November 1, 2019

Sight Diagnostics Ltd.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street Suite 2300
Philadelphia, Pennsylvania 19103

Re: K190898
Trade/Device Name: Sight OLO
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: April 5, 2019
Received: April 5, 2019

Dear Janice Hogan:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Takeesha Taylor-Bell
Acting Deputy Director
Division of Immunology
and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: June 30, 2020
See PRA Statement on last page

510(k) Number *(if known)*

Device Name

Sight OLO

Indications for Use *(Describe)*

The Sight OLO is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening capillary or venous whole blood samples collected in K_2EDTA blood collection tubes, or fingertip samples collected using the Sight OLO test kit micro-capillary tubes.

When used with the Sight OLO cartridge, the Sight OLO enumerates the following CBC parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH %/#, MONO %/#, EOS%/#, and BASO%/#.

The Sight OLO is indicated for use in clinical laboratories to identify and classify one or more of the formed elements of blood in children 3 months and above, adolescents and adults.

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

510(k) SUMMARY

Sight Diagnostics Ltd.'s Sight OLO

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

Sarah Levy
CTO
Sight Diagnostics Ltd.
Derech Menachem Begin 23
Tel Aviv, Israel
Tel: +972 3 5418580
Fax: +972 2 6737371
E-mail: sarah@sightdx.com

Date Prepared: October 21, 2019

Name of Device:

Sight OLO

Common or Usual Name:

Automated Hematology Analyzer

Classification:

21 CFR 864.5220, Class II, Product Code: GKZ

Predicate Devices

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

Reference device

PixCell Medical Technologies, Ltd.'s HemoScreen Hematology Analyzer (K180020)

Device Description

The Sight OLO device is a computer vision based platform for blood analysis. The platform combines computer-vision algorithms for image processing to identify and quantify blood components (*e.g.,* red blood cells) and their characteristics (*e.g.,* cell volume) in an automated fashion. Using dedicated staining, the proposed platform provides complete blood count analysis. The Sight OLO is a compact device, designed to be automated and simple to operate, to enable rapid testing and analysis. The Sight OLO consists of a scanning and analyzing device and a CBC test kit, including disposable cartridges and sample preparation tools. The disposable cartridge containing the blood sample is loaded into the device through the loading slot. The device is operated through the touch screen interface.

The Sight OLO provides complete blood count information with 5-part differentials for white blood cell types. Specifically, the CBC parameters measured by the Sight OLO are listed below and include: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH %/#, MONO %/#, EOS%/# and BASO%/#. In addition, the Sight OLO signals specific WBC abnormal cases by flagging the sample.

Intended Use / Indications for Use

The Sight OLO is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening capillary or venous whole blood samples collected in K_2EDTA blood collection tubes, or fingertip samples collected using the Sight OLO test kit micro-capillary tubes.

When used with the Sight OLO cartridge, the Sight OLO enumerates the following CBC parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH %/#, MONO %/#, EOS%/#, and BASO%/#.

The Sight OLO is indicated for use in clinical laboratories to identify and classify one or more of the formed elements of blood in children 3 months and above, adolescents and adults.

Summary of Substantial Equivalence

The Sight OLO has the same intended use, similar indications for use and technological characteristics compared to the Sysmex XN predicate device. Both devices are quantitative, multi-parameter, automated in vitro diagnostic hematology analyzers. Both devices screen whole blood samples collected from venous and/or capillary blood. The Sight OLO diagnostic parameters are encompassed by those of the Sysmex XN predicate device.

The general components and functions of the Sight OLO are similar to those of the predicate device. The Sight OLO includes a scanning and analyzing device (including microscope) and a test kit (including a disposable cartridge, a Microsafe micro-capillary tube, a dropper cap containing dried reagents and attached to another micro-capillary tube and a mixing bottle containing liquid diluent). Similarly, the Sysmex XN predicate device includes a main unit that aspirates, dilutes, mixes, and analyzes the samples (including container and cartridge reagents). The Sysmex XN device includes a unit that automatically supplies the samples to the main unit, and a unit that processes data from the main unit and provides the operator interface with the system. The Sight OLO design incorporates and automates the different units (e.g., user interface/display, samples processing) within the device, and carries out all processes automatically after the samples have been manually loaded into the disposable cartridge chambers. Therefore, both devices incorporate similar general steps necessary for blood analysis within the device design (i.e., proceeding from sample provided to processing of sample and analysis of the sample).

For the Sysmex XN predicate, calibration is performed as needed. The Sight OLO is factory calibrated prior to shipping to end user, and does not require further calibration. Whole blood quality control material (three levels; high, medium, low) is available for both devices to monitor the performance of the analyzers.

