).

6. Detection Limit:

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

| **Measurand** | **Results** | | |
|---|---|---|---|
| | **LoB** | **LoD** | **LoQ** |
| WBC ($x10^3$ /µL) | 0.01 | 0.02 | 0.04 |
| RBC ($x10^6$ /µL) | 0.00 | 0.01 | 0.01 |
| HGB (g/dL) | 0.08 | 0.11 | 0.15 |
| PLT ($x10^3$ /µL) | 0.15 | 0.38 | 0.46 |

7. Assay Cut-Off:

Not applicable

8. Accuracy (Instrument):

Not applicable

9. Carry-Over:

Alinity hq susceptibility to potential carryover was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document H26-A2.

## B Comparison Studies:

1. Method Comparison with Predicate Device:

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

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

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

Alinity hq testing was performed using a minimum of 1 reagent lot, 1 control lot at each site and a minimum of 1 lot of the Alinity h-series HemCal commercial calibrator. The Sysmex XN-10/20 was calibrated using its recommended commercial calibrators at each site.

A Passing-Bablok regression analysis was performed with the investigational method as the dependent variable (y) and the predicate method as the independent variable (x). A Deming regression analysis was used in place of Passing-Bablok analysis where there are very low numeric values. Bias at medical decision points 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. Overall, the Alinity h-series System demonstrated comparable performance to the predicate device, Sysmex XN-10/20 (K112605) in an intended use population in a clinical laboratory setting.

**All Sites Combined – Regression Analysis Results**

| Measurand | N | Sample Range | r (95% CI) | Slope (95% CI) | Intercept (95% CI) |
|---|---|---|---|---|---|
| WBC ($x10^3/\mu L$) | 2002 | 0.07 – 436.00 | 1.00 (1.00, 1.00) | 1.00 (1.00, 1.00) | 0.01 (0.00, 0.03) |
| %NEU (%) | 1551 | 7.56 – 98.30 | 0.99 (0.99, 1.00) | 1.00 (1.00, 1.01) | 0.22 (-0.10, 0.50) |
| %LYM (%) | 1640 | 0.34 – 84.60 | 1.00 (1.00, 1.00) | 1.00 (0.99, 1.00) | 0.08 (0.00, 0.16) |
| %MONO (%) | 1646 | 0.03 – 49.20 | 0.98 (0.97, 0.98) | 0.99 (0.98, 1.00) | -0.03 (-0.13, 0.06) |
| %EOS (%) | 1712 | 0.00 – 37.50 | 0.99 (0.99, 0.99) | 1.02 (1.01, 1.03) | 0.02 (0.01, 0.03) |
| %BASO (%) | 1854 | 0.00 – 8.37 | 0.45 (0.41, 0.49) | 1.53 (1.47, 1.59) | -0.14 (-0.17, -0.11) |
| %IG (%) | 1545 | 0.00 – 12.50 | 0.59 (0.56, 0.62) | 0.59 (0.45, 0.73) | -0.07 (-0.13, -0.01) |
| NRBC ($x10^3/\mu L$) | 1945 | 0.00 – 17.70 | 0.91 (0.90, 0.92) | 0.88 (0.70, 1.07) | 0.01 (0.00, 0.02) |
| NR/W | 1949 | 0.00 – 228.00 | 0.99 (0.99, 0.99) | 0.97 (0.93, 1.02) | -0.07 (-0.13, -0.01) |
| RBC ($x10^6/\mu L$) | 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 – 23.00 | 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) |
| %RETIC (%) | 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 ($x10^3/\mu L$)* | 1933 | 1.21 – 5144.00 | 0.99 (0.99, 0.99) | 0.97 (0.97, 0.98) | 0.27 (-0.41, 1.08) |
| 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 (%)** | 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 ($x10^3/\mu L$) | 1551 | 0.10 – 55.00 | 1.00 (1.00, 1.00) | 1.01 (1.01, 1.01) | 0.00 (-0.02, 0.02) |
| LYM ($x10^3/\mu L$) | 1640 | 0.05 – 27.20 | 0.99 (0.99, 1.00) | 0.99 (0.99, 1.00) | 0.02 (0.01, 0.03) |
| MONO ($x10^3/\mu L$) | 1646 | 0.00 – 8.84 | 0.99 (0.99, 1.00) | 1.02 (1.01, 1.03) | -0.02 (-0.03, -0.01) |
| EOS ($x10^3/\mu L$) | 1712 | 0.00 – 4.19 | 0.99 (0.99, 0.99) | 1.02 (1.01, 1.03) | 0.00 (0.00, 0.00) |
| BASO | 1854 | 0.00 – 8.11 | 0.22 (0.18, 0.26) | 1.31 (1.27, 1.37) | 0.00 (-0.01, 0.00) |

