February 3, 2025

CytoChip Inc.
Wendian Shi
Chief Executive Officer
18 Technology Dr, Suite 200
Irvine, California 92618

Re: K240402
Trade/Device Name: Cito CBC System
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: February 9, 2024
Received: February 9, 2024

Dear Wendian Shi:

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

Please note that if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 864.9(c), your device will require a new 510(k) prior to marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 864.9.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240402

Device Name
Cito CBC System

Indications for Use *(Describe)*
The Cito CBC system is a quantitative automated hematology analyzer intended for in-vitro diagnostic use to determine the following parameters with whole blood anticoagulated with K2EDTA (Venous):

- CBC parameters: white blood cell count (WBC), red blood cell count (RBC), platelet count (PLT), hemoglobin concentration (HGB), hematocrit (HCT), and mean corpuscular volume (MCV);

- 5-Part WBC Differential (WBC Diff): neutrophil count and percentage (NEUT and NEUT%), lymphocyte count and percentage (LYMPH and LYMPH%), monocyte count and percentage (MONO and MONO%), eosinophil count and percentage (EO and EO%), basophil count and percentage (BASO and BASO%).

It is not indicated for use in diagnosing or monitoring of oncology patients, critically ill patients, or children under the age of 2 years.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

I Contact Details

1. 510(k) Number

K240402

2. Applicant Name

CytoChip Inc.

3. Applicant Address

18 Technology Dr, Suite 200, Irvine, CA 92618, United States

4. Applicant Contact Telephone

+1-949-556-4266

5. Applicant Contact

Dr. Wendian Shi

6. Applicant Contact Email

wendian@cytochipinc.com

II Device Name

1. Device Trade Name

Cito CBC System

2. Common Name

Automated differential cell counter

3. Classification Name

Counter, Differential Cell

4. Regulation Number

864.5220

5. Product Code

GKZ – Counter, Differential Cell

III Legal Marketed Predicate Device

Predicate #	Predicate Trade Name	Product Code
K112605	Sysmex XN-Series Automated Hematology Analyzer	GKZ

IV Device Description Summary

The Cito CBC system is an automated hematology analyzer that is intended to analyze human whole blood, and report results of 16 hematology parameters. The system consists of a tabletop analyzer, the Cito CBC Analyzer, and a disposable test cartridge, the Cito CBC Cartridge. The analyzer includes software with Graphic User Interface to guide users to complete test procedure. To perform a test, the test cartridges and other test consumables are provided as a test kit. The current version of the test cartridge is designed for testing whole blood anticoagulated with K2EDTA. The current version of the test kit is designed for testing venous whole blood collected in a vacutainer tube.

The Cito CBC analyzer utilizes the principle of fluorescent flow cytometry for cell count and cell classification. A laser is used as the light source, and fluorescence and light scattering signals are detected for the measurements. For fluorescent labeling, blood cells are treated with a fluorescent dye that has high affinity binding to nucleic acid. Additionally, the analyzer utilizes the principle of two-wavelength photometry for the measurement of hemoglobin. Blood cells are lysed to release hemoglobin. Meanwhile, the light scattering signal measured from the flow cytometry and the light absorption signals measured from the photometry are both used to quantify the hematocrit and the mean corpuscular volume.

The Cito CBC cartridge is self-contained with all reagents to perform a test. The blood sample is applied to the test cartridge, and the test cartridge is inserted into the analyzer to complete the test. The analyzer has a pneumatic module which provides pressure to the cartridge and drives the applied sample to mix with reagents to form multiple sample mixtures. The cartridge has transparent flow cells to support the measurements of sample mixtures by fluorescent flow cytometry and photometry. The sample mixtures and the measurement wastes are all self-contained inside the cartridge for safe disposal after the test.

V Intended Use/Indications for Use

The Cito CBC system is a quantitative automated hematology analyzer intended for in-vitro diagnostic use to determine the following parameters with whole blood anticoagulated with K2EDTA (Venous):

- CBC parameters: white blood cell count (WBC), red blood cell count (RBC), platelet count (PLT), hemoglobin concentration (HGB), hematocrit (HCT), and mean corpuscular volume (MCV);

- 5-Part WBC Differential (WBC Diff): neutrophil count and percentage (NEUT and NEUT%), lymphocyte count and percentage (LYMPH and LYMPH%), monocyte count and percentage (MONO and MONO%), eosinophil count and percentage (EO and EO%), basophil count and percentage (BASO and BASO%).

It is not indicated for use in diagnosing or monitoring of oncology patients, critically ill patients, or children under the age of 2 years.

VI Indication for Use Comparison

The Cito CBC System has similar indications for use when compared to the predicate device Sysmex XN-Series (XN10/20). Both devices are quantitative, multi-parameter, automated in vitro diagnostic hematology analyzers intended for classifying and enumerating CBC parameters.