In terms of the technology underlying the analyses, both the Sight OLO and the predicate device utilize similar methods of analyzing cell morphology and fluorescence. Although the Sysmex XN uses different technological methods from the Sight OLO, i.e., DC detection, flow cytometry, and Sodium Lauryl Sulfate (SLS)-hemoglobin, these differences do not raise different types of safety or effectiveness question. For both devices, the same question remains as to whether the device will be able to accurately and reproducibly provide complete blood count information. In addition, the HemoScreen reference device also uses computer vision algorithms to scan and analyze the stained blood samples similar to the Sight OLO, and was found to be substantially equivalent to the Sysmex XN predicate device.

Therefore, the minor differences in features between the Sight OLO and its predicate device do not present new types of safety or effectiveness questions. Furthermore, performance testing demonstrated comparable performance characteristics between the Sight OLO and its predicate.

A table comparing the Sight OLO to the predicate device is included below.

	Sight Diagnostics Sight OLO	**Sysmex® XN-Series (XN-10, XN-20) Automated Hematology Analyzers (K112605)**
Regulation	21 CFR 864.5220	21 CFR 864.5220
Product code	GKZ	GKZ
Indications	The Sight OLO is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening capillary or venous whole blood samples collected in K_2EDTA blood collection tubes, or fingertip samples collected using the Sight OLO test kit micro-capillary tubes. When used with the Sight OLO cartridge, the Sight OLO enumerates the following CBC parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH %/#, MONO %/#, EOS%/#, and BASO%/#. The Sight OLO is indicated for use in clinical laboratories to identify and classify one or more of the formed elements of blood in children 3 months and above, adolescents and adults.	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 K2 or K3EDTA anticoagulant and, Serous and Synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.
Components	Scanning and analyzing device (including	(1) Two Main Units (XN-10, XN-20) which

	microscope) Test kit (including a disposable cartridge, a Microsafe micro-capillary tube, a dropper cap containing dried reagents and attached to another micro-capillary tube and a mixing bottle containing liquid diluent)	aspirate, dilute, mix, and analyze blood and body fluid samples (includes container and cartridge reagents (diluent, lyse, stain)); (2) Two Auto Sampler Units (SA-10, SA-20) which supply samples to the Main Unit automatically; (3) IPU (Information Processing Unit) which processes data from the Main Unit and provides the operator interface with the system; (4) Pneumatic Unit which supplies pressure and vacuum from the Main Unit.
Test Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH %/#, MONO %/#, EOS%/#, and BASO%/#	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, NRBC%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IG%/#, RET-He#, IPF, WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF
Analysis modes	Whole blood (capillary and venous)	Whole blood (capillary and venous) Body fluid
Specimen collection	Either capillary and venous anticoagulated whole blood samples collected into K_2EDTA microtubes / tubes, or capillary samples collected directly from the fingertip into the OLO test kit micro-capillary tubes	Capillary or venous whole blood samples collected into K_2 Or K_3EDTA microtubes / tubes
Sample volume	27 µL	88 µL (aspiration volume)
Calibration / Quality Control	Factory calibrated Optional control kit CBC-OPT (3 levels) will be provided to user (used if needed)	Whole Blood: XN-Check - 3 Levels XN CAL (XN-10/X-20 Calibrator) XN CAL PF (Platelet F Calibrator) Body Fluid: Body Fluid: XN Check BF – 2 Levels
Assay Principle(s)/ Detection Method	Computer-vision algorithms visually scan stained blood sample under device fluorescence microscope and analyze the captured images. Software identifies visual differences between different blood components while relying on characteristics such as size, shape, intensity, and morphology. Optical density measurement (Hgb)	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS hemoglobin method. Radiofrequency (RF) / Direct-current (DC) Detection Method, Sheath Flow DC Detection Method, and Flow Cytometry Methods using a Semiconductor Laser and Sodium Lauryl Sulfate (SLS)-hemoglobin. Particle characterization and identification is based on detection of forward scatter, fluorescence and adaptive cluster analysis.

Performance Data

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

Method comparison study with predicate device (CLSI H20-A2, H26-A2 and EP09-A3)

Method comparison studies were conducted to assess the performance of the Sight OLO device, compared to the predicate device. The testing was conducted at three (3) US sites using a total of 679 residual clinical K_2EDTA whole blood samples that were collected from both adults (≥22 years old) and pediatric patients (3 months to 21 years old). The majority of samples were venous samples while a few pediatric samples were capillary whole blood samples collected into tubes or micro tubes. All samples were run in singlet on the predicate Sysmex XN and within 2 hours in singlet on the Sight OLO device.

