510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K251249

B Applicant

Truvian Health

C Proprietary and Established Names

Tru Hematology Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GKZ	Class II	21 CFR 864.5220 – Automated different cell counter	HE – Hematology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, Other WBC%/#

C Type of Test:

Quantitative test for complete blood counts (CBC) with 3-part white blood cell differential

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Tru Hematology Test is part of the TruWellness Panel™ and is intended for use on the Tru Analyzer. The Tru Hematology Test (part of the TruWellness Panel™) is an in vitro diagnostic device and intended to classify and enumerate WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Lymph#, Lymph%, Neut#, Neut%, Other WBC#, and Other WBC% in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings.

The Tru Hematology Test (part of the TruWellness Panel™) is intended for use in adults 18 years of age or older. It is not intended for use in diagnosing or monitoring critical disease states such as oncology.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

D Special Instrument Requirements:

Tru Analyzer (K251058)

IV Device/System Characteristics:

A Device Description:

The Tru Hematology Test Panel contains the following reagents:

Component	Quantity kit
Potassium Cyanide	1.0 µg
Potassium Ferricyanide	3.8 µg
Buffers, Dyes, Preservatives, Stabilizers	N/A

The single-use consumable kit houses all the components needed to process as well as analyze samples on the Tru Analyzer, including dried reagents, internal process control solutions, barcodes that manage the identity of the kit lot (e.g., Disc and Support Pack ID), calibration information, dilution buffers, and single-use plastic pipette tips. It also serves as a waste container which the user discards of at the end of the run. The Support Pack contains a feature to accept a standard 4 mL blood tube. The Support Pack also houses 22 pipette tips for transferring and mixing samples and reagents, 11 dilution wells to support reagent processing activities within the test system (e.g., sample dilution, reagent dilution, rehydration of dried reagents), and 6 x 2 ml tubes that contain additional wet and dry reagents.

B Principle of Operation:

The Tru Analyzer uses a digital microscopy unit and a fluorescent imaging module for measurement of hematology parameters.

Hematocrit (HCT): The Tru system employs the classical microhematocrit method to determine hematocrit. Whole blood is transferred into the hematocrit channel located on the consumable kit disc by the Tru analyzer. After centrifugation, images are collected by the hematocrit channel with its on-board CCD camera to determine the percentage of the sample volume occupied by the red blood cells (i.e., hematocrit).

Hemoglobin (HGB): The Tru system quantitatively measures the concentration of hemoglobin spectrophotometrically. Whole blood is diluted in water in the support pack's dilution wells to release hemoglobin. The diluted/lysed sample is transferred to the disc where is combined with dried reagents which convert hemoglobin to cyanmethemoglobin. The color change of the sample is measured at a wavelength of 540 nm.

Complete Blood Count: The Tru system utilizes a combination of brightfield and fluorescence microscopy to complete a complete blood count with differential analysis on whole blood samples. Whole blood is transferred to reservoirs on the support pack where it is diluted with saline and combined with dried reagents. After the stained and de-clumped blood is transferred to the support pack monolayer, high resolution fluorescent images with its Cell Imager (CI) are collected by Tru analyzer and then processed and analyzed on-board the instrument to determine RBC, PLT, and WBC counts as well as WBC 3-part differential, which consists of Neutrophil#, Lymphocytes#, and Other WBC# (combination of Monocytes#, Eosinophils#, and Basophils#).

Mean corpuscular volume (MCV) is calculated using the following equation:

$$\text{MCV} = \frac{Hematocrit}{RBC} \text{ x } 10$$

Mean corpuscular hemoglobin (MCH) is calculated using the following equation:

$$MCH = \frac{Hemoglobin}{RBC} \text{ x } 10$$

Mean corpuscular hemoglobin concentration (MCHC) is calculated using the following equation:

$$MCHC = \frac{Hemoglobin}{Hematocrit} \text{ x } 100$$

Neutrophils (%) are calculated by using the following equation:

$$\text{Neutrophiles\%} = \frac{\text{Neutrophil (Absolute)}}{WBC} \text{ x } 100$$

Lymphocytes (%) are calculated by using the following equation:

$$\text{Lymphocytes\%} = \frac{\text{Lymphocytes (Absolute)}}{WBC} \text{ x } 100$$

Other WBC% is the sum of monocytes, eosinophils, and basophils and is calculated by using the following equation:

$$\text{Others\%} = \frac{\text{Others (Absolute)}}{WBC} \text{ x } 100$$

V Substantial Equivalence Information:

A Predicate Device Name(s):

Sight OLO

B Predicate 510(k) Number(s):