| Measurand | N | Sample Range | r (95% CI) | Slope (95% CI) | Intercept (95% CI) |
|---|---|---|---|---|---|
| ($x10^3/\mu L$) | | | | | |
| IG ($x10^3/\mu L$) | 1545 | 0.00 – 3.15 | 0.81 (0.80, 0.83) | 1.01 (0.85, 1.18) | -0.07 (-0.09, -0.05) |
| 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 ($x10^3/\mu L$) | 1935 | 1.96 – 614.00 | 0.96 (0.96, 0.97) | 1.05 (1.04, 1.06) | 0.79 (0.02, 1.64) |

* Alinity was compared to Sysmex XN-10 with the PLT-F channel.

** %rP(%) on Alinity h-series System is equivalent to Sysmex XN-10 IPF measurand.

2. Matrix Comparison:

**Anticoagulants Comparability - K2EDTA versus K3EDTA**

Anticoagulant comparability (K2EDTA versus K3EDTA) was evaluated at three sites (1 internal site and 2 external clinical sites) based on guidance from CLSI EP35. A total of 190 unique donor venous whole blood samples (normal and abnormal) collected in the control tube type (K2EDTA) and in the evaluation tube type (K3EDTA) were included in the study. The K2EDTA and K3EDTA whole blood samples for one donor constituted one donor set. The clinical sites aimed to enroll donor sets that covered all relevant medical decision points and were representative of the proposed analytical measurement ranges. Comparability between the anticoagulants was assessed for all measurands based on the mean difference or % difference and a regression analysis. All reportable parameters that were evaluated met their predefined bias acceptance criteria.

**Matrix Comparability – Venous versus Capillary**

A study was conducted to evaluate the comparability of matrices (venous versus capillary) using whole blood specimens tested on the Alinity h-series System. Paired venous and capillary samples were obtained from donors (normal and abnormal) in standard K2EDTA tubes (K981013) (venous, control condition) and Microtainer Microtube for Automated Process (MAP) Microtubes (K093972) (capillary, test condition). The blood collection tubes from one individual constituted one donor set. The samples were tested on the Alinity h-series System (1+0 instrument configuration and 2+1 instrument configuration) in a minimum of 2 replicates with the CBC+Diff+Retic test selection using a minimum of 1 set of reagent lots and 1 control lot.

An evaluation was performed, regressing the first valid replicate of each measurand from the capillary tube (y-axis) against the first replicate of each measurand from the venous tube (x-axis). The slope and intercept of the regression line, and the two-sided 95% CI around the slope and intercept were calculated. The predicted bias and % bias, as well as the two-sided 95% CI around the bias and % bias, were calculated around the medical decision points as applicable. All reportable parameters that were evaluated met their predefined bias acceptance criteria.

**Microtube for Automated Process (MAP) versus Microtainer Capillary**

Comparability between the K2EDTA Microtainer Microtube for Automated Process (MAP) versus K2EDTA Microtainer Capillary tube was evaluated. A total of 44 unique normal specimens were collected in the Microtainer Microtube for Automated Process (MAP, K093972) and K2EDTA Microtainer Capillary (K182078) blood collection tube types and tested in 1 replicate in the open-tube processing mode. Two assessments were performed:

- MAP Open (test condition) vs. MAP Closed (control condition)
- Microtainer Capillary Open (test condition) vs MAP Open (control condition)

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.

**Sample/Tube Processing Mode Comparability - Closed Mode versus Open Mode**

Sample processing mode comparability was evaluated. Unique venous specimens (normal and abnormal) were collected (from 3 testing sites) in K2EDTA tubes. The samples were tested 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 on the Alinity h-series System (1+0 instrument configuration or 2+1 instrument configuration) using a minimum of 1 set of reagent lots and 1 control lot. The Alinity h-series Systems were calibrated at the clinical sites using a minimum of 1 lot of Alinity h-series HemCal calibrator.

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.