The studies included normal and pathological samples to assess the OLO performance across the analytical measuring range (AMR) as well as around medical decision points. The pathological samples included the following conditions: acute inflammation, bacterial and viral infections, aplastic anemia, acute and chronic leukemias (lymphocytic or myelocytic), multiple myeloma (plasma cell leukemia), microcytic anemia, normocytic anemia, macrocytic anemia, hemoglobinopathies, thalassemia, iron and folate deficiencies and giant platelets. The samples collected covered an age range of 3 months to 94 years old, 32% of samples were pediatric samples (3 months to 21 years of age), and the study population included 355 males (52%) and 324 females (48%).

The results demonstrated that all measurands met the pre-specified acceptance criteria for correlation, bias, slope, intercept (and the 95% two-sided confidence interval (CI) around the slope and intercept). A summary of the results is presented in the table below:

Table 1: Method Comparison Acceptance Criteria

Measurand	N	Results Range	Correlation Coefficient (r)	Slope (95% CI)	Intercept (95% CI)	Median Bias	Median Relative Bias (%)
WBC $x10^3/\mu L$	608	0.30 to 97.16	0.9973	1.011 (1.003, 1.020)	0.033 (-0.016, 0.082)	0.1	1.6%
RBC $x10^6/\mu L$	657	1.86 to 7.69	0.9906	1.019 (1.008, 1.030)	0.089 (0.043, 0.129)	0.16	4.1%
PLT $x10^3/\mu L$	624	22 to 985	0.9849	1.006 (0.994, 1.021)	8.937 (6.103, 11.801)	10	5.2%
HGB g/dL	673	4.9 to 21.2	0.9904	1.031 (1.020, 1.042)	-0.028 (-0.150, 0.104)	0.3	2.9%
HCT	657	15.2 to 63.7	0.9824	1.030 (1.014, 1.045)	-0.639 (-1.214, -0.044)	0.4	1.3%

MCV fL	657	57.3 to 121.2	0.9414	0.889 (0.862, 0.916)	7.489 (5.119, 9.821)	-2.3	-2.6%
RDW	647	10.6 to 29.4	0.9393	1.000 (0.980, 1.036)	-0.100 (-0.607, 0.171)	-0.1	-0.7%
MCH pg	652	14.9 to 42.0	0.9781	1.000 (0.986, 1.007)	-0.400 (-0.583, 0.046)	-0.4	-1.3%
MCHC g/dL	652	26.0 to 36.6	0.6931	0.667 (0.625, 0.731)	11.567 (9.431, 12.944)	0.5	1.5%
NEUT%	419	0.4 to 96.4	0.9894	0.994 (0.980, 1.008)	0.980 (0.051, 1.861)	0.5	0.9%
NEUT# $x10^3/\mu L$	412	0.01 to 52.59	0.9953	1.023 (1.011, 1.033)	0.020 (-0.014, 0.070)	0.12	2.9%
LYMPH%	423	0.9 to 99.6	0.992	1.000 (0.989, 1.013)	0.800 (0.452, 1.033)	0.8	3.3%
LYMPH# $x10^3/\mu L$	415	0.02 to 8.44	0.9867	1.025 (1.007, 1.044)	0.050 (0.022, 0.083)	0.09	5.7%
MONO%	423	0.0 to 23.4	0.8861	0.962 (0.910, 1.000)	-0.646 (-0.900, -0.264)	-0.9	-12.5%
MONO# $x10^3/\mu L$	415	0.00 to 3.74	0.9635	0.982 (0.941, 1.000)	-0.049 (-0.060, -0.027)	-0.06	-10.9%
EOS%	436	0.0 to 33.3	0.9792	1.023 (1.000, 1.071)	0.170 (0.100, 0.200)	0.2	11.1%
EOS# $x10^3/\mu L$	427	0.00 to 4.24	0.9856	1.042 (1.000, 1.094)	0.014 (0.009, 0.020)	0.02	15.0%
BASO%	438	0.0 to 3.1	0.6701	1.500 (1.333, 1.667)	-0.250 (-0.300, -0.167)	0	0.0%
BASO# $x10^3/\mu L$	429	0.00 to 0.34	0.6412	1.333 (1.200, 1.500)	-0.010 (-0.015, -0.006)	0	0.0%

Repeatability study (CLSI EP05-A3)

Repeatability studies were performed at 3 US sites according to CLSI EP05-A3 to evaluate the precision of the Sight OLO. Within-run repeatability studies were performed using residual K_2EDTA whole blood samples around medical decision levels and within the laboratory reference range. Each of the 3 sites collected a minimum of 11 samples to cover the laboratory reference range, medical decision levels for HGB, PLT and WBC and the upper range for RBC, HGB, WBC and PLT. Each sample was measured 20 consecutive times by 2 operators at each site using the Sight OLO device. For each measurand, the mean, standard deviation (SD) and coefficient of variation (CV) were computed.

All measurands in all tested ranges met the predefined acceptance criteria, as summarized in **Table 2** below.

