December 21, 2023

Sysmex America, Inc.
Yvonne Doswell
Sr. Scientist, Regulatory Affairs
577 Aptakisic Road
Lincolnshire, Illinois 60069

Re: K230887
Trade/Device Name: Sysmex XQ-Series (XQ-320) Automated Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: March 30, 2023
Received: March 31, 2023

Dear Yvonne Doswell:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230887

Device Name

Sysmex XQ-Series (XQ-320) Automated Hematology Analyzer

Indications for Use *(Describe)*

The XQ-Series analyzer (XQ-320) is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories.

The XQ-320 analyzer classifies and enumerates the following parameters in venous and capillary whole blood samples collected in K2 or K3 EDTA anticoagulant: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW-SD, RDW-CV, MPV, NEUT%/#, LYMPH%/#, and MXD%/#.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(K) SUMMARY

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

Submitter's name, address, telephone number, a contact person, and date the summary was prepared:

Submitter's Name: Sysmex America, Inc.

Submitter's Address: 577 Aptakisic Road
Lincolnshire, IL 60069

Submitter's Contact: Yvonne Doswell
Senior Scientist, Regulatory Affairs
E-Mail: doswelly@sysmex.com
Phone: (678) 274-8024

Date 510(k) Summary Prepared: December 21, 2023

Name of the device, including the trade or proprietary name, the common or usual name, and the classification name:

Proprietary Name: Sysmex XQ-Series (XQ-320) Automated Hematology Analyzer

Common Name: Automated Hematology Analyzer

Classification Name: Automated Differential Cell Counter

Regulation Description: Automated Differential Cell Counter

Regulation Section: 21 CFR 864.5220

Device Class: 2

Product Code: GKZ

Related Reagents, Controls and Calibrator:

Product Code: 81GIF
CELLPACK (Diluent)

Product Code: 81GGK
STROMATOLYSER-WH (Lyse)

Product Code: 81KSA
SCS-1000 (Calibrator)

Product Code: 81PPM
CELLCLEAN (Cleaning solution)

Product Code: 81JPK
EIGHTCHECK-3WP X-TRA (3 Controls)

Predicate Device and 510(k) number: Sysmex XN-Series (XN-10, XN-20) Automated Hematology Analyzer, K112605

Description of the Device:

The Sysmex XQ-Series (XQ-320) automated hematology analyzer is a multi-parameter hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XQ-320 analyzer classifies and enumerates whole blood parameters by DC (Direct Current) detection method and non-cyanide HGB analysis method (Colorimetric

method) on whole blood samples collected in K_2 or K_3EDTA anticoagulant. The XQ-320 analyzer consists of one unit which aspirates and dispenses diluent to prepare blood dilutions and analyzes whole blood samples. The operator must mix the sample manually then introduce the sample tube to the aspiration pipette with the cap off, and presses the start switch to execute aspiration and analysis. The XQ-320 analyzer uses a built-in monitor to operate the analyzer and process data.

Statement of Intended Use:

The XQ-Series analyzer (XQ-320) is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories.

The XQ-320 analyzer classifies and enumerates the following parameters in venous and capillary whole blood samples collected in K_2 or K_3 EDTA anticoagulant: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW-SD, RDW-CV, MPV, NEUT%/#, LYMPH%/#, and MXD%/#.

Summary of Comparison of Technological Characteristics:

Table 5-1 compares the similarities and differences between the Sysmex XQ-320 Automated Hematology analyzer with the predicate XN-10 Automated Hematology analyzer.

Table 5-1: Comparison of the Predicate XN-10 and the Subject XQ-Series (XQ-320) Automated Hematology Analyzers

Item	Predicate Device: XN-Series (XN-10) K112605	Subject Device: XQ-Series (XQ-320)
Device Similarities		
Intended Use	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	The XQ-Series analyzer (XQ-320) is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XQ-320 analyzer classifies and enumerates the following parameters in venous and capillary whole blood samples collected in K_2 or K_3 EDTA anticoagulant: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW-SD, RDW-CV, MPV, NEUT%/#, LYMPH%/#, and MXD%/#.

	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.	
Specimen Type	Whole Blood collected in K_2 or K_3EDTA	SAME
Test Principle	Performs hematology analyses using DC Detection	SAME
Parameters	Whole Blood Mode: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, RDW-CV, RDW-SD, MPV	SAME
Analysis Modes	Manual Analysis Mode [Whole Blood] mode [Pre-Dilute] mode	SAME
Sample Aspiration/ Fluidic Pathway	Single Pathway	SAME
Measuring Channels	RBC/PLT, HGB	SAME
Item	**Predicate Device: XN-Series (XN-10) K112605**	**Subject Device: XQ-Series (XQ-320)**
Device Differences		
Specimen Type	Body Fluids Analysis Mode (CSF, Peritoneal, Pleural, and Synovial Fluids)	Not Available
Test Principle	Flow cytometry method (using a semiconductor laser) and SLS-hemoglobin method.	DC detection method, Non-cyanide hemoglobin analysis method
Parameters	IG%/#, RET%/#, IPF, IRF, RET-He PLT (PLT-F), NRBC%/#, WBC BF, RBC-BF, MN%/#, PMN%/#, and TC-BF	Not Available
	MONO%/#, EO%/#, BASO%/#	MXD%/# (MONO+EO+BASO)