VII Technological Comparison

The Cito CBC System has the same technological characteristics as the predicate device. Both devices use flow cytometry for cell counting and differential. Both devices use photometry for HGB measurement.
Furthermore, as described in the performance testing summary below, the verification and validation (bench and clinical) testing successfully demonstrated substantial equivalence for the Cito CBC System to the predicate device per 21 CFR § 807.92(b)(3).

Item	Device Cito CBC System	Predicate Sysmex XN series
Intended use	The Cito CBC System is a quantitative automated hematology analyzer intended for in-vitro diagnostic use to determine the following parameters with whole blood anticoagulated with K_2EDTA (Venous): - CBC parameters: white blood cell count (WBC), red blood cell count (RBC), platelet count (PLT), hemoglobin concentration (HGB), hematocrit (HCT), and mean corpuscular volume (MCV); - 5-Part WBC Differential (WBC Diff): neutrophil count and percentage (NEUT and NEUT%), lymphocyte count and percentage (LYMPH and LYMPH%), monocyte count and percentage (MONO and MONO%), eosinophil count and percentage (EO and EO%), basophil count and percentage (BASO and BASO%). It is not indicated for use in diagnosing or monitoring of oncology patients, critically ill patients, or children under the age of 2 years.	The XN-Series modules (XN-10, XN-20) 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 in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC#/%, RET%/#, IPF, IRF, 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 fluid (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.
Sample type	Whole blood anticoagulated with K_2EDTA (venous)	Whole blood anticoagulated with K_2EDTA or K_3EDTA (venous or capillary) Body fluid
Parameters	WBC, RBC, PLT, HGB, HCT, MCV, NEUT, NEUT%, LYMPH, LYMPH%, MONO, MONO%, EO, EO%, BASO, and BASO%	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC%/#, RET%/#, IPF, IRF, RET-He, WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF#

Testing principle	Performs hematology analyses with flow cytometry method (using a semiconductor laser) to count and differentiate WBC, RBC and PLT cells. Use photometry method to quantify HGB. Use the flow cytometer method and the photometry method together to quantify HCT and MCV.	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS hemoglobin method.
Analysis Mode	Whole Blood (venous)	Whole blood (venous) Whole blood (capillary) Body fluid
Sample volume	15-20 µL	88 µL (aspiration volume)
Throughput	7 samples/hour	100 samples/hour maximum depending on mode used
Calibration	Factory calibrated	XN CAL (XN-10/X-20 Calibrator) XN CAL PF (Platelet F Calibrator)

VIII Non-Clinical and/or Clinical Tests Summary

Non-Clinical Study Summary

1. Precision-Repeatability Study with Whole Blood at Clinical Sites (CLSI EP05-A3)
Precision performance was evaluated by testing fresh whole blood at CLIA-waived sites by untrained operators. Venous whole blood (K2EDTA anticoagulated) was used to evaluate the precision of reported CBC parameters. Three CLIA-waived sites participated in this study, and each site used one analyzer and at least two untrained operators. For the three sites in total, 45 blood samples were selected and tested to cover the three intervals (low, normal, high) for WBC, RBC, PLT, HGB, HCT and MCV. 10 consecutive tests were performed for each sample. The study calculates the StDev (standard deviation) and %CV (coefficient of variation) for each reported parameter of each sample. The study results pool the StDev and %CV together across the three sites into three intervals (low, normal, high), following the protocol of CLIS EP05-A3. The pooled StDev and pooled %CV met the acceptance criteria for all reported parameters in the three intervals (low, normal, high) and at the medical decision levels.

2. Reproducibility Study with QC material at Clinical Sites (CLSI EP05-A3)
The reproducibility performance was evaluated by testing QC material at CLIA-waived Sites by untrained operators. Three CLIA-waived sites participated in this study, and each site used one analyzer and at least two untrained operators. At each site, the study was performed for 5 days. In each day, 2 test runs were performed with 3 replicates per run.

One lot of the QC material (three levels: low, normal, and high) was used and a total of 90 tests were performed for each control level over the study (3 sites×5 days×2 test runs×3 replicates per run). In total, 270 tests were performed for all three control levels (low, normal, and high). ANOVA analysis was performed according to CLSI EP05-A3 to calculate the within-run %CV/StDev, between-run/between operator %CV/StDev, between-day %CV/StDev, between-site %CV/StDev, and total %CV/StDev for each control level. The total %CV/StDev of reported parameters for each of the three levels all met the acceptance criteria.

3. Linearity Study (CLSI EP06 Ed2)
The linearity interval of the WBC, RBC, PLT, HGB, HCT and MCV were evaluated using fresh whole blood (venous blood anticoagulated with K2EDTA). A 9-concentration sample panel was tested for each parameter and each sample was tested twice on the Study Device and twice on the predicate device (Sysmex XN Hematology Analyzer). Linear Regression was performed for data analysis and percentage bias thresholds were defined for each parameter to quantify the linear range. The study results established the linearity intervals of the reported parameters.