## C Clinical Studies:

1. Clinical Sensitivity:

Sensitivity and specificity performance with the Alinity h-series System were assessed for accuracy of identifying distributional abnormalities and morphological flags (PLT Clumps, RBC Fragments) by comparing to a 400-cell differential derived from two independent 200-cell microscopic reviews of a blood smear (reference method) from negative (normal) and positive (abnormal) specimens. A subset of 674 venous and capillary specimens collected in $K_2$EDTA for the method comparison study were included in this study. Testing was performed at each of 6 clinical sites. One (1) replicate of each specimen was analyzed using the CBC+Diff+Retic test selection in the Open or Closed tube processing mode on the Alinity hq. Three blood films were prepared for each sample.

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

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

Results from all specimens tested in this study were evaluated against the respective reference ranges for each differential cell type. Results within the lower and upper limits of the reference ranges were considered normal (negative). Results not within the lower and upper limits of the respective reference ranges for Microscopy or Alinity hq were considered abnormal (positive). Specimens were classified as morphologically abnormal (morphological positive) based on predefined criteria for Blast, left shift, variant lymphocytes, PLT clumps, RBC fragments/schistocytes. Distributional classification and morphological flagging were categorized as True Positive (TP), False Positive (FP), False Negative (FN), and True Negative (TN) per the following contingency table based on agreement between Alinity hq and Microscopic results. For this analysis, separate 2x2 tables were constructed in order to determine sensitivity and specificity for both morphological and distributional abnormalities.

**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 | 676 | 78 | 125 | 36 | 437 | 68.42% (59.05%, 76.81%) | 77.76% (74.09%, 81.13%) | 76.18% (72.79%, 79.35%) |
| Any Distributional Abnormalities | 662 | 227 | 75 | 50 | 310 | 81.95% (76.90%, 86.30%) | 80.52% (76.20%, 84.36%) | 81.12% (77.92%, 84.03%) |
| 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%) |

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

2. Clinical Specificity:

   See sensitivity.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

## D Clinical Cut-Off:

Not applicable

## E Expected Values/Reference Range:

Reference range studies were performed based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP28-A3 to establish adult (> 21 years old) reference intervals for male and female populations and to establish reference intervals 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 from apparently healthy subjects and tested on the Alinity h-series System.

Adult Reference Range Study

A total of 262 unique venous or capillary whole blood specimens collected in K2EDTA from apparently healthy male (126) and healthy female (136) adult subjects were tested. The samples were tested on the Alinity h-series System (1+0 instrument configuration or 2+1 instrument configuration) using a minimum of 1 set of reagent lots and 1 control lot. The Alinity h-series Systems were calibrated at the clinical sites using a minimum of 1 lot of Alinity h-series HemCal calibrator.

| **Adult Reference Intervals** | | | | |
|---|---|---|---|---|
| **Measurand** | **Female** | | **Male** | |
| | **N** | **Reference Range** | **N** | **Reference Range** |
| WBC ($x10^3/\mu L$) | 136 | 3.68 – 12.20 | 126 | 3.95 – 11.21 |
| %NEU (%) | 136 | 38.44 – 72.73 | 125 | 39.25 – 83.05 |
| %LYM (%) | 136 | 14.53 – 47.59 | 125 | 11.48 – 44.80 |
| %MONO (%) | 136 | 5.03 – 13.56 | 125 | 5.25 – 12.40 |
| %EOS (%) | 136 | 0.16 – 7.37 | 125 | 0.06 – 9.72 |
| %BASO (%) | 136 | 0.25 – 2.39 | 125 | 0.16 – 1.76 |
| NEU ($x10^3/\mu L$) | 136 | 1.83 – 7.06 | 125 | 1.75 – 8.59 |
| LYM ($x10^3/\mu L$) | 136 | 1.01 – 4.14 | 125 | 0.84 – 3.47 |
| MONO ($x10^3/\mu L$) | 136 | 0.27 – 0.93 | 125 | 0.29 – 0.95 |
| EOS ($x10^3/\mu L$) | 136 | 0.01 – 0.61 | 125 | 0.01 – 0.66 |
| BASO ($x10^3/\mu L$) | 136 | 0.02 – 0.15 | 125 | 0.01 – 0.13 |
| IG ($x10^3/\mu L$) | 136 | 0.00 – 0.09 | 125 | 0.00 – 0.09 |
| %IG (%) | 136 | 0.00 – 1.00 | 125 | 0.00 – 0.82 |
| NRBC ($x10^3/\mu L$) | 136 | 0.00 – 0.00 | 126 | 0.00 – 0.00 |
| NR/W | 136 | 0.00 – 0.00 | 126 | 0.00 – 0.00 |
| RBC | 136 | 3.78 – 5.34 | 126 | 3.81 – 5.81 |