Reagents	FLUOROCELL WNR (Stain) FLUOROCELL WDF (Stain) FLUOROCELL RET (Stain) FLUOROCELL PLT (Stain)	Not Available
	CELLPACK DFL (Diluent) CELLPACK DCL (Diluent)	Not Available CELLPACK (Diluent)
	SULFOLYSER® (Lyse) LYSERCELL WNR (Lyse) LYSERCELL WDF (Lyse)	STROMATOLYSER-WH (Lyse)
	CELLCLEAN AUTO (Cleaning solution)	CELLCLEAN (Cleaning solution)
Measured Channels	WNR, WPC, WDF, PLT-F, RET	Not Available
WBC Differential	5-Part	3-Part
Controls/ Calibrators	Controls: XN-Check -3 levels XN Check BF – 2 levels Calibrator: XN CAL, XN CAL PF	Controls: EIGHTCHECK-3WP_X-TRA 3 levels Calibrator: SCS-1000
Analysis Modes	Sampler Analysis Mode: Sample rack Sampler Manual Analysis Mode: [LWBC] Mode Body Fluid Mode	Sampler Analysis Mode: Not available Manual Analysis Mode: Not Available
Throughput	Whole Blood Mode:100 samples/hour maximum depending on mode used. Pre-Dilution mode: Approximately 90 samples/hour maximum depending on mode used. Body Fluid Mode: 40 samples/hour	Whole Blood Mode: Approximately 70 samples/hour Pre-Dilution mode: Approximately 60 samples/hour Body Fluid Mode: Not Available
Sample Aspiration Volumes	Whole Blood Mode: 88 µL Pre-Dilution Mode: 70 µL Body Fluid Mode: 88 µL	Whole Blood Mode: 16 µL Pre-Dilution Mode: 65 µL Body Fluid Mode: Not Available
Main Unit Dimensions (W x D x H mm)	With Sampler (including the sampler (SA-10) 645 x 755 x 855	Without Sampler 365 x 450 x 440

The XQ-320 analyzer Indications for Use statement is similar to the predicate device with minor differences. The XQ-320 analyzer also has similar technological characteristics as the predicate device with minor variation. Both devices measure similar parameters. The data collection and data management software functionality are similar to the predicate device with minor variation.

The XQ-320 analyzer differs from the predicate with a slower throughput and smaller sample aspiration volumes, fewer measuring channels, measurement of specimen types (i.e., body fluids), and fewer parameters measured, however it is very similar in fundamental scientific technology as the predicate device to establish equivalence. In addition, XQ-320 control material and calibrator are specific for the XQ-320 analyzer. The XQ-320 analyzer performs a 3-part differential while the XN-10 performs a 5-part differential.

To demonstrate that differences in technological characteristics between the subject device and predicate device do not impact safety and effectiveness, the following clinical performance studies were conducted utilizing the XQ-320 analyzer.

Summary of Performance Testing:

Clinical testing was conducted on the XQ-Series (XQ-320) analyzer to show equivalent performance to the XN-10 analyzer. Testing included:

Method Comparison

The method comparison study was conducted based on CLSI EP09c, 3rd edition at three (3) external US clinical sites and one (1) internal site to assess the performance of XQ-320 when compared to the predicate XN-10. A total of 628 unique residual and prospectively collected venous whole blood samples collected in K2EDTA anticoagulant from pediatrics (<21 years) and adult (≥21 years) subjects including a variety of disease states (chronic leukemia (lymphocytic), pathological WBCs, hepatocellular carcinoma, bacterial infection, acute encephalopathy etc.) were enrolled in the study. Of the total samples enrolled, 611 were native, and 17 samples were manipulated to achieve pathological values at the upper and lower analytical measuring range, following CLSI H26-A2 Concentration and Dilution procedures.

Sample demographics from all sites included 172 pediatric subjects (<21 years) and 433 adults (≥21 years) and 23 subjects with age not reported. Of this total, 43.8% were male, 52.2% female and 4.0% with sex not reported.

Samples were tested in singlet within 8 hours of receipt in the testing laboratory and within two hours on both analyzers. Diluted and/or spiked samples were used when native samples were not available to adequately span the full analytical measuring range, but no more than 10% of the total samples tested.

