November 14, 2023

Ad Astra Diagnostics, Inc.
Jasper Pollard
Cto
633 Davis Drive
Suite 460
Morrisville, North Carolina 27560

Re: K230878
Trade/Device Name: QScout Lab; QScout RLD
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: October 12, 2023
Received: October 12, 2023

Dear Jasper Pollard:

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)*
K230878

Device Name
QScout™ Lab;
QScout™ RLD

Indications for Use *(Describe)*
The QScout™ Lab is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations 18 years and older found in clinical laboratories and point-of-care (POC) settings. The QScout Lab is used with the QScout RLD test to enumerate and classify the following parameters in venous K2/K3EDTA whole blood:

- White blood cell count (WBC)
- Neutrophils (NEUT#)
- Lymphocytes (LYMPH#)
- Monocytes (MONO#)
- Eosinophils (EOS#)
- Basophils (BASO#)
- Immature Granulocytes (IG#)
- Percent Neutrophils (NEUT%)
- Percent Lymphocytes (LYMPH%)
- Percent Monocytes (MONO%)
- Percent Eosinophils (EOS%)
- Percent Basophils (BASO%)
- Percent Immature Granulocytes (IG%)
- Neutrophil to Lymphocyte Ratio (NLR)

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person

Jasper Pollard, CTO
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E-mail: JPollard@aadiagnostics.com

Date Prepared

November 14, 2023

Name of Device

QScout™ Lab (analyzer) and QScout™ RLD (assay)

Common or Usual Name

Automated Differential Cell Counter

Classification

21 CFR 864.5220, Class II, Product Code: GKZ

Predicate Device

Beckman Coulter UniCel® DxH 800 Coulter® Cellular Analysis System (K140911)

Device Description

The QScout™ system is intended for *in vitro* diagnostic use in screening patient populations 18 years and older found in clinical laboratories and point-of-care (POC) settings. It includes the QScout Lab analyzer, the QScout RLD (Rapid Leukocyte Differential) test, software, and handheld barcode scanner. The QScout system reports white blood cell count and neutrophil to lymphocyte ratio and enumerates and classifies six white blood cell types including immature granulocytes.

The QScout RLD test includes a microfluidic chamber of predetermined volume containing a dried reagent of organic compounds to stain and fluoresce white blood cells. Once venous whole blood is transferred to the QScout RLD test, white blood cells mix with the reagent. The QScout RLD test is inserted into the QScout Lab, a quantitative multi-parameter automated hematology analyzer, where an optical imaging system takes images of the test chamber. A machine vision algorithm identifies cells from the images in real time. When analysis is complete, the results are displayed on the screen and can be printed.

Intended Use/ Indications for Use

The QScout™ Lab is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations 18 years and older found in clinical laboratories and point-of-care (POC) settings. The QScout Lab is used with the QScout RLD test to enumerate and classify the following parameters in venous K_2/K_3EDTA whole blood:

- White blood cell count (WBC)
- Neutrophils (NEUT#)
- Lymphocytes (LYMPH#)
- Monocytes (MONO#)
- Eosinophils (EOS#)
- Basophils (BASO#)
- Immature Granulocytes (IG#)
- Percent Neutrophils (NEUT%)
- Percent Lymphocytes (LYMPH%)
- Percent Monocytes (MONO%)
- Percent Eosinophils (EOS%)
- Percent Basophils (BASO%)
- Percent Immature Granulocytes (IG%)
- Neutrophil to Lymphocyte Ratio (NLR)

Summary of Substantial Equivalence

The QScout™ system has the same intended use and similar technological characteristics to the Beckman Coulter UniCel® DxH800 Coulter® Cellular Analysis System. Both devices are quantitative, multi-parameter, automated *in vitro* diagnostic hematology analyzers. Both devices screen venous whole blood samples.