| Adult Reference Intervals | | | | |
|---|---|---|---|---|
| **Measurand** | **Female** | | **Male** | |
| | **N** | **Reference Range** | **N** | **Reference Range** |
| ($x10^6/\mu L$) | | | | |
| HGB (g/dL) | 136 | 11.19 – 15.56 | 126 | 12.14 – 17.98 |
| HCT (%) | 136 | 33.74 – 46.53 | 126 | 36.85 – 54.32 |
| MCV (fL) | 136 | 75.98 – 101.58 | 126 | 78.89 – 101.00 |
| MCH (pg) | 136 | 25.03 – 34.47 | 126 | 26.10 – 33.97 |
| MCHC (g/dL) | 136 | 31.79 – 35.56 | 126 | 32.00 – 36.20 |
| RDW (%) | 136 | 12.00 – 15.69 | 126 | 12.20 – 16.38 |
| RETIC ($x10^3/\mu L$) | 136 | 29.30 – 140.58 | 126 | 40.58 – 155.95 |
| %R (%) | 136 | 0.69 – 3.22 | 126 | 0.86 – 3.62 |
| IRF | 136 | 0.03 – 0.21 | 126 | 0.03 – 0.23 |
| PLT ($x10^3/\mu L$) | 136 | 166.23 – 384.75 | 125 | 118.20 – 364.50 |
| MPV (fL) | 136 | 8.90 – 12.56 | 124 | 9.04 – 12.79 |
| %rP (%) | 136 | 0.97 – 7.04 | 125 | 1.13 – 10.53 |
| MCHr (pg) | 136 | 28.44 – 39.20 | 126 | 30.58 – 40.96 |

Pediatric Reference Range Study

In the study for pediatric range establishment, prospectively collected or leftover venous or capillary whole blood specimens collected in K2EDTA blood collection tubes [i.e., Vacutainer (K981013) or MAP (K093972) blood collection tubes] were enrolled by the clinical sites under the IRB-approved clinical study protocol. These prospectively collected or leftover whole blood specimens were collected from apparently healthy pediatric subjects, as defined in the IRB-approved clinical study protocol.

The whole blood specimens were tested in a minimum of one replicate on the Alinity hq using the CBC+Diff+Retic test selection and closed tube processing mode. The samples were tested on the Alinity h-series System (1+0 instrument configuration or 2+1 instrument configuration) using a minimum of 1 set of reagent lots and 1 control lot. The Alinity h-series Systems were calibrated at the clinical sites using a minimum of 1 lot of Alinity h-series HemCal calibrator.

A total of 320 unique venous or capillary whole blood specimens were included in the establishment of pediatric reference intervals for the Alinity h-series System. The median, minimum value, maximum value, 2.5th percentile, and 97.5th percentile for each measurand

were calculated. In addition, the 2-sided 95% confidence limits around the lower limit (2.5th percentile) and upper limit (97.5th percentile) of the reference intervals were calculated.