The results of the regression analyses including 95% confidence interval (CI) for the slope and y-intercept, mean difference (bias), and percent difference (% bias) were computed for each parameter with results from the XQ-320 analyzer against the results from the Sysmex XN-10 analyzer. Bland-Altman plots were generated to show differences between the two devices for all reportable parameters using the data from all sites combined.

All Sites Combined - Regression Analysis

Measurand	N	Result Range	Correlation Coefficient	Slope	95% Confidence Interval	Intercept	95% Confidence Interval
WBC ($\times 10^3/\mu L$)	378	0.31 to 98.67	0.9994	0.992	0.988 to 0.996	0.215	0.144 to 0.285
RBC ($\times 10^6/\mu L$)	385	1.10 to 6.78	0.9984	0.970	0.965 to 0.976	0.107	0.083 to 0.130
HGB (g/dL)	385	3.2 to 23.8	0.9987	0.974	0.969 to 0.979	0.45	0.39 to 0.52
HCT (%)	379	11.1 to 59.1	0.9965	0.964	0.956 to 0.972	0.62	0.30 to 0.93
MCV (fL)	385	52.5 to 131.6	0.9881	1.005	0.990 to 1.021	-1.98	-3.43 to -0.53
MCH (pg)	385	13.1 to 40.9	0.9861	0.997	0.981 to 1.014	0.57	0.08 to 1.06
MCHC (g/dL)	385	22.4 to 40.2	0.8914	0.880	0.839 to 0.922	4.83	3.52 to 6.13
PLT ($\times 10^3/\mu L$)	382	6 to 941	0.9960	0.989	0.980 to 0.998	-1.9	-4.9 to 1.0
RDWSD (fL)	384	33.6 to 105.5	0.9467	1.028	0.995 to 1.062	-5.03	-6.83 to -3.23
RDWCV (%)	385	11.2 to 26.5	0.9645	1.167	1.136 to 1.198	-3.15	-3.65 to -2.65
MPV (fL)	359	8.2 to 14.5	0.9027	0.912	0.870 to 0.954	0.40	-0.05 to 0.86
NEUT# ($\times 10^3/\mu L$)	262	0.36 to 57.75	0.9959	1.020	1.009 to 1.031	-0.176	-0.299 to -0.052
Lymph# ($\times 10^3/\mu L$)	363	0.10 to 99.84	0.9962	1.012	1.003 to 1.021	0.109	-0.005 to 0.222
MXD# ($\times 10^3/\mu L$)	262	0.02 to 3.00	0.8525	1.280	1.197 to 1.364	-0.247	-0.394 to -0.101
NEUT% (%)	262	15.9 to 96.7	0.9600	1.017	0.981 to 1.052	-2.32	-4.58 to -0.06
LYMPH% (%)	364	0.5 to 95.2	0.9827	1.031	1.011 to 1.051	0.18	-0.56 to 0.91
MXD% (%)	262	1.0 to 18.0	0.5933	1.415	1.268 to 1.562	-4.25	-6.06 to -2.44

[1] N less than 385 were due to sample related errors (masked results [---]).

Sensitivity and Specificity

Clinical sensitivity/specificity (estimates of agreement) was conducted to evaluate the flagging capabilities of the XQ-320 analyzer in identifying/flagging samples with possible abnormalities in the distribution and morphology of white blood cell, red blood cell and platelet parameters, for further investigation and/or review of a blood smear by an experienced medical technologist. The study was conducted in accordance with CLSI H20-A2.

The study was conducted using the flagging results obtained from the samples used in the method comparison study. The flagging results from the XQ-320 analyzers for normal (no flags) and abnormal (flags present) were compared to manual differential counts and peripheral blood smear review by experienced examiners using light microscopy (reference method).

Separate 2x2 tables were constructed to determine sensitivity for both distributional and morphological abnormalities following CLSI EP12-A2. The sample size (N), and number of true positives (TP), false positives (FP), true negative (TN), false negatives (FN), sensitivity, specificity, and overall percent agreement are presented in the following table for the 3 combined external sites and separately for the one (1) internal site.

The study met predefined overall percent agreement criteria and were found to be acceptable.

Distributional and Morphological Abnormal Flagging Summary – Three External Clinical Sites

	Reference Method – Manual Microscopy								
	Abnormal Flag Category	**N**	**TP**	**FP**	**TN**	**FN**	**Sensitivity (95% CI)**	**Specificity (95% CI)**	**Overall % Agreement**
Sysmex XQ-320	Any Abnormal Distributional Flag	237	128	23	71	15	89.5 (83.29, 94.01)	75.5 (65.58, 83.81)	84.0 (78.66, 88.40)
	Any Abnormal Morphological Flag	353	120	46	146	41	74.5 (67.08, 81.06)	76.0 (69.37, 81.89)	75.4 (70.52, 79.76)
	Any Abnormal Distributional and/or Abnormal Morphological Flag	360	224	49	64	23	90.7 (86.36, 94.01)	56.6 (46.99, 65.93)	80.0 (75.49, 84.01)