Table 2: Repeatability Results

Pooled Results of Repeatability Study						
Measurand	**Units**	**Target Range**	**Mean**	**Pooled SD**	**Pooled CV%**	**Status**
WBC	10^3/µL	0.5-4.0	2.04	0.12	7.0%	Pass
WBC	10^3/µL	4.0-80.0	9.26	0.40	4.1%	Pass
RBC	10^6/µL	1.0-3.5	3.02	0.06	2.20%	Pass
RBC	10^6/µL	3.5-8.0	5.04	0.11	2.10%	Pass
PLT	10^3/µL	20-150	78.52	4.76	6.90%	Pass
PLT	10^3/µL	150-800	309.01	16.69	4.80%	Pass
HGB	g/dL	5-11	8.95	0.2	2.20%	Pass
HGB	g/dL	11-25	14.81	0.28	1.90%	Pass
HCT	%	10-70	40.45	0.91	2.20%	Pass
MCV	fL	50-150	85.28	0.58	0.70%	Pass
RDW	%	10-40	15	0.34	2.20%	Pass
MCH	pg	10-45	28.5	0.2	0.70%	Pass
MCHC	g/dL	26-38	33.26	0.28	0.80%	Pass
NEUT%	%	WBC≤4.0x10^3/µL	56.97	1.78	3.1%	Pass
NEUT%	%	WBC>4.0x10^3/µL	66.82	1.41	2.3%	Pass
NEUT#	10^3/µL	WBC≤4.0x10^3/µL	0.97	0.09	11.4%	Pass
NEUT#	10^3/µL	WBC>4.0x10^3/µL	6.45	0.31	4.8%	Pass
LYMPH%	%	WBC≤4.0x10^3/µL	31.80	2.00	6.3%	Pass
LYMPH%	%	WBC>4.0x10^3/µL	22.62	1.26	6.3%	Pass
LYMPH#	10^3/µL	WBC≤4.0x10^3/µL	0.84	0.07	9.5%	Pass
LYMPH#	10^3/µL	WBC>4.0x10^3/µL	1.89	0.13	7.3%	Pass
MONO%	%	WBC≤4.0x10^3/µL	8.30	1.20	14.5%	Pass
MONO%	%	WBC>4.0x10^3/µL	7.74	0.86	12.2%	Pass
MONO#	10^3/µL	WBC≤4.0x10^3/µL	0.16	0.03	26.9%	Pass
MONO#	10^3/µL	WBC>4.0x10^3/µL	0.69	0.09	12.8%	Pass
EOS%	%	WBC≤4.0x10^3/µL	2.00	0.63	31.4%	Pass
EOS%	%	WBC>4.0x10^3/µL	2.29	0.49	30.6%	Pass
EOS#	10^3/µL	WBC≤4.0x10^3/µL	0.04	0.02	65.1%	Pass

EOS#	10^3/µL	WBC>4.0x10^3/µL	0.19	0.04	30.5%	Pass
BASO%	%	WBC≤4.0x10^3/µL	0.94	0.40	42.6%	Pass
BASO%	%	WBC>4.0x10^3/µL	0.54	0.25	51.4%	Pass
BASO#	10^3/µL	WBC≤4.0x10^3/µL	0.02	0.01	90.1%	Pass
BASO#	10^3/µL	WBC>4.0x10^3/µL	0.04	0.02	50.8%	Pass

Reproducibility study (CLSI EP05-A3)

A reproducibility study of the Sight OLO was conducted at 3 sites, including 2 US sites, over 5 days with 4 replicates per 2 runs per day by 2 operators and 2 instruments per site. Study used 3 lots of commercial control material (low, normal and high concentrations of all reported parameters) for a total of 240 measurements per each level of control material. The data generated from this assessment was used to calculate within run, between run, between day, between instrument, between site and total precision. For each reported parameter and for each level of control tested, the mean, SD and %CV of the various components of precision.

All components of variation that were calculated met the pre-defined acceptance criteria. The results are summarized below.