The QScout system includes the QScout Lab (an analyzing device with optical imaging system) and the QScout RLD test (a disposable test with a microfluidic chamber and self-contained reagent). Similarly, the predicate device includes a specimen processing module that aspirates, dilutes, mixes, and analyzes whole blood (including reagents). The predicate device also includes a unit that processes data from the analyzing unit and provides the operator interface with the system. The QScout Lab integrates the different units (data processing and operator interface) within the device and carries out all processes automatically after the sample has been manually loaded into the disposable QScout RLD test. The general components and functions of the QScout Lab are similar to the predicate device: a sample is provided, a sample is processed, and a sample is analyzed.

The QScout Lab is factory calibrated prior to shipping to the end user and does not require further calibration. The predicate device is calibrated as needed. Both devices use a three-level control to monitor system performance of WBC and differential parameters. Both devices use a second control to monitor system performance based on test principle; a control monitors counting capability and optical system performance of the QScout Lab, and a control monitors electrical processing and fluidic flow rate systems of the UniCel® DxH800 Coulter® Cellular Analysis System.

For both devices, questions of safety and effectiveness are concerned with the ability to provide white blood cell counts and differentials accurately and reproducibly. Minor differences in features between the QScout Lab and the predicate device do not present new questions of safety and effectiveness.

	QScout™ Lab, QScout™ RLD **K230878**	**Beckman Coulter UniCel® DxH 800 Coulter® Cellular Analysis System** **K140911**
Regulation	21 CFR 864.5220	21 CFR 864.5220
Product Code	GKZ	GKZ
Class	Class II	Class II
Intended Use	Quantitative, multi-parameter, automated hematology analyzer	Quantitative, multi-parameter, automated hematology analyzer
Intended Use Sites	Clinical Laboratory, Point of Care	Clinical Laboratory
Indications for Use	*In vitro* diagnostic use	*In vitro* diagnostic use
Target Population	Patient populations found in clinical laboratories and point-of-care (POC) settings	Patient populations found in clinical laboratories
Test Parameters	WBC, NEUT%/#, LYMPH%/#, MONO%/#, EOS%/#, BASO%/#, IG%/#, Neutrophil to Lymphocyte Ratio (NLR)	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, NE%/#, LY%/#, MO%/#, EO%/#, BA%/#, NRBC%/#, RET%/#, MRV, IRF, TNC
Specimen Type/Collection	Venous anticoagulated whole blood samples collected into K_2/K_3EDTA tubes	Venous or capillary whole blood samples collected into K_2/K_3EDTA microtubes/tubes
Calibration	Factory Calibrated	As needed by the operator
Quality Control	3 Level Biological Controls 2 Level Synthetic Controls	3 Level Whole Blood Control Electrical processing/flow rate Control
Test Principle	White blood cells are stained within a microfluidic chamber and scanned with an optical imaging system. Each image is analyzed by a machine vision algorithm to count and differentiate the white blood cells.	1. Coulter principle of automated cell counting and sizing. 2. Photometric measurement of HgB. 3. VCSn technology for WBC differential, NRBC, and RET. Cells are mixed with reagent and the prepared sample is delivered to a flow cell where light scatter, cell volume, and cell conductivity are measured.
Throughput	25 samples/hour	≥ 72 samples/hour depending on mode
Sample Volume	10 µL	165 µL (aspiration volume)

Performance Data

The following clinical and nonclinical performance testing has been conducted in accordance with relevant standards to support the substantial equivalence of the QScout system to its predicate device.

Method Comparison Study with the Predicate Device *(CLSI EP09c, H20-A2, and H26-A2)*

Method comparison studies were conducted to assess the performance of the QScout system compared to the predicate device. The testing was conducted at a clinical laboratory and seven point-of-care sites using a total of 396 K_2EDTA/K_3EDTA whole blood samples.

The studies included normal and pathological samples to assess the QScout Lab performance across the analytical measuring range. The pathological samples included the following conditions: allergic reaction, anemia, autoimmune / rheumatological diseases, B12 or folate deficiency, bacterial infection, cardiovascular diseases, chronic inflammation, hemoglobinopathies / hereditary RBC diseases, iron deficiency, acute and chronic leukemias (lymphocytic or myelocytic), lymphoma, liver disease, myelodysplastic syndromes, respiratory diseases, severe trauma or bleeding due to surgery or childbirth, solid tumor or other oncological conditions, and viral infections.