| Measurand[a] | Age Bucket | N | Reference Interval |
|---|---|---|---|
| WBC ($x10^3/\mu L$) | Neonate (Birth to 1 Month) | 51 | 6.33 – 29.15 |
| | Infant (>1 Month to 2 Years) | 56 | 5.46 – 18.69 |
| | Child (>2 Years to 12 Years) | 103 | 4.07 – 12.29 |
| | Adolescent (>12 Years to 21 Years) | 110 | 4.35 – 12.01 |
| %NEU (%) | Neonate (Birth to 1 Month) | 50 | 14.02 – 78.35 |
| | Infant (>1 Month to 2 Years) | 56 | 13.14 – 77.49 |
| | Child (>2 Years to 12 Years) | 103 | 23.85 – 69.41 |
| | Adolescent (>12 Years to 21 Years) | 110 | 34.01 – 73.59 |
| %LYM (%) | Neonate (Birth to 1 Month) | 51 | 9.99 – 71.21 |
| | Infant (>1 Month to 2 Years) | 56 | 13.96 – 73.64 |
| | Child (>2 Years to 12 Years) | 103 | 21.30 – 63.69 |
| | Adolescent (>12 Years to 21 Years) | 110 | 15.94 – 52.11 |
| %MONO (%) | Neonate (Birth to 1 Month) | 50 | 3.10 – 21.59 |
| | Infant (>1 Month to 2 Years) | 56 | 4.02 – 18.19 |
| | Child (>2 Years to 12 Years) | 103 | 4.53 – 13.44 |
| | Adolescent (>12 Years to 21 Years) | 110 | 5.22 – 14.31 |
| %EOS (%) | Neonate (Birth to 1 Month) | 51 | 0.21 – 9.95 |
| | Infant (>1 Month to 2 Years) | 56 | 0.08 – 8.86 |
| | Child (>2 Years to 12 Years) | 103 | 0.84 – 12.48 |
| | Adolescent (>12 Years to 21 Years) | 110 | 0.30 – 7.97 |
| %BASO (%) | Neonate (Birth to 1 Month) | 50 | 0.13 – 1.38 |
| | Infant (>1 Month to 2 Years) | 56 | 0.07 – 1.49 |
| | Child (>2 Years to 12 Years) | 103 | 0.34 – 2.22 |
| | Adolescent (>12 Years to 21 Years) | 110 | 0.24 – 1.79 |
| NEU ($x10^3/\mu L$) | Neonate (Birth to 1 Month) | 50 | 1.18 – 19.95 |
| | Infant (>1 Month to 2 Years) | 56 | 1.45 – 12.10 |
| | Child (>2 Years to 12 Years) | 103 | 1.31 – 6.99 |
| | Adolescent (>12 Years to 21 Years) | 110 | 1.84 – 7.40 |
| LYM ($x10^3/\mu L$) | Neonate (Birth to 1 Month) | 51 | 0.77 – 11.13 |
| | Infant (>1 Month to 2 Years) | 56 | 1.44 – 9.89 |
| | Child (>2 Years to 12 Years) | 103 | 1.16 – 5.04 |
| | Adolescent (>12 Years to 21 Years) | 110 | 1.06 – 4.38 |
| MONO ($x10^3/\mu L$) | Neonate (Birth to 1 Month) | 50 | 0.37 – 2.77 |
| | Infant (>1 Month to 2 Years) | 56 | 0.29 – 2.24 |
| | Child (>2 Years to 12 Years) | 103 | 0.27 – 1.07 |
| | Adolescent (>12 Years to 21 Years) | 110 | 0.32 – 1.04 |
| EOS ($x10^3/\mu L$) | Neonate (Birth to 1 Month) | 51 | 0.04 – 1.37 |
| | Infant (>1 Month to 2 Years) | 56 | 0.01 – 0.94 |
| | Child (>2 Years to 12 Years) | 103 | 0.05 – 0.90 |
| | Adolescent (>12 Years to 21 Years) | 110 | 0.02 – 0.62 |