Distributional and Morphological Abnormal Flagging Summary – One Internal Site

	Reference Method – Manual Microscopy								
	Abnormal Flag Category	**N**	**TP**	**FP**	**TN**	**FN**	**Sensitivity (95% CI)**	**Specificity (95% CI)**	**Overall % Agreement**
Sysmex XQ-320	Any Abnormal Distributional Flag	200	74	9	110	7	91.4 (83.00, 96.45)	92.4 (86.13, 96.48)	92.0 (87.33, 95.36)
	Any Abnormal Morphological Flag	189	11	9	141	28	28.2 (15.00, 44.87)	94.0 (88.92, 97.22)	80.4 (74.04, 85.83)
	Any Abnormal Distributional and/or Abnormal Morphological Flag	200	76	9	100	15	83.5 (74.27, 90.47)	91.7 (84.90, 96.15)	88.0 (82.67, 92.16)

Precision (Repeatability)

Repeatability studies were performed across three XQ-320 analyzers in accordance with the CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard, Second Edition, to evaluate the precision (repeatability) of all claimed parameters on the XQ-320 analyzer.

The studies were conducted using residual K_2EDTA venous whole blood samples targeting medical decision levels, the normal range and upper and lower end of the analytical measuring range of direct measured parameters (WBC, RBC, HGB, HCT and PLT). All samples were tested in replicates of ten and the mean, standard deviation (SD), and coefficient of variation were calculated for each parameter.

All pooled results met the predefined acceptance criteria and were determined to be acceptable.

Precision Repeatability Study

Measurand	Sample level	N replicates	Interval	Mean	Pooled SD	Pooled %CV
WBC (x 10^3/uL)	MDL	30	0.67 - 0.84	0.75	0.04	4.45
	Low	30	1.21 - 1.91	1.64	0.04	2.44
	Normal	30	9.81 - 10.65	10.28	0.15	1.45
	High	30	70.97 - 93.53	83.94	0.61	0.73
RBC (x 10^6/uL)	Low	30	2.03 - 2.85	2.53	0.02	0.99
	Normal	30	4.41 - 4.94	4.70	0.04	0.84
	High	30	6.16 - 6.80	6.43	0.07	1.05
HGB (g/dL)	Low	30	6.1 - 6.9	6.49	0.06	0.92
	Normal	30	13.5 - 15.5	14.36	0.11	0.79
	High	30	17.4 - 19.2	18.05	0.07	0.38
HCT(%)	Low	30	18.2 - 23.0	20.50	0.24	1.16
	Normal	30	40.2 - 44.6	42.10	0.39	0.93
	High	30	52.3 - 58.7	54.99	0.48	0.87
PLT (10^3/µL)	MDL	30	9 - 26	14.33	2.60	17.11
	Low	30	30 - 44	37.10	3.06	8.28
	Normal	30	216 - 311	271.57	6.50	2.46
	High	30	618 - 982	815.30	13.02	1.67
MCV (fL)	Low	30	66.4 - 88.0	77.73	0.26	0.33
	Normal	30	82.2 - 91.1	86.50	0.43	0.50
	High	30	102.9 - 112.6	108.77	0.52	0.47
MCH (pg)	Low	30	20.3 - 25.7	23.50	0.30	1.26
	Normal	30	26.4 - 31.0	28.33	0.29	1.02
	High	30	30.7 - 41.8	35.73	0.54	1.45
MCHC (g/dL)	Low	30	26.2 - 28.9	27.80	0.36	1.31
	Normal	30	28.6 - 32.2	30.87	0.31	1.00
	High	30	32.1 - 36.9	34.50	0.47	1.35
RDW-SD (fL)	Low	30	33.7 - 45.5	38.87	0.64	1.67
	Normal	30	41.1 - 58.2	47.77	0.76	1.60
	High	30	72.6 - 96.0	81.40	1.46	1.80