4. Detection Limit Study - Limit of Quantification (LoQ) (CLSI EP17-A2)
Four venous whole blood samples were diluted with homologous plasma to make low-level samples and were used in this study to evaluate LoQ of WBC, RBC, PLT, HGB, HCT and MCV. For each sample, 9 replicate tests were performed with each cartridge lot, and two cartridge lots were used to capture the reagent variability (in total 18 tests for each sample). For the four samples, a total of 72 tests were performed, with 36 tests for each cartridge lot. The LoQ was determined individually for two cartridge lots, and the greater LoQ between the two cartridge lots was taken as the LoQ for each parameter.

5. Assay Measuring Range Study (CLSI H26-A2)
The Assay Measuring Ranges for WBC, RBC, PLT, HGB, HCT and MCV are determined from the Linearity and the LoQ study results. The lower limit of the measuring range is determined by the higher one of the following two: A) lower limit of the linearity interval; and B) LoQ. The upper limit of the measuring range is determined by the upper limit of the linearity interval.
After establishing the Measuring Ranges, the reportable ranges are chosen to be equal to or narrower than the Measuring Ranges, by applying a set of suppression levels for CLIA Waived setting. After applying the suppression levels to the Measuring Ranges, the Reportable Ranges (with Suppression) are established. The analyzer only reports numeric results within the Reportable Ranges (with Suppression), while numeric results outside these ranges are suppressed.

6. Interference Study (CLSI EP07 Ed3)
A study was conducted to determine the interference level for the following interfering substances: conjugated bilirubin, unconjugated bilirubin, K2EDTA, chyle, intralipid, and hemolytic hemoglobin. The interference levels were evaluated by testing fresh whole blood (venous blood anticoagulated with K2EDTA) spiked with the interferents at target concentration levels. For each interferent, blood samples were spiked with the interferent,

and five replicate tests were performed with both control group (no spiking) and test group (with spiking) for comparison. A total of three blood samples were tested for each interferent.
The results of the interference study demonstrated that:
There was no significant conjugated bilirubin interference up to a concentration of 40 mg/dL for WBC, RBC, PLT, HGB, HCT, and MCV.
There was no significant unconjugated bilirubin interference up to a concentration of 40 mg/dL for WBC, RBC, PLT, HGB, HCT, and MCV.
There was no significant K2EDTA interference up to a concentration of 8 mg/mL for WBC, RBC, PLT, HGB, HCT, and MCV.
There was no significant Chyle interference up to a concentration of 2,524 FTU for WBC, RBC, PLT, HGB, HCT, and MCV.
There was no significant intralipid interference up to a concentration of 2,000 mg/dL for WBC, PLT, and HGB, and up to a concentration of 500 mg/dL for RBC, HCT, and MCV. Samples with intralipid higher than 500 mg/dL trigger a fail-alert mechanism and the impacted results (RBC, HCT and MCV) are automatically suppressed.
There was no significant hemolytic hemoglobin interference up to a concentration of 1.0 g/dL for WBC, RBC, PLT, HGB, and MCV, and up to a concentration of 0.5 g/dL for HCT.

7. Metrological Traceability Study (CLSI EP32-R)
The traceability of the Device was established by using the predicate device (Sysmex XN Hematology Analyzer, K112605) as the reference method following CLSI EP32-R guideline. The predicate device has established traceability by the commercial calibrators (XN CAL/XN CAL PF, K141962/K120747) to internationally recognized reference methods:
- WBC and RBC: Reference method for the enumeration of erythrocytes and leucocytes, ICSH Expert Panel on Cytometry, Clin Lab Haematol. 1994; 16, 131-138;
- HGB: Recommendation for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specification for international haemiglobincyanide standard (4th edition), ICSH Expert Panel on Haemoglobinometry, J Clin Pathol 1996; 49: 271-274;
- HCT: Recommendations for Reference Method for the Packed Cell Volume (ICSH Standard 2001), ICSH Expert Panel on Cytometry, Clin Lab Hematol. 2001; 7:148-170;
- PLT: ICSH Expert Panel on Cytometry, Platelet Counting by the RBC/Platelet Ratio Method-Mar. 2001, American Journal of Clinical Pathology.

8. Specimen Stability Study
Specimen stability of venous whole blood (K2EDTA anticoagulated) was evaluated for specimens stored at the following conditions, room temperature condition (15 °C – 25 °C) or refrigerated temperature condition (2 °C – 8 °C). For each of the two conditions, 6 normal samples and 4 abnormal samples were tested respectively. At time zero (0 hour), the samples were tested in triplicates to establish the baseline. These samples were tested again in duplicate at the following time points: 4.5 hours, 6.5 hours, and 8.5 hours. For each time point, the results were compared to the baseline results, and the mean percentage difference was calculated. The results of all tested time points met the acceptance criteria, supporting the claim of an 8-hour blood sample stability duration.