The results demonstrated that all parameters met the pre-defined acceptance criteria for correlation, slope, and bias. A summary of the results is presented in Table 1.

Table 1 Method Comparison Study Combined Sites Results

Parameter	N	Sample range	Slope (95% CI)	Intercept (95% CI)	Pearson's r
WBC	396	0.51 - 59.45	1.008 (0.998, 1.020)	0.020 (-0.033, 0.087)	0.996
NEUT#	396	0.00 - 45.87	0.976 (0.963, 0.987)	0.078 (0.040, 0.125)	0.985
LYMPH#	396	0.08 - 41.15	1.036 (1.018, 1.053)	-0.004 (-0.027, 0.018)	0.972
MONO#	396	0.00 - 13.06	1.100 (1.050, 1.146)	-0.007 (-0.030, 0.015)	0.907
EOS#	396	0.00 - 1.82	0.900 (0.867, 0.995)	0.010 (0.004, 0.017)	0.883
BASO#	396	0.00 - 1.61	0.720 (0.644, 0.861)	0.010 (0.010, 0.010)	0.922
IG#	139	0.00 - 7.55	1.194 (1.004, 1.538)	-0.003 (-0.011, 0.003)	0.926
NEUT%	396	0.3 - 96.0	0.954 (0.939, 0.968)	1.830 (0.882, 2.860)	0.981
LYMPH%	396	0.7 - 99.0	0.983 (0.968, 0.997)	0.719 (0.430, 1.018)	0.979
MONO%	396	0.0 - 75.1	0.985 (0.931, 1.033)	0.603 (0.264, 1.008)	0.928
EOS%	396	0.0 - 25.3	0.897 (0.860, 0.929)	0.129 (0.092, 0.200)	0.949
BASO%	396	0.0 - 4.9	0.889 (0.800, 1.000)	-0.056 (-0.100, 0.000)	0.690
IG%	139	0.0 - 21.5	0.862 (0.713, 1.010)	0.471 (0.272, 0.671)	0.896
NLR	396	0.00 - 120.71	0.914 (0.891, 0.934)	0.089 (0.060, 0.146)	0.947

Repeatability Study *(CLSI H26-A2)*

Within-in run repeatability studies were performed to evaluate the precision of the QScout system using K_2EDTA/K_3EDTA whole blood samples around medical decision levels and within the laboratory reference range. Each sample was measured at least 20 times using a single QScout Lab analyzer and single lot of QScout RLD tests. For each parameter, the mean, standard deviation (SD), and coefficient of variation (CV) were computed. The results of the study are summarized in Table 2.

Table 2 Pooled Results of Repeatability Study

Parameter	WBC Range	N Samples	N Replicates	Mean	Pooled SD	Pooled CV%
WBC $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	1.55	0.08	6.07
	WBC≥4 $x10^3/\mu L$	19	20 - 31	10.84	0.42	3.64
NEUT# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.79	0.05	15.05
	WBC≥4 $x10^3/\mu L$	19	20 - 31	7.36	0.33	4.22
LYMPH# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.54	0.05	11.45
	WBC≥4 $x10^3/\mu L$	19	20 - 31	2.06	0.13	6.01
MONO# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.17	0.02	25.17
	WBC≥4 $x10^3/\mu L$	19	20 - 31	0.93	0.08	9.87
EOS# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.03	0.01	N/A
	WBC≥4 $x10^3/\mu L$	19	20 - 31	0.11	0.02	28.14
BASO# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.01	0.01	N/A
	WBC≥4 $x10^3/\mu L$	19	20 - 31	0.03	0.01	N/A
IG# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.02	0.01	N/A
	WBC≥4 $x10^3/\mu L$	19	20 - 31	0.34	0.07	33.42
NEUT%	WBC<4 $x10^3/\mu L$	12	21 - 31	42.89	2.31	13.21
	WBC≥4 $x10^3/\mu L$	19	20 - 31	65.13	1.31	2.34
LYMPH%	WBC<4 $x10^3/\mu L$	12	21 - 31	41.69	2.37	8.84
	WBC≥4 $x10^3/\mu L$	19	20 - 31	21.78	0.80	5.22
MONO%	WBC<4 $x10^3/\mu L$	12	21 - 31	11.90	1.94	23.54
	WBC≥4 $x10^3/\mu L$	19	20 - 31	8.87	0.81	8.82
EOS%	WBC<4 $x10^3/\mu L$	12	21 - 31	1.69	0.54	80.58
	WBC≥4 $x10^3/\mu L$	19	20 - 31	1.09	0.24	28.26
BASO%	WBC<4 $x10^3/\mu L$	12	21 - 31	0.66	0.45	93.77
	WBC≥4 $x10^3/\mu L$	19	20 - 31	0.42	0.12	N/A
IG%	WBC<4 $x10^3/\mu L$	12	21 - 31	1.17	0.69	67.87
	WBC≥4 $x10^3/\mu L$	19	20 - 31	2.70	0.59	31.95
NLR	WBC<4 $x10^3/\mu L$	12	21 - 31	2.49	0.56	18.48
	WBC≥4 $x10^3/\mu L$	19	20 - 31	6.15	0.62	6.21