Measurand	Sample level	N replicates	Interval	Mean	Pooled SD	Pooled %CV
RDW-CV (%)	Low	30	9.5 - 12.6	11.20	0.58	1.04
	Normal	30	13.1 - 15.5	14.37	0.67	1.17
	High	30	17.2 - 29.9	22.60	0.69	1.13
MPV (fL)	Low	30	8.2 - 8.8	8.53	0.95	1.75
	Normal	30	8.3 - 10.4	9.50	1.10	2.01
	High	30	11.1 - 13.0	11.97	1.40	2.50
NEUT (x 10^3/uL)	Low	30	0.39 - 1.37	0.91	3.99	7.91
	Normal	30	1.21 - 8.70	4.69	1.85	3.56
	High	30	3.36 - 41.53	16.38	1.58	2.85
NEUT (%)	Low	30	21.0 - 57.2	38.40	4.88	7.16
	Normal	30	45.9 - 86.2	61.20	1.91	2.50
	High	30	72.5 - 95.9	84.83	2.47	2.72
LYMPH (x 10^3/uL)	Low	30	0.34 - 0.73	0.49	0.01	4.31
	Normal	30	0.67 - 48.39	16.47	0.40	3.15
	High	30	2.23 - 75.29	26.63	0.33	2.29
LYMPH (%)	Low	30	3.4 - 9.9	5.70	0.37	5.95
	Normal	30	19.8 - 32.9	27.97	0.85	3.10
	High	30	61.0 - 87.6	77.67	0.71	0.99
MXD (x 10^3/uL)	Low	30	0.39 - 1.70	0.81	0.08	10.60
	Normal	30	0.59 - 2.39	1.27	0.15	13.11
	High	30	0.39 - 15.45	5.85	0.27	7.47
MXD (%)	Low	30	2.6 - 14.5	6.87	0.65	10.11
	Normal	30	6.7 – 19.2	11.67	1.60	13.00
	High	30	10.0 - 31.6	22.03	1.55	7.17

Reproducibility

Reproducibility studies were performed at three external US sites to evaluate the within run, between run, between day, between site, and total imprecision of all claimed parameters on the XQ-320 analyzer in accordance with the CLSI EP05-A3 approved guidelines.

Testing was conducted by 2-4 operators at each site using 3 levels of EIGHTCHECK-3WP X-TRA whole blood control material. Each level was run in triplicate, twice a day for 5 days using a single calibration and reagent lot across 3 sites for a total of 90 results per control level.

The results were analyzed by analysis of variance (ANOVA) method. The SD and %CV were calculated for within-run, between-run, between-day, between-site and total imprecision for each control level and presented in the table below. All results met the predefined acceptance criteria and were determined to be acceptable.

All Sites Combined – Reproducibility Study

XQ-320 All Combined Sites				Within Run		Between Run		Between Day		Between Site		Total	
Measurand (unit)	**Control Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
WBC ($x\ 10^3$/uL)	Low	90	3.42	0.000	0.00	0.064	1.87	0.042	1.23	0.000	0.00	0.077	2.24
	Normal	90	7.38	0.000	0.00	0.120	1.60	0.050	0.68	0.056	0.75	0.140	1.89
	High	90	19.3	0.040	0.21	0.190	0.97	0.100	0.54	0.110	0.59	0.250	1.28
RBC ($x\ 10^6$/uL)	Low	90	2.45	0.000	0.00	0.034	1.39	0.014	0.56	0.000	0.00	0.037	1.49
	Normal	90	4.59	0.000	0.00	0.047	1.01	0.023	0.51	0.000	0.00	0.052	1.13
	High	90	5.58	0.000	0.00	0.065	1.16	0.027	0.48	0.000	0.00	0.070	1.25
HGB (g/dL)	Low	90	6.61	0.00	0.00	0.05	0.77	0.06	0.92	0.04	0.71	0.09	1.40
	Normal	90	13.3	0.04	0.33	0.04	0.36	0.05	0.39	0.12	0.90	0.15	1.09
	High	90	17.3	0.00	0.00	0.08	0.49	0.06	0.39	0.11	0.61	0.15	0.88
HCT (%)	Low	90	18.5	0.00	0.00	0.26	1.39	0.09	0.53	0.11	0.62	0.30	1.61
	Normal	90	37.4	0.00	0.00	0.40	1.06	0.14	0.37	0.22	0.59	0.47	1.27
	High	90	48.5	0.19	0.39	0.53	1.10	0.05	0.11	0.24	0.50	0.62	1.28
MCV (fL)	Low	90	75.3	0.00	0.00	0.37	0.49	0.37	0.48	0.36	0.48	0.64	0.84
	Normal	90	81.4	0.00	0.00	0.30	0.37	0.45	0.55	0.41	0.50	0.67	0.83
	High	90	86.9	0.07	0.08	0.33	0.38	0.30	0.34	0.41	0.47	0.61	0.70
MCH (pg)	Low	90	27.0	0.00	0.00	0.43	1.59	0.13	0.48	0.25	0.92	0.51	1.90
	Normal	90	29.0	0.00	0.00	0.29	1.01	0.07	0.27	0.28	0.98	0.42	1.43
	High	90	31.0	0.12	0.40	0.34	1.09	0.00	0.00	0.21	0.67	0.42	1.34
MCHC (g/dL)	Low	90	35.8	0.00	0.00	0.56	1.57	0.33	0.93	0.51	1.43	0.83	2.32
	Normal	90	35.6	0.02	0.08	0.35	1.00	0.23	0.65	0.52	1.46	0.67	1.89
	High	90	35.7	0.25	0.71	0.36	1.02	0.00	0.00	0.42	1.16	0.61	1.70
PLT ($x\ 10^3$/uL)	Low	90	78	0.00	0.00	4.31	5.48	1.80	2.29	1.05	1.33	4.79	6.09
	Normal	90	238	0.00	0.00	6.99	2.94	2.68	1.13	2.03	0.85	7.76	3.26
	High	90	560	0.00	0.00	13.80	2.47	8.94	1.60	5.49	0.98	17.30	3.10
RDW-SD (fL)	Low	90	26.1	0.00	0.00	0.52	1.99	0.24	0.93	0.51	1.96	0.77	2.95
	Normal	90	28.3	0.00	0.00	0.47	1.65	0.26	0.91	0.22	0.78	0.58	2.04
	High	90	30.8	0.24	0.78	0.37	1.22	0.12	0.40	0.62	2.00	0.77	2.50
RDW-CV (%)	Low	90	9.41	0.00	0.00	0.26	2.75	0.20	2.11	0.08	0.92	0.34	3.58
	Normal	90	8.77	0.00	0.00	0.18	2.01	0.24	2.77	0.00	0.00	0.30	3.42
	High	90	8.58	0.00	0.00	0.17	2.02	0.20	2.28	0.08	0.94	0.27	3.19
MPV (fL)	Low	90	9.08	0.00	0.00	0.16	1.81	0.11	1.20	0.16	1.78	0.26	2.81
	Normal	90	8.90	0.00	0.00	0.09	1.10	0.01	0.21	0.18	2.07	0.21	2.36
	High	90	8.84	0.00	0.00	0.10	1.15	0.05	0.59	0.18	2.02	0.21	2.39
NEUT ($x\ 10^3$/uL)	Low	90	2.40	0.000	0.00	0.075	3.13	0.008	0.32	0.021	0.89	0.078	3.27
	Normal	90	4.20	0.046	1.10	0.100	2.44	0.000	0.00	0.050	1.19	0.120	2.93
	High	90	9.10	0.000	0.00	0.200	2.15	0.000	0.00	0.093	1.02	0.220	2.38
NEUT% (%)	Low	90	70.1	0.00	0.00	1.75	2.50	0.40	0.57	0.37	0.53	1.84	2.62
	Normal	90	57.0	0.24	0.43	1.15	2.01	0.00	0.00	0.21	0.36	1.19	2.09
	High	90	47.3	0.00	0.00	0.90	1.90	0.19	0.41	0.31	0.65	0.97	2.05