9. Cartridge Lot-to-Lot Variability Study (CLSI EP05-A3)
A study was performed to evaluate the lot-to-lot variability of the test cartridge. Three consecutive cartridge lots were used for the study, and venous whole blood (K2EDTA anticoagulated) was tested to assess the within-lot, between-lot and total variability. A total of 19 samples covering normal and abnormal ranges were tested in this study. For each sample, 5 replicate tests were performed for each cartridge lot (15 tests per sample for the three cartridge lots). ANOVA analysis was performed according to CLSI EP05-A3 to calculate the within-lot %CV/StDev, between-lot %CV/StDev, and total %CV/StDev, which all met the acceptance criteria.

10. QC Material – Lot-to-Lot reproducibility (CLSI EP05-A3)
This study was to evaluate the lot-to-lot reproducibility of the QC kit. Three lots of QC materials were selected for testing. From each lot, one QC kit was selected which included three levels (low, normal and high levels). Each level of the QC material was tested for 5 days×2 runs×3 replicates. In total, 270 tests were performed. For each lot, ANOVA analysis was performed according to CLSI EP05-A3 to calculate the within-lot %CV/StDev, between-lot %CV/StDev, and total %CV/StDev. For each QC parameter of each level, the pooled total CV/StDev of the three lots were determined, and the results met the acceptance criteria.

Clinical Study Summary

1. Method Comparison (CLSI H26-A2, CLSI H20-A2, CLSI EP09-A3)
Method comparison studies were performed across three CLIA-waived testing sites (with nine untrained operators in total) to evaluate the performance of the Study Device compared to the Comparative Method, Sysmex XN Automated Hematology Analyzer.
A total of 481 venous whole blood samples collected in K2EDTA vacutainer tube were tested. The samples fully covered the reportable ranges of the device and a wide variety of clinical conditions, including Anemia, Chronic Inflammation, Bacterial Infection, Viral Infection, Respiratory Disease, Cardiovascular Disease, Liver Disease, Kidney Disease, Metabolic Disease, Autoimmune/Rheumatological Disease, Hemoglobinopathies/Hereditary RBC disease (including Iron deficiency, Hb variant), Leukemia (including Acute Myeloid Leukemia, Acute Lymphocytic Leukemia, Chronic Myeloid Leukemia, and Chronic Lymphocytic Leukemia), Lymphoma, Benign Leukopenia, Myelodysplastic Syndrome (MDS), Solid Tumor, Cancer and other oncological conditions, etc.
Statistical analysis for the method comparison was performed based on correlation plots with Deming regression and Bland-Altman plot for bias. For each reported parameter, the slope, intercept, and correlation coefficient from the Deming fittings, and the mean bias between the Cito CBC Analyzer and the Comparative Method were analyzed, and the results fully met the acceptance criteria.

2. Flagging Comparison (CLSI H20-A2)
Flagging comparison studies were performed across five CLIA-waived testing sites and one point-of-care site to evaluate the flagging agreement between the Study Device and the Comparative Method, Sysmex XN Automated Hematology Analyzer.
A total of 1,082 venous whole blood samples collected in K2EDTA vacutainer tube were

tested, which covered a wide variety of abnormalities including distribution abnormalities, morphological abnormalities, and other abnormal conditions (e.g. warm/cold agglutinins, in vivo hemolysis).
Based on the reported flags, each sample was categorized as either Negative (no sample abnormalities) or Positive (with sample abnormalities). The Positive Percent Agreement, Negative Percent Agreement and Overall Agreement were calculated. The results of the flagging agreement (Positive Agreement 91.9%, Negative Agreement 95.3%, and Overall Agreement 93.7%) fully met the acceptance criteria.

3. Reference Interval (CLSI EP28-A3c)
A referent interval study was performed to determine the reference intervals of adults and pediatrics on the Study Device. Healthy subjects were enrolled at CLIA-waived sites for the study, including 253 adults over 21 years old (127 male, 126 female), 46 adolescents between 12-21 years old (21 male, 25 female), and 41 children between 2-12 years old (20 male, 21 female). Venous samples of whole blood anticoagulated with K2EDTA were collected from each subject and tested on the Study Device. For the adult group (over 21 years old), reference intervals are established by non-parametric method following CLSI EP28-A3c. For the adolescent group (12-21 years old) and the children group (2-12 years old), the reference intervals published in literature were verified on the Study Device.

IX Non-Clinical and/or Clinical Tests Conclusions

The performance data in nonclinical and clinical tests demonstrated substantial equivalence with the predicate device.