Table 3: Reproducibility Results

Measurand	Level	N	Mean	Within run		Between Run		Between Day		Between instrument		Between Site		Total	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
WBC	Low	240	3.33	0.17	5.2	0.06	1.7	0.00	0.0	0.11	3.3	0.00	0.0	0.21	6.4
	Normal	240	8.19	0.26	3.2	0.09	1.1	0.00	0.0	0.17	2.1	0.00	0.0	0.32	4.0
	High	240	23.02	0.62	2.7	0.25	1.1	0.10	0.4	0.39	1.7	0.00	0.0	0.78	3.4
RBC	Low	240	2.61	0.04	1.5	0.04	1.7	0.00	0.0	0.07	2.8	0.00	0.0	0.09	3.6
	Normal	240	5.14	0.05	0.9	0.04	0.8	0.00	0.0	0.10	1.9	0.00	0.0	0.12	2.2
	High	240	5.91	0.06	1.0	0.03	0.6	0.02	0.4	0.10	1.7	0.00	0.0	0.12	2.1
PLT	Low	240	70.7	5.1	7.2	1.0	1.4	0.0	0.0	1.5	2.1	3.1	4.4	6.2	8.8
	Normal	240	218.2	9.4	4.3	2.5	1.2	2.1	0.9	3.1	1.4	2.7	1.2	10.8	4.9
	High	240	432.6	19.7	4.5	7.0	1.6	6.9	1.6	10.9	2.5	0.0	0.0	24.5	5.7
HGB	Low	240	7.05	0.10	1.4	0.09	1.2	0.00	0.0	0.10	1.4	0.00	0.0	0.16	2.3
	Normal	240	14.41	0.10	0.7	0.05	0.4	0.02	0.1	0.11	0.7	0.11	0.8	0.19	1.3
	High	240	17.32	0.13	0.7	0.06	0.3	0.05	0.3	0.11	0.6	0.20	1.2	0.27	1.6
HCT	Low	240	21.15	0.39	1.9	0.25	1.2	0.10	0.5	0.51	2.4	0.00	0.0	0.70	3.3
	Normal	240	43.99	0.60	1.4	0.35	0.8	0.00	0.0	0.81	1.8	0.00	0.0	1.06	2.4

	High	240	56.55	0.84	1.5	0.44	0.8	0.17	0.3	0.82	1.5	0.00	0.0	1.26	2.2
MCV	Low	240	80.91	0.84	1.0	0.74	0.9	0.00	0.0	0.79	1.0	0.00	0.0	1.37	1.7
	Normal	240	85.62	0.81	1.0	0.72	0.8	0.00	0.0	0.98	1.1	0.00	0.0	1.46	1.7
	High	240	95.66	0.86	0.9	0.52	0.5	0.00	0.0	1.51	1.6	0.00	0.0	1.82	1.9
RDW	Low	240	14.20	0.26	1.8	0.07	0.5	0.01	0.1	0.03	0.2	0.16	1.2	0.32	2.2
	Normal	240	13.17	0.19	1.5	0.00	0.0	0.01	0.1	0.06	0.5	0.07	0.6	0.22	1.6
	High	240	12.57	0.19	1.5	0.00	0.0	0.00	0.0	0.07	0.6	0.07	0.5	0.21	1.7
MCH	Low	240	26.99	0.19	0.7	0.17	0.6	0.05	0.2	0.49	1.8	0.00	0.0	0.55	2.1
	Normal	240	28.04	0.18	0.6	0.15	0.5	0.00	0.0	0.44	1.6	0.00	0.0	0.50	1.8
	High	240	29.30	0.22	0.7	0.04	0.1	0.05	0.2	0.46	1.6	0.00	0.0	0.52	1.8
MCHC	Low	240	33.37	0.38	1.1	0.26	0.8	0.00	0.0	0.60	1.8	0.00	0.0	0.76	2.3
	Normal	240	32.76	0.39	1.2	0.23	0.7	0.02	0.1	0.46	1.4	0.00	0.0	0.65	2.0
	High	240	30.63	0.40	1.3	0.15	0.5	0.00	0.0	0.32	1.0	0.31	1.0	0.62	2.0
NEUT%	Low	240	50.32	2.44	4.9	0.00	0.0	0.46	0.9	0.43	0.9	0.97	1.9	2.70	5.4
	Normal	240	41.73	1.62	3.9	0.00	0.0	0.00	0.0	0.21	0.5	0.00	0.0	1.64	3.9
	High	240	54.35	1.05	1.9	0.16	0.3	0.19	0.4	0.48	0.9	0.63	1.2	1.34	2.5
NEUT#	Low	240	1.68	0.12	7.0	0.02	1.4	0.03	1.7	0.05	3.2	0.00	0.0	0.13	8.0
	Normal	240	3.42	0.16	4.7	0.05	1.3	0.00	0.0	0.06	1.9	0.00	0.0	0.18	5.2
	High	240	12.51	0.39	3.1	0.14	1.2	0.10	0.8	0.26	2.1	0.16	1.3	0.53	4.2
LYMPH%	Low	240	17.62	1.69	9.6	0.29	1.6	0.00	0.0	0.00	0.0	0.00	0.0	1.71	9.7
	Normal	240	36.41	1.42	3.9	0.00	0.0	0.30	0.8	0.00	0.0	0.29	0.8	1.48	4.1
	High	240	25.30	0.91	3.6	0.00	0.0	0.17	0.7	0.07	0.3	0.00	0.0	0.93	3.7
LYMPH#	Low	240	0.59	0.06	10.4	0.02	3.7	0.00	0.0	0.01	2.5	0.00	0.0	0.07	11.4
	Normal	240	2.98	0.15	5.2	0.01	0.5	0.02	0.7	0.08	2.5	0.00	0.0	0.17	5.8
	High	240	5.82	0.28	4.7	0.00	0.0	0.03	0.6	0.09	1.5	0.00	0.0	0.29	5.0
MONO%	Low	240	12.21	1.53	12.5	0.00	0.0	0.22	1.8	0.73	6.0	0.59	4.9	1.81	14.8
	Normal	240	8.44	0.89	10.6	0.14	1.6	0.07	0.9	0.30	3.6	0.43	5.1	1.05	12.4
	High	240	11.88	0.76	6.4	0.00	0.0	0.00	0.0	0.42	3.6	0.72	6.0	1.12	9.5
MONO#	Low	240	0.41	0.05	13.4	0.00	0.0	0.00	0.0	0.04	9.3	0.01	1.5	0.07	16.4
	Normal	240	0.69	0.08	11.2	0.02	2.3	0.00	0.0	0.04	5.2	0.03	3.7	0.09	13.1
	High	240	2.73	0.19	7.0	0.03	0.9	0.00	0.0	0.12	4.4	0.14	5.0	0.26	9.7
EOS%	Low	240	11.75	1.69	14.4	0.30	2.6	0.00	0.0	0.00	0.0	0.41	3.5	1.76	15.0
	Normal	240	7.09	0.85	11.9	0.19	2.7	0.00	0.0	0.08	1.1	0.14	2.0	0.88	12.5
	High	240	3.94	0.47	11.9	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.47	11.9
EOS#	Low	240	0.39	0.06	16.2	0.01	2.2	0.00	0.0	0.02	5.3	0.01	1.3	0.07	17.2
	Normal	240	0.58	0.07	12.4	0.02	3.9	0.00	0.0	0.02	2.8	0.00	0.0	0.08	13.3