XQ-320 All Combined Sites				Within Run		Between Run		Between Day		Between Site		Total	
Measurand (unit)	**Control Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
LYMPH (x 10^3/uL)	Low	90	0.65	0.009	1.34	0.031	4.83	0.015	2.25	0.000	0.00	0.036	5.49
	Normal	90	2.26	0.000	0.00	0.072	3.19	0.022	0.96	0.000	0.00	0.075	3.33
	High	90	6.96	0.000	0.00	0.130	1.90	0.076	1.10	0.059	0.85	0.160	2.35
LYMPH% (%)	Low	90	19.0	0.00	0.00	0.86	4.54	0.24	1.24	0.00	0.00	0.89	4.70
	Normal	90	30.6	0.00	0.00	0.83	2.70	0.00	0.00	0.30	0.98	0.88	2.87
	High	90	36.1	0.00	0.00	0.55	1.51	0.14	0.40	0.21	0.58	0.60	1.67
MXD (x 10^3/uL)	Low	90	0.37	0.000	0.00	0.060	16.20	0.000	0.00	0.012	3.10	0.061	16.50
	Normal	90	0.91	0.000	0.00	0.079	8.60	0.020	2.16	0.011	1.23	0.082	8.95
	High	90	3.20	0.000	0.00	0.170	5.32	0.000	0.00	0.000	0.00	0.170	5.32
MXD% (%)	Low	90	10.9	0.00	0.00	1.76	16.20	0.00	0.00	0.40	3.69	1.81	16.60
	Normal	90	12.4	0.23	1.84	1.02	8.27	0.00	0.00	0.00	0.00	1.05	8.47
	High	90	16.6	0.00	0.00	0.89	5.35	0.00	0.00	0.03	0.18	0.89	5.35

Linearity

Linearity studies were performed in accordance with the CLSI EP06-ED2, Evaluation of Linearity of Quantitative Measurement Procedures; 2020 using WRP CHECK control material.

Testing was conducted at one internal site across three XQ-320 analyzers, using a single calibrator and reagent lot. System diluent (CELLPACK) was used to create serial dilutions of sample (WRP CHECK control material) concentrations which spanned the full measurement range of all direct measured parameters (WBC, RBC, HGB, HCT and PLT). A minimum of seven and maximum of 11 sample dilutions and three replicate measurements of each sample dilution were tested for each parameter.

All results met the predefined acceptance criteria and were determined to be acceptable.