Reproducibility Study *(CLSI EP05-A3 and H26-A2)*

A reproducibility study of the QScout system was conducted at three sites. The study was performed over five days with three QScout Labs (one per site), six lots of QScout RLD tests, and one lot of tri-level quality control material (Low, Normal, and High). Two runs per day and six replicates per run were performed by two operators at each site for each control level. A total of 60 measurements were generated at each site for each level of control. The data generated was used to calculate standard deviation (SD) and coefficient of variation (%CV) for within-run, between-run, between-day, between-lot, between-site, and total precision as shown in Table 3. The results demonstrated that all parameters met the pre-defined acceptance criteria.

Table 3 Reproducibility Study Results

Parameter	Control Level	Mean Value	N	Within Run		Between Run		Between Day		Between Lot		Between Site		Reproducibility	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
WBC	Low	3.17	180	0.15	4.69	0.04	1.20	0.00	0.00	0.04	1.23	0.08	2.59	0.18	5.54
	Normal	8.02	180	0.28	3.48	0.26	3.24	0.08	0.95	0.00	0.00	0.14	1.68	0.41	5.10
	High	20.90	180	0.78	3.71	0.40	1.92	0.00	0.00	0.23	1.08	0.23	1.10	0.93	4.45
NEUT#	Low	1.52	180	0.09	6.20	0.00	0.00	0.00	0.00	0.03	1.84	0.02	1.12	0.10	6.45
	Normal	4.64	180	0.19	3.99	0.14	2.95	0.04	0.86	0.00	0.00	0.07	1.44	0.24	5.23
	High	13.22	180	0.59	4.46	0.22	1.63	0.04	0.30	0.15	1.15	0.12	0.87	0.66	4.98
LYMPH#	Low	1.09	180	0.08	6.88	0.04	3.21	0.02	1.83	0.00	0.00	0.04	3.85	0.10	8.66
	Normal	1.89	180	0.11	5.68	0.09	4.87	0.03	1.75	0.00	0.00	0.08	4.18	0.17	8.62
	High	3.17	180	0.17	5.44	0.13	4.10	0.04	1.36	0.00	0.00	0.09	2.87	0.24	7.44
MONO#	Low	0.35	180	0.04	12.68	0.01	3.14	0.00	0.57	0.01	2.29	0.03	8.57	0.06	15.79
	Normal	0.59	180	0.05	8.53	0.02	2.54	0.01	2.03	0.02	3.90	0.03	4.41	0.06	10.80
	High	1.10	180	0.09	7.88	0.04	4.00	0.00	0.00	0.00	0.00	0.08	7.00	0.12	10.91
EOS#	Low	0.14	180	0.02	16.17	0.01	7.14	0.00	0.00	0.00	0.00	0.00	0.00	0.03	18.27
	Normal	0.67	180	0.08	11.45	0.00	0.00	0.00	0.00	0.02	2.39	0.02	2.39	0.08	11.86
	High	2.62	180	0.25	9.70	0.03	1.07	0.00	0.00	0.06	2.14	0.03	0.95	0.26	9.91
BASO#	Low	0.03	180	0.01	39.89	0.00	10.00	0.00	3.33	0.00	0.00	0.00	6.67	0.01	42.28
	Normal	0.14	180	0.03	22.82	0.01	9.29	0.00	0.00	0.01	9.29	0.02	10.71	0.04	27.80
	High	0.52	180	0.08	14.47	0.00	0.00	0.00	0.00	0.03	4.81	0.02	4.04	0.08	15.60