	High	240	0.91	0.11	12.6	0.00	0.0	0.01	1.4	0.01	0.6	0.00	0.0	0.12	12.7
BASO%	Low	240	8.12	1.23	15.1	0.00	0.0	0.20	2.5	0.03	0.3	0.21	2.6	1.26	15.5
	Normal	240	6.33	0.75	11.9	0.00	0.0	0.00	0.0	0.00	0.0	0.16	2.5	0.77	12.1
	High	240	4.54	0.48	10.5	0.13	2.8	0.00	0.0	0.00	0.0	0.12	2.5	0.51	11.2
BASO#	Low	240	0.27	0.04	15.4	0.01	2.3	0.01	1.9	0.00	1.8	0.00	1.0	0.04	15.8
	Normal	240	0.52	0.07	12.6	0.00	0.0	0.00	0.0	0.01	1.7	0.01	2.6	0.07	12.9
	High	240	1.04	0.11	10.7	0.04	3.5	0.00	0.0	0.03	3.1	0.02	2.4	0.12	11.9

Detection limits studies, including LoB, LoD, and LoQ (CLSI EP17-A2)

The study for LoB was conducted using two Sight OLO instruments. To determine LoB, testing was performed with two reagent lots. Each reagent lot was scanned on four test days conducting 60 measurements on each instrument with 15 measurements performed on each testing day. For the WBC and PLT LoB determination, preserved RBC samples, which contained no white blood cells or platelets, were used. For the HGB LoB determination, a diluent without any blood cells was used. The study results are provided in the following table. The limit of blank was determined as the 95th percentile of the distribution of the study variable, and the data are summarized below for all three measurands of interest.

For the LoD and LoQ study, six low concentration samples using concentrated and diluted venous blood samples were each measured 10 times for a total of 60 repeated measurements using three instruments over the course of six days. Each sample was also measured on a reference device in triplicate. This was then repeated with a different test reagent lot for another 60 measurements. Based on the LoB results and the study measurements the LoD was determined mathematically. The LoQ was defined as the lowest concentration (≥LoD) in which predetermined total error (TE) accuracy goals were satisfied.

The LoB, LoD, and LoQ for the three measurands are shown in the table below.

Table 4: LoB, LoD, and LoQ of Sight OLO

Measurand	LoB	LoD	LoQ
WBC	0.04 x 10^3/µL	0.17 x 10^3/µL	0.18 x 10^3/µL
PLT	8.00 x 10^3/µL	11.00 x 10^3/µL	13.40 x 10^3/µL
HGB	0 g/dL	3.9 g/dL	3.9 g/dL

Linearity studies (CLSI H26-A2 and EP06-A)

Ten (10) venous whole blood samples were manipulated to create the linearity panels for WBC, RBC, HGB, and PLT. Seven concentrations were used for WBC and PLT. Ten concentrations were used for RBC and HGB. Each concentration was scanned in duplicate. For each measurand, the linearity study was repeated on three OLO devices.