| Measurand[a] | Age Bucket | N | Reference Interval |
|---|---|---|---|
| BASO ($x10^3/\mu L$) | Neonate (Birth to 1 Month) | 50 | 0.01 – 0.24 |
| | Infant (>1 Month to 2 Years) | 56 | 0.01 – 0.14 |
| | Child (>2 Years to 12 Years) | 103 | 0.02 – 0.16 |
| | Adolescent (>12 Years to 21 Years) | 110 | 0.02 – 0.12 |
| IG ($x10^3/\mu L$) | Neonate (Birth to 1 Month) | 51 | 0.00 – 0.95 |
| | Infant (>1 Month to 2 Years) | 56 | 0.00 – 0.74 |
| | Child (>2 Years to 12 Years) | 103 | 0.00 – 0.06 |
| | Adolescent (>12 Years to 21 Years) | 110 | 0.00 – 0.06 |
| %IG (%) | Neonate (Birth to 1 Month) | 51 | 0.00 – 4.65 |
| | Infant (>1 Month to 2 Years) | 56 | 0.00 – 4.82 |
| | Child (>2 Years to 12 Years) | 103 | 0.00 – 0.39 |
| | Adolescent (>12 Years to 21 Years) | 110 | 0.00 – 0.41 |
| NRBC ($x10^3/\mu L$) | Neonate (Birth to 1 Month) | 50 | 0.00 – 2.08 |
| | Infant (>1 Month to 2 Years) | 55 | 0.00 – 0.21 |
| | Child (>2 Years to 12 Years) | 103 | 0.00 – 0.15 |
| | Adolescent (>12 Years to 21 Years) | 109 | 0.00 – 0.10 |
| NR/W | Neonate (Birth to 1 Month) | 50 | 0.00 – 11.75 |
| | Infant (>1 Month to 2 Years) | 55 | 0.00 – 1.94 |
| | Child (>2 Years to 12 Years) | 103 | 0.00 – 2.21 |
| | Adolescent (>12 Years to 21 Years) | 109 | 0.00 – 1.15 |
| RBC ($x10^6/\mu L$) | Neonate (Birth to 1 Month) | 51 | 3.07 – 7.19 |
| | Infant (>1 Month to 2 Years) | 56 | 3.36 – 5.38 |
| | Child (>2 Years to 12 Years) | 103 | 3.84 – 5.39 |
| | Adolescent (>12 Years to 21 Years) | 110 | 3.79 – 5.63 |
| HGB (g/dL) | Neonate (Birth to 1 Month) | 50 | 9.66 – 23.56 |
| | Infant (>1 Month to 2 Years) | 56 | 9.99 – 14.08 |
| | Child (>2 Years to 12 Years) | 103 | 11.38 – 15.12 |
| | Adolescent (>12 Years to 21 Years) | 110 | 11.53 – 16.31 |
| HCT (%) | Neonate (Birth to 1 Month) | 51 | 26.36 – 83.38 |
| | Infant (>1 Month to 2 Years) | 56 | 28.82 – 41.93 |
| | Child (>2 Years to 12 Years) | 103 | 32.89 – 44.16 |
| | Adolescent (>12 Years to 21 Years) | 110 | 34.14 – 48.84 |
| MCV (fL) | Neonate (Birth to 1 Month) | 51 | 88.43 – 117.65 |
| | Infant (>1 Month to 2 Years) | 56 | 68.56 – 94.60 |
| | Child (>2 Years to 12 Years) | 103 | 72.91 – 95.04 |
| | Adolescent (>12 Years to 21 Years) | 110 | 78.91 – 96.29 |
| MCH (pg) | Neonate (Birth to 1 Month) | 50 | 31.24 – 38.66 |
| | Infant (>1 Month to 2 Years) | 56 | 22.63 – 31.72 |
| | Child (>2 Years to 12 Years) | 103 | 23.89 – 31.72 |
| | Adolescent (>12 Years to 21 Years) | 110 | 26.29 – 33.16 |
| MCHC (g/dL) | Neonate (Birth to 1 Month) | 50 | 30.43 – 36.92 |
| | Infant (>1 Month to 2 Years) | 56 | 31.20 – 36.53 |
| | Child (>2 Years to 12 Years) | 103 | 31.25 – 36.11 |