Parameter	Control Level	Mean Value	N	Within Run		Between Run		Between Day		Between Lot		Between Site		Reproducibility	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
IG#	Low	0.04	180	0.01	31.63	0.00	0.00	0.00	0.00	0.00	10.00	0.00	10.00	0.01	35.26
	Normal	0.10	180	0.03	27.14	0.01	13.00	0.00	0.00	0.00	0.00	0.02	20.00	0.04	35.82
	High	0.27	180	0.06	20.71	0.02	8.89	0.00	0.00	0.02	7.04	0.06	20.37	0.09	30.89
NEUT%	Low	48.06	180	1.74	3.62	0.78	1.62	0.47	0.97	0.00	0.00	0.78	1.61	2.11	4.36
	Normal	57.81	180	1.35	2.34	0.23	0.40	0.32	0.55	0.00	0.00	0.25	0.44	1.43	2.44
	High	63.25	180	1.45	2.29	0.14	0.22	0.40	0.63	0.00	0.00	0.00	0.00	1.51	2.40
LYMPH%	Low	34.49	180	1.65	4.79	0.57	1.66	0.59	1.71	0.00	0.00	0.46	1.34	1.90	5.48
	Normal	23.51	180	1.01	4.31	0.58	2.45	0.27	1.14	0.00	0.00	0.57	2.43	1.33	5.54
	High	15.18	180	0.67	4.44	0.44	2.87	0.24	1.56	0.00	0.00	0.28	1.83	0.88	5.65
MONO%	Low	10.96	180	1.39	12.70	0.00	0.00	0.08	0.68	0.25	2.32	0.65	5.90	1.56	14.21
	Normal	7.39	180	0.62	8.35	0.20	2.65	0.11	1.46	0.20	2.68	0.22	3.02	0.72	9.75
	High	5.24	180	0.42	8.08	0.15	2.90	0.11	2.12	0.00	0.00	0.31	5.84	0.56	10.42
EOS%	Low	4.47	180	0.69	15.43	0.23	5.08	0.00	0.00	0.00	0.00	0.12	2.60	0.74	16.62
	Normal	8.31	180	0.86	10.31	0.00	0.00	0.00	0.00	0.24	2.83	0.35	4.20	0.95	11.40
	High	12.53	180	1.08	8.65	0.00	0.00	0.14	1.13	0.20	1.60	0.14	1.11	1.12	9.06
BASO%	Low	0.87	180	0.33	37.51	0.11	12.76	0.04	4.37	0.00	0.00	0.10	10.80	0.36	41.29
	Normal	1.70	180	0.37	21.72	0.15	8.53	0.00	0.00	0.16	9.24	0.22	12.88	0.48	27.22
	High	2.48	180	0.35	14.04	0.03	1.37	0.00	0.00	0.10	4.15	0.13	5.36	0.39	15.67
IG%	Low	1.15	180	0.37	32.00	0.00	0.00	0.02	1.91	0.13	10.87	0.13	11.48	0.41	35.76
	Normal	1.28	180	0.34	26.18	0.13	10.08	0.00	0.00	0.00	0.00	0.25	19.53	0.44	34.21
	High	1.31	180	0.27	20.82	0.11	8.63	0.03	2.52	0.08	6.11	0.28	21.53	0.42	32.02
NLR	Low	1.40	180	0.11	7.48	0.05	3.57	0.04	2.86	0.00	0.00	0.04	3.07	0.13	9.10
	Normal	2.47	180	0.14	5.72	0.09	3.48	0.05	1.82	0.00	0.00	0.07	2.87	0.19	7.32
	High	4.18	180	0.20	4.85	0.14	3.37	0.09	2.03	0.00	0.00	0.09	2.13	0.28	6.36

Detection Limits Studies including Limit of Blank, Limit of Detection, and Limit of Quantitation *(CLSI EP17-A2 and CLSI H26-A2)*

Limit of blank was determined using five centrifuged venous blood samples to deplete plasma of white blood cells, red blood cells, and platelets. Each of the five plasma samples was assayed six times on two QScout Labs and two RLD test lots for a total of 60 measurements of WBC per RLD test lot.