Determination of linearity was performed using 1st (linear), 2nd and 3rd order polynomials regressions. The data analysis was performed on each instrument separately and the final linearity range of the OLO device was determined as the intersection of the results from the three instruments, and no lower than the LoD.

The linear ranges of these measurands were determined as follows:

Table 5: Linearity Ranges for Sight OLO

Measurand	Range
HGB (g/dL)	(3.9-21.75)
PLT (10^3/µL)	(18-1028.5)
WBC (10^3/µL)	(0.18-100.13)

Analytical specificity/interference study (CLSI EP07-A2 and EP09-2)

Interference studies for D-Glucose, Billirubin C, Billirubin F, Hemolytic Hemoglobin, Chyle and Intralipids (Lipemia) were performed on the Sight OLO. For the first five substances, a by-bias study was initially conducted to evaluate whether any of the main measurands (RBC, WBC, HGB, HCT and PLT) is susceptible to the presence of clinically high levels of each interferant. For the measurands that were susceptible a by-addition dose response was subsequently conducted to determine the critical concentration of the interferant, as well as to determine the critical concentration of intralipids for all main measurands. In addition, interference by abnormal specimen studies were performed to characterize the susceptibility of the Sight OLO device to three potential interfering conditions due to abnormal specimen: RBC fragments, high leukocytosis (WBC > $50x10^3$/µL), and high thrombocytosis (PLT > $500x10^3$/µL).

The results of the interference studies demonstrated that:

1) There was no significant D-glucose interference at a concentration of 55 mmol/dL (1g/dL) for RBC, WBC, HGB, HCT and PLT parameters.

2) There was no significant bilirubin F interference at a concentration of 20 mg/dL for RBC, HGB, HCT and PLT parameters. There was no significant bilirubin F interference up to a concentration 8.86 mg/dL for the WBC parameter.

3) There was no significant bilirubin C interference at a concentration of 342 µmol/L for RBC, WBC, HGB, HCT and PLT parameters.

4) There was no significant chyle interference at a concentration of 2800 FTU for RBC, WBC, HGB, and HCT parameters. There was no significant chyle interference up to a concentration 530 FTU for the PLT parameter.

5) There was no significant hemolytic hemoglobin interference at a concentration of 200 mg/dL for RBC, WBC, HGB, HCT and PLT parameters.

6) There was no significant intralipid interference up to a concentration of 4.20 mg/mL for PLT, up to a concentration of 3.10 mg/mL for WBC, up to a concentration of 2.77 mg/mL for RBC, up to a concentration 2.42 mg/mL for HGB, and of up to a concentration of 1.94 mg/mL for HCT.

7) No interference was noted from RBC fragments, high leukocytosis (WBC > 50x103/µL), and high thrombocytosis (PLT > 500x103/µL).

Stability studies, including sample stability, test kit stability, and device calibration stability (CLSI EP25-A)

Sample Stability

Sample stability was determined for 10 freshly collected venous whole blood samples including 7 normal whole blood samples and 3 whole blood samples around medical decision levels. The venous blood samples were collected into K_2EDTA tubes. The samples were stored at room temperature (18-26°C) and were analyzed again, in quadruplicate at the following time points: 4 hours, 6 hours, 8 hours and 10 hours. For each time point, results were compared to the respective baseline results. The data support a sample stability claim of 8 hours from blood collection at room temperature for all Sight OLO measurands with the exception of RDW, which has a stability of 4 hours after blood collection when stored at room temperature.

Test Kit Shelf-Life

Real-time stability study is being conducted to establish the shelf-life stability of the Sight OLO TK1 Test Kit when it is stored at the recommended storage conditions. Three lots of test kits are tested. Each test lot is stored at room temperature (18-26°C) and tested at defined time points (4, 8, 12, 13, 18, 24, 26, 30, 36, 38 months), for a total of 11 time points per lot, including baseline.

At each predefined time point, the test kits are subjected to functional tests and analytical tests. The test kit lot is considered no longer stable only when the same acceptance criterion is not met for two consecutive time points for a specific measurand with the same test kit lot. The last time point before this happens is the time for which the test kit is considered stable. The overall shelf-life is the minimum of the shelf-life for three lots.

The initial shelf life for the test kit was set at 6 months at the recommended temperature, based on an internal study that included stability verification at 7 months after release. Functional and analytical tests were conducted and results met the predefined acceptance criteria.

Transportation studies

The stability of the Sight OLO during transportation has been tested for the device and for the test kit separately, in accordance with ASTM D7386-16. The results of this testing indicated that the Sight OLO device maintains its calibration and functional specifications during shipping per the acceptance criteria. The Sight OLO test kit met all acceptance criteria for functionality and expected analytical results when exposed to expected environmental conditions during shipment of the kits.