Claimed Linearity Specifications

Parameter	Linearity range
WBC (x 10^3/µL)	0.20 – 99.90
RBC (x 10^6/µL)	0.01 – 7.00
HGB (g/dL)	0.1 – 25.0
HCT (%)	0.2 – 60.0
PLT (x 10^3/µL)	5 - 999

Carryover

Carryover on the XQ-320 analyzer was performed in accordance with CLSI H26-A2 Validation, Verification, and Quality Assurance of Hematology Analyzers; Approved Standard, Second Edition, 2010 using venous whole blood K_2EDTA samples.

Testing was conducted at three US sites by testing samples with high counts in replicates of three followed by samples with low counts for targeted WBC, RBC, HGB, HCT and PLT parameters. Three sets of carryover sequences were run for each parameter.

All results were determined to be acceptable.

Interfering Substances Study

Interfering substances studies were conducted in accordance with CLSI EP07-Ed3 guideline for Bilirubin F, Bilirubin C, Chyle, Hemolytic Hemoglobin, Lipids interferents to determine the concentration of well-known interferences that impact parameters on the XQ-320 analyzer.

In addition, interference by abnormal specimen studies were performed to characterize the susceptibility of the XQ-320 device to three potential interfering conditions due elevated WBCs, elevated RBCs, and elevated PLTs.

All results met the predefined acceptance criteria and were determined to be acceptable.

Interferent	Conclusion
Bilirubin F	There was no significant Bilirubin F interference up to a concentration of 40.0 mg/dL for all parameters.
Bilirubin C	There was no significant Bilirubin C interference up to a concentration of 40 mg/dL for all parameters.
Chyle	There was no significant Chyle interference up to a concentration of 2,880 FTU (Formazine Turbidity Unit) for WBC, up to a concentration of 1,440 FTU for NEUT%, LYMPH%, and MXD% and up to a concentration of 720 FTU for LYMPH#. There was no significant Chyle interference up to a concentration of 3,600 FTU for the other parameters. Significant chyle interference was observed for MXD# at a concentration of 720 FTU.
Hemolytic Hemoglobin	There was no significant Hemolysis interference up to a concentration of 800 mg/dL for HGB and 400 mg/dL for MCHC. For the other parameters, no significant interference was observed up to a concentration of 1,000 mg/dL.
Lipids	There was no significant Lipid interference up to a concentration of 0.20 g/dL for HGB, MCH, and MCHC and 1.00 g/dL for MPV. There was no significant Lipid interference up to a concentration of 2.00 g/dL for the other parameters.
High white blood cell counts	There was no significant WBC interference up to a concentration of 93.53 x 10^3 cells/µL for RBC, HGB, HCT and MCV. There was no significant WBC interference up to a concentration of 72.08 x 10^3 cells/µL for PLT.
High red blood cell counts	There was no interference from high RBCs at the upper measuring range in measuring WBC, RBC, HGB, and PLT. There was no significant RBC interference up to a concentration of 6.64 x 10^6 cells/µL for HCT.
High platelet counts	There was no significant PLT interference up to a concentration of 955 x 10^3 cells/µL for WBC, RBC, HGB, HCT, PLT, and MPV.

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

The Limit of Blank (LoB), Limit of Detection (LoD, and the Limit of Quantitation (LoQ) were established for the direct measured WBC, RBC, HGB, HCT and PLT parameters on the XQ-320 analyzer in accordance with CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition. 2012.

Testing was conducted over a minimum of three days using 2 reagent lots, a minimum of 4 samples per day with a minimum of four replicates per sample.

The LoB, LoD and LoQ results met the manufacturer's specifications shown in the table below.

Limit of Blank, Detection and Quantitation

Parameter	LoB (N=120)	LoD (N=120)	LoQ (N=120)
WBC (x 10^3/µL)	0.00	0.03	0.17
RBC (x 10^6/µL)	0.00	0.01	0.01
HGB (g/dL)	0.0	0.1	0.1
HCT (%)	0.0	0.1	0.1
PLT (x 10^3/µL)	0	1	2

Sample Stability

The evaluation of whole blood sample stability was conducted at one site using twenty (10 normal and 10 abnormal) residual K_2EDTA anticoagulated whole blood samples. Samples were split into two sets room temperature (18-26°C) and refrigerated temperature (18-26°C).

Room temperature samples were tested in singlet at baseline or zero (0) time, 4, 8, 12 and 13 hours and refrigerated samples were tested at baseline or zero (0) time, 8, 12, 24 and 25 hours in singlet.

Whole blood sample stability supports storage condition: 12 hours at room temperature (18-26°C) and 24 hours at refrigerated temperature (2-8°C) provided in the instructions for use labeling.

Anticoagulant Comparability (K_2EDTA vs. K_3EDTA)

Comparability between K_2EDTA vs. K_3EDTA anticoagulated whole blood samples on the XQ-320 analyzer was conducted using a total of 53 paired (K_2 and K_3EDTA) whole blood samples collected from consented adult (>21 years) donors.