Limit of detection was determined using five low WBC concentration samples using diluted venous whole blood samples. Each of the low WBC samples was assayed six times on two QScout Lab and two RLD test lots for a total of 60 measurements of WBC per RLD test lot.

Limit of quantitation was determined using four low WBC concentration samples using diluted venous whole blood samples. Each of the low WBC samples was assayed five times on two QScout Labs and two RLD test lots for a total of 40 measurements of WBC per RLD test lot. The LoQ was defined as the lowest WBC concentration in which the predetermined total error accuracy goal was satisfied.

The LoB, LoD, and LoQ for WBC is shown in Table 4.

Table 4 Detection Limits of the QScout System

Parameter	Limit of Blank (LoB)	Limit of Detection (LoD)	Limit of Quantitation (LoQ)	Units
WBC	0.02	0.08	0.38	x 10^3/µL

Linearity Studies *(CLSI EP06-Ed2 and H26-A2)*

Two venous whole blood samples were manipulated to create linearity panels of 10 concentrations for WBC. Each concentration was measured at least four times using one QScout Lab and two RLD test lots. Determination of linearity was performed using weighted least squares regression. The linear range is shown in Table 5.

Table 5 Linear Range of the QScout System

Parameter	Linear Range
WBC	0.5 – 60.0 x 10^3/µL

Analytical Specificity/Interference Studies *(CLSI EP07 and EP37)*

Interference studies for glucose, hemolysate, lipemia (triglyceride-rich lipoproteins), conjugated bilirubin, unconjugated bilirubin, total protein, and thrombocytosis were performed on the QScout system. Paired-difference screening tests were conducted to evaluate whether WBC is susceptible to the presence of clinically high levels of each interferent. If susceptible, dose response tests were conducted to determine the critical concentration of the interferent.

The results of the interference studies demonstrated that:

1. There was no significant glucose interference at a concentration of 1000 mg/dL.
2. There was no significant hemolysate interference at a concentration of 1000 mg/dL.
3. There was no significant lipemia interference at a concentration of 1500 mg/dL.

4. There was no significant conjugated bilirubin interference at a concentration of 40 mg/dL.
5. There was no significant unconjugated bilirubin interference up to a concentration of 20 mg/dL.
6. There was no significant total protein interference up to a concentration of 12.3 g/dL.
7. There was no significant thrombocytosis interference at a concentration of 750 x 10^3 platelets/µL.

Nucleated Red Blood Cells (nRBCs): For nRBCs the QScout system raises a flag in the presence of nRBCs ≥ 0.56 per 100 WBC. At levels lower than the threshold, there is no interference with WBC differential parameters. For levels above the threshold, nRBC is flagged and excluded from the WBC differential.

Sample Stability *(CLSI EP25-A and H26-A2)*

Sample stability was determined for 11 venous whole blood samples including six normal and five whole blood samples around medical decision levels. The samples were tested in replicate within one hour of collection, stored at room temperature, and tested in replicate again at two, three, four, five, and six hours after collection. The data support a sample stability claim of three hours.

QScout RLD Test Stability *(CLSI EP09c and EP25-A)*

A real-time stability study is being conducted to establish shelf-life stability of the QScout RLD test when it is stored at the recommended storage conditions. Six lots of RLD tests are tested. Each test lot is stored at 18 - 32°C and tested at defined time points.

QScout BCS Stability

A real-time stability study was conducted using three lots of QScout BCS (biological control solution). The study verified 75 days of shelf-life stability when the control is stored upright at 2-8°C, protected from overheating and freezing.