Flagging study (CLSI H20-A2)

Flagging studies were conducted, where Sight OLO was compared to manual light microscopy for normal (no flags) and abnormal (flags present) for 208 samples collected at 3 clinical study sites. Three blood films were prepared for each sample. Two qualified morphology examiners evaluated one of the three blood films. In each blood film a 200 cells count was performed for a total of 400 cells count for the two examiners together. The third blood film was saved for reading by a third qualified morphology examiner in the event that there was disagreement between the first two readers. Two types of abnormalities were evaluated: (1) distributional abnormal samples, which are samples where the quantity of at least one of the WBC diff % parameters resides outside of the normal concentrations, and (2) morphological abnormal samples, which are samples that contain atypical forms of the normal cell types contained in ordinary blood samples. The manual microscopy readings were compared to the results obtained with the Sight OLO for the same patient blood sample.

The overall flagging capabilities of the Sight OLO device met the predefined acceptance criteria for both sensitivity and specificity, as seen in the table below:

Sensitivity (PPA)	93.0%
Specificity (NPA)	80.6%
Overall Agreement	86.5%

Adult and pediatric reference intervals studies (CLSI EP28-A3c)

The adult reference intervals study was conducted at a single US site to establish adult reference intervals for the Sight OLO device. The study followed CLSI EP28-A3c and was performed using K_2EDTA venous whole blood samples collected from 240 (120 male and 120 female) apparently healthy adults (≥22 years). Each of the venous samples was analyzed in singlet on one Sight OLO device for all 19 measurands. Outliers were identified by the Reed-Dixon method and replaced with new samples. The reference intervals were calculated for each measurand. The lower and upper limits of the 95% reference intervals

were determined based on the 2.5th and 97.5th percentiles of all valid measurements for each sex group, respectively.

Pediatric reference intervals based on literature reference limits were verified on the Sight OLO instrument. The study followed CLSI EP28-A3c and was performed using residual blood samples collected from 80 apparently healthy pediatric subjects, including 20 samples per each of the pediatric subpopulations: baby (3 to 23 months); child (2 to <12 years old); adolescent (12 to < 18 years old); and transitional adolescent (18 to < 22 years old). Each of the samples was analyzed in singlet on one Sight OLO device. The results were compared to the literature reference intervals. The result supports the validity of the pre-established pediatrics reference intervals for the Sight OLO.

Matrix comparison studies between different sample collection methods (CLSI EP09-A3)

Capillary vs. Venous Matrix Comparison

The study was performed to demonstrate equivalency between K_2EDTA capillary whole blood samples and K_2EDTA venous whole blood samples on the Sight OLO Device. A total of 67 normal and pathological paired capillary and venous whole blood specimens were collected. Paired specimens collected from the same individuals were assayed in duplicate on the OLO device to compare performance between capillary whole blood samples and venous whole blood samples, and the results were analyzed for all applicable measurands.

The results show comparable performance characteristics for capillary and venous whole blood specimens. Therefore, the study results support the claim of using the two specimen types for measurement on the OLO device.

Capillary Microtube vs. Sight OLO Test Kit Micro-capillaries Matrix Comparison

This study was conducted to demonstrate the equivalency between (a) approximately 350µL of capillary whole blood samples collected from fingertip into a K_2EDTA microtube and (b) 2-drops of capillary whole blood from fingertip collected using the Sight OLO test kit directly.

A total of 40 paired K_2EDTA anticoagulated capillary microtube samples and the 2-drop finger prick samples were collected from healthy volunteer subjects at the company's internal laboratory. The specimens were compared to assess matrix effects on all applicable measurands. The K_2EDTA anticoagulated capillary microtube samples were run in duplicate on the Sight OLO device and two of the 2-drop blood samples were collected from two different fingers and run on the same device.

The results of the regression and bias analysis showed comparable performance between the K_2EDTA anticoagulated microtube capillary samples and the 2-drop fingertip samples. Therefore, the study results support the claim of using the two specimen types for measurement on the OLO device.

In addition, usability, electromagnetic compatibility and electrical safety testing, as well as software testing, were conducted for the Sight OLO device.

In all instances, the Sight OLO functioned as intended. Therefore, these studies demonstrate that the performance, functionality, and reliability of the Sight OLO analyzer are substantially equivalent to the predicate device.

Conclusions

The Sight OLO and its predicate device have the same intended use as well as similar indications for use, technological characteristics, and principles of operation. The differences between the devices do not present new issues of safety or effectiveness. Furthermore, performance testing demonstrated comparable performance characteristics between the Sight OLO and its predicate. Substantial equivalence is further supported by the comparison with the reference device. Thus, the Sight OLO is substantially equivalent to its predicate device.