| Measurand[a] | Age Bucket | N | Reference Interval |
|---|---|---|---|
| | Adolescent (>12 Years to 21 Years) | 110 | 31.50 – 35.73 |
| RDW (%) | Neonate (Birth to 1 Month) | 51 | 12.82 – 18.70 |
| | Infant (>1 Month to 2 Years) | 56 | 12.10 – 19.51 |
| | Child (>2 Years to 12 Years) | 103 | 11.92 – 14.83 |
| | Adolescent (>12 Years to 21 Years) | 110 | 12.32 – 15.44 |
| RETIC ($x10^3/\mu L$) | Neonate (Birth to 1 Month) | 51 | 35.85 – 380.30 |
| | Infant (>1 Month to 2 Years) | 56 | 36.74 – 198.77 |
| | Child (>2 Years to 12 Years) | 103 | 32.82 – 113.59 |
| | Adolescent (>12 Years to 21 Years) | 110 | 34.77 – 125.98 |
| %RETIC (%) | Neonate (Birth to 1 Month) | 51 | 0.92 – 7.88 |
| | Infant (>1 Month to 2 Years) | 56 | 0.85 – 5.86 |
| | Child (>2 Years to 12 Years) | 103 | 0.75 – 2.28 |
| | Adolescent (>12 Years to 21 Years) | 110 | 0.80 – 2.78 |
| IRF | Neonate (Birth to 1 Month) | 51 | 0.06 – 0.42 |
| | Infant (>1 Month to 2 Years) | 56 | 0.04 – 0.38 |
| | Child (>2 Years to 12 Years) | 103 | 0.02 – 0.15 |
| | Adolescent (>12 Years to 21 Years) | 110 | 0.02 – 0.14 |
| PLT ($x10^3/\mu L$) | Neonate (Birth to 1 Month) | 51 | 82.87 – 552.73 |
| | Infant (>1 Month to 2 Years) | 56 | 123.71 – 458.58 |
| | Child (>2 Years to 12 Years) | 103 | 142.30 – 440.06 |
| | Adolescent (>12 Years to 21 Years) | 110 | 149.44 – 440.19 |
| MPV (fL) | Neonate (Birth to 1 Month) | 51 | 7.95 – 11.11 |
| | Infant (>1 Month to 2 Years) | 56 | 8.58 – 11.59 |
| | Child (>2 Years to 12 Years) | 103 | 9.02 – 12.80 |
| | Adolescent (>12 Years to 21 Years) | 110 | 9.01 – 12.45 |
| %rP (%) | Neonate (Birth to 1 Month) | 51 | 1.51 – 13.70 |
| | Infant (>1 Month to 2 Years) | 56 | 0.73 – 6.78 |
| | Child (>2 Years to 12 Years) | 103 | 0.95 – 7.76 |
| | Adolescent (>12 Years to 21 Years) | 110 | 0.80 – 7.69 |
| MCHr (pg) | Neonate (Birth to 1 Month) | 50 | 23.99 – 38.86 |
| | Infant (>1 Month to 2 Years) | 56 | 21.73 – 37.83 |
| | Child (>2 Years to 12 Years) | 103 | 27.41 – 38.21 |
| | Adolescent (>12 Years to 21 Years) | 110 | 31.12 – 40.00 |

## F Other Supportive Instrument Performance Characteristics Data:

### Smear and Stain Acceptability

A study was conducted to verify that the Alinity h-series System can prepare acceptable May-Grünwald-Giemsa (MGG) and Wright-Giemsa (WG) stained smears from venous whole blood specimens collected externally in K2EDTA and K3EDTA anticoagulated tubes. The tested specimens included:

- a minimum of 100 K2EDTA specimens, stained with MGG
- a minimum of 100 K2EDTA specimens, stained with WG
- a minimum of 100 K3EDTA specimens, stained with MGG

- a minimum of 100 K3EDTA specimens, stained with WG

The K3EDTA and K2EDTA specimens were collected internally. In addition, K2EDTA leftover specimens were collected from patients undergoing routine care at the 2 external testing sites.

K2EDTA and K3EDTA slides prepared internally using native specimens were contrived to have an HCT ranging between 19.3% to 58.1%. K2EDTA slides prepared externally using native specimens were contrived to have an HCT ranging between 15.0% to 60.0%.

Specimens with a WBC < 4.0 x $10^3$/µL, fragile WBC, abnormal plasma proteins (i.e., cold agglutinin disease, myeloma), lipemia, icterus, or hemolysis were excluded from the evaluation of stained smears per CLSI H20-A2*, Section 6.

The slides were evaluated for suitability for microscopy by 2 qualified reviewers using the criteria per CLSI H20-A2* as detailed below. If their assessment did not agree, a 3rd reviewer assessed the quality of the same slides. The criteria reviewed included:

- Sufficient working area
- Minimum 2.5 cm in length terminating at least 1 cm from the end of the slide
- Gradual transition in thickness from the thick to the thin areas, ending in a feather edge
- Acceptable morphology within the working area
- Narrower than the slide on which the film is spread, with smooth continuous side margins that are accessible for oil immersion examination
- No artifact introduced by the technique
- Minimum distributional distortion
- A far end that becomes gradually thinner, without grainy streaks, troughs, or ridges, all of which indicate an increased number of WBC carried into this area.

The study results were considered acceptable if ≥ 95% of the slides made from K2EDTA and K3EDTA whole blood and stained with MGG or WG by the Alinity h-series System were suitable for morphological use.

Overall, the study verified that the Alinity h-series System can prepare acceptable May-Grünwald-Giemsa and Wright-Giemsa stained smears from venous blood specimens collected in K2EDTA and K3EDTA anticoagulated tubes.

## VIII Proposed Labeling:

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

## IX Conclusion:

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