Each sample was run in singlet within 8 hours of collection. The results from the K_2EDTA whole blood samples were compared to the corresponding results of the K_3EDTA sample for the same donor.

The results of the regression analysis and bias estimates between K_2EDTA and K_3EDTA anticoagulated whole blood samples met the acceptance criteria.

Venous Whole Blood vs. Capillary Whole Blood (K_2EDTA)

Comparability between venous whole blood and capillary whole blood samples on the XQ-320 analyzer was conducted using forty-two paired venous whole blood and capillary whole blood samples (K_2EDTA) drawn from consented adult (>21 years) donors.

Each sample was run in singlet within 8 hours of collection. The venous whole blood sample results were compared to the corresponding results of the capillary sample for the same donor.

The results of the regression analysis and bias estimates between venous and capillary K2EDTA whole blood samples met acceptance criteria.

Whole Blood K_2EDTA Normal Tubes vs. Micro-collection Tube

K_2EDTA tubes and micro-collection tubes without anticoagulant were performed to determine the presence or absence of matrix effect between the sample tubes on the XQ-320 analyzer.

This study used a total of 183 residual K_2EDTA (4 mL tubes) whole blood samples with analyte concentrations representative of patient samples, across medical decision levels, and to the extent possible of the full analytical measuring range. Whole blood K2EDTA normal tubes were premixed and run in singlet. Within two hours of analysis of the K2EDTA normal tubes, the samples were remixed, then transferred to micro-collection tubes without anticoagulant additive, then analyzed in singlet.

The results from the K_2EDTA whole blood samples were compared to the corresponding results of the micro-collection sample tube for the same patient sample. The results of the regression analysis and bias estimates between the whole blood normal K_2EDTA to micro-tube comparison samples met acceptance criteria.

Whole Blood K_2EDTA Mode vs. Pre-dilute Mode

Comparability between the whole blood and predilute mode on the XQ-320 analyzer was performed using 35 residual K_2EDTA anticoagulated whole blood samples. The K_2EDTA whole blood samples were premixed from end to end by gentle inversion, then run in the whole blood mode with caps off. Following the analysis of the whole blood samples, a 1:7 predilute sample was prepared for each whole blood sample by adding 120 µL of system diluent (CELLPACK) and 20 µL of whole blood into plain micro-collection tubes. The prediluted samples were thoroughly mixed by gentle inversion and run in the predilute mode of the XQ-320 analyzer with caps off. The results from the predilute mode are automatically multiplied by 7 before results are displayed, therefore no additional calculation is required. The results from the K_2EDTA whole blood samples were compared to the corresponding results of the prediluted sample for the same patient sample. The results of the regression analysis and bias estimates between the whole blood and predilute mode samples met acceptance criteria.

Reference Intervals

Verification of adult and pediatric reference intervals was conducted on the XQ-320 analyzer to demonstrate comparability of whole blood reference intervals for an adult population (>21 years) to the ranges established for the Sysmex pocH-100i (K032677) and pediatric population (birth to <21 years) to ranges based on literature reference intervals. Verification was conducted according to CLSI EP28-A3c.

The verification of adult reference ranges was conducted by comparing sample results that were reported as 'Negative' judgment (without flags) from apparently normal, healthy adult subjects in the method comparison study to previously established reference intervals to determine if the ranges are applicable for use with the XQ-320 analyzer.

Results from pediatric samples enrolled in the method comparison study were compared to literature reference intervals for acceptable use with the XQ-320.

The reference ranges were previously established for the Sysmex pocH-100i, which include MXD# and MXD%, and these ranges are applicable for use with the XQ-320 analyzer. Reference intervals for adults were established by evaluating 99 unique male and female (43 male and 56 female) whole blood samples collected from generally healthy, consenting donors, >21 years of age to verify normal reference ranges.

Reference intervals for adults were determined to be acceptable if the proposed reference intervals overlapped the 95% confidence intervals (lower and upper limit) of the dataset.

The results from 226 pediatric subjects including each pediatric subpopulations: 34 neonates (birth-1 month); 63 infants (>1 month-2 years); 63 children (>2 years-12 years); and 66 adolescents (>12 years-21 years) were compared to literature reference intervals.

Conclusions:

The XQ-Series (XQ-320) Automated Hematology analyzer and its predicate device, XN-10 Automated Hematology analyzer (K112605), have similar Indications for Use, fundamental technology, and principles of operation. Performance, verification, and validation testing were conducted to characterize the performance of the XQ-320 analyzer using predetermined acceptance criteria. Results of this testing have documented that the XQ-320 analyzer is substantially equivalent to the XN-10 analyzer. The differences in the XQ-320 analyzer and the predicate device (XN-10 analyzer) do not raise any questions regarding safety and effectiveness.