Transportation Studies

The stability of the QScout Lab during transportation has been tested in accordance with ASTM D7386-16. The results of this testing indicate that the QScout Lab maintains performance specifications during shipping. The stability of the RLD test during shipping is being evaluated as part of the real-time stability study in accordance with ASTM D7386-16.

Clinical Sensitivity/Flagging Study *(CLSI H20-A2)*

The clinical sensitivity, or flagging rate, of the QScout system was compared to a 400-cell manual differential reference method for 200 samples from one clinical laboratory and seven point-of-care sites. Two types of abnormalities were evaluated: (1) distributional abnormal samples, which are samples where the quantity of at least one of the parameters resided outside the reference interval, and (2) morphological abnormal samples, which are samples that contain atypical forms of the normal cell types contained in ordinary blood. The ability to identify abnormal samples was evaluated by creation of predictive value tables for distributional and morphological abnormalities, separately and combined. From these tables, the overall agreement, sensitivity, and specificity were calculated. The overall flagging capability of the QScout system met the predefined acceptance criteria as seen in Table 8.

Table 6 Distributional Flagging

	Overall Agreement % (95% CI)	Sensitivity % (95% CI)	Specificity % (95% CI)
Distributional Flagging	87.00 (81.53, 91.33)	87.88 (79.78, 93.58)	86.14 (77.84, 92.21)

Table 7 Morphological Flagging

	Overall Agreement % (95% CI)	Sensitivity % (95% CI)	Specificity % (95% CI)
Morphological Flagging	97.50 (94.26, 99.18)	81.25 (54.35, 95.95)	98.91 (96.13, 99.87)

Table 8 Overall Flagging

	Overall Agreement % (95% CI)	Sensitivity % (95% CI)	Specificity % (95% CI)
Overall Flagging	87.00 (81.53, 91.33)	88.00 (79.98, 93.64)	86.00 (77.63, 92.13)

Reference Interval Study *(CLSI EP28-A3c)*

A reference interval study was conducted to establish adult reference intervals for all QScout system parameters. The study was performed using venous whole blood samples collected from 265 (139 female and 126 male) apparently healthy adults (≥ 18 years). The lower and upper limits of the 95% reference intervals were determined based on the 2.5th and 97.5th percentiles of measurements for each sex group, respectively.

Table 9 QScout System Reference Intervals

Parameter	Female n=139	Male n=126	Units
WBC	4.00-11.30	3.78-12.12	x10^3/µL
NEUT#	1.68-7.42	1.56-7.89	x10^3/µL
LYMPH#	1.25-3.98	1.08-3.92	x10^3/µL
MONO#	0.27-0.92	0.25-1.08	x10^3/µL
EOS#	0.04-0.61	0.03-0.76	x10^3/µL
BASO#	0.01-0.11	0.01-0.16	x10^3/µL
IG#	0.00-0.04	0.00-0.06	x10^3/µL
NEUT%	33.8-71.4	33.7-75.0	%
LYMPH%	19.2-54.0	15.6-55.7	%
MONO%	4.8-13.2	4.6-13.1	%
EOS%	0.4-8.1	0.5-7.2	%
BASO%	0.2-1.5	0.1-2.2	%
IG%	0.0-0.5	0.0-0.7	%
NLR	0.63-3.76	0.62-4.89	N/A

Matrix Comparison Study Between K_2EDTA and K_3EDTA *(CLSI EP09c and H26-A2)*

A matrix study was performed to demonstrate equivalence between K_2EDTA and K_3EDTA venous whole blood samples. A total of 40 paired samples were compared. The results show comparable performance characteristics and support the claim of using the two specimen types on the QScout system.

Device Testing

Electromagnetic compatibility, electrical safety testing, and software testing were conducted for the QScout system. In all instances, these tests demonstrate that the performance, functionality, and reliability the QScout system functioned as intended.

Conclusion

Through a range of clinical and nonclinical CLSI recommended studies, the QScout system, including the QScout Lab and QScout RLD test, has been shown to be substantially equivalent to the Beckman Coulter UniCel® DxH 800 Coulter® Cellular Analysis System. The conclusions drawn from the clinical and nonclinical data demonstrate that the QScout system is safe and effective for its intended use.