K190898

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251249	K190898
Device Trade Name	Tru Hematology Test	Sight OLO
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Tru Hematology Test is part of the TruWellness Panel™ and is intended for use on the Tru Analyzer. The Tru Hematology Test (part of the TruWellness Panel™) is an in vitro diagnostic device and intended to classify and enumerate WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Lymph#, Lymph%, Neut#, Neut%, Other WBC#, and Other WBC% in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings. The Tru Hematology Test (part of the TruWellness Panel™) is intended for use in adults 18 years of age or older. It is not intended for use in diagnosing or monitoring critical disease states such as oncology.	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 K2EDTA 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.
Analytes	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT#, NEUT%, LYMPH#, LYMPH%, Other WBC#, and Other WBC%.	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT#, NEUT%, LYMPH#, LYMPH%, MONO#, MONO%, EOS#, EOS%, BASO#, and BASO%.
Product code	GKZ	Same
Operating principles	HGB: Photometric / Colorimetric method HCT: Image analysis All other test parameters: Image analysis	Same
Calibration	Self-calibrating: Barcode with factory calibrated lot specific data	Same
General Device Characteristic Differences		
Specimen Type	Venous whole blood	Whole blood (venous and capillary)
Anticoagulant Type	Lithium heparin	K2-EDTA
Intended Use Setting	Clinical laboratory or point-of-care setting for professional use	Clinical laboratory
Analytical Measuring Range	WBC: 1.0 – 100 $x10^3/\mu L$ RBC: 1.0 – 7.5 $x10^6/\mu L$ HGB: 4.0 – 22.0 g/dL HCT: 15.0 – 60.0 % PLT: 15 – 1,000 $x10^3/\mu L$ LYMPH#: 0.0 – 100.0 $x10^3/\mu L$ NEUT#: 0.0 – 100.0 $x10^3/\mu L$ Other WBC#: 0.0 – 100.0 $x10^3/\mu L$	WBC: 0.18 – 100.13 $x10^3/\mu L$ RBC: 1.22 – 7.55 $x10^6/\mu L$ HGB: 4.0 – 21.75 g/dL HCT: 15.2 – 63.7 % PLT: 15.0 – 1000 $x10^3/\mu L$ LYMPH#: 0.0 – 100 $x10^3/\mu L$ NEUT#: 0.0 – 100 $x10^3/\mu L$ MONO#: 0.0 – 100 $x10^3/\mu L$ EOS#: 0.0 – 100 $x10^3/\mu L$ BASO#: 0.0 – 100 $x10^3/\mu L$
Sample Volume	300 µL	27 µL
Communication	USB ports, Ethernet port, Wireless module	USB ports, Ethernet port

VI Standards/Guidance Documents Referenced:

CLSI EP05-A3 (R2019), Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition.

CLSI EP06, Evaluation of Linearity of Quantitative Measurement Procedures; Approved Guideline – 2nd Edition.
CLSI EP07-ED3, Interference Testing in Clinical Chemistry; Approved Guideline – Third Edition.
CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition.
CLSI EP25, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline – Second Edition.
CLSI EP28-A3c, Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition.
CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry – First Edition
CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard – Second Edition.
CLSI GP41-Ed.7, Collection of Diagnostic Venous Blood Specimens – Seventh Edition.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Reproducability
Reproducibility was evaluated in this study for the candidate device using control material. The study was conducted at three external point-of-care (POC) sites, with three analyzers per site and at least three POC operators per site. Testing was conducted over five days using a single lot of consumables and consisted of three levels of control samples at low, medium, and high concentrations, with six replicates run per day, three runs in the morning and three runs in the afternoon (each replicate is run on an individual instrument). Overall, there were 90 replicates for each precision control sample level (3 sites x 1 sample x 3 replicates per run x 2 runs per day x 5 days = 90 replicates). The total precision as well as within-run, between-day, and between-site precision were estimated. All samples met acceptance criteria requirements, and the results are summarized below.

Parameter (units)	Level	n	Mean	Within-Run		Between-Run		Between-Day		Between-Site		Total	
				SD	CV%	SD	CV%	SD	CV%	SD	CV %	SD	CV%
WBC (x $10^3/\mu L$)	Low	90	2.6	0.1	5.3	0.0	1.3	0.0	0.0	0.01	0.3	0.1	5.5
	Med	90	7.9	0.2	2.8	0.0	0.0	0.0	0.0	0.2	2.2	0.3	3.6
	High	90	17.2	0.4	2.2	0.0	0.0	0.1	0.7	0.2	1.3	0.4	2.6
RBC (x $10^6/\mu L$)	Low	90	2.2	0.0	1.7	0.0	0.6	0.0	0.1	0.0	0.0	0.0	1.8
	Med	90	4.2	0.1	1.2	0.0	0.3	0.0	0.0	0.1	1.5	0.1	2.0
	High	90	6.1	0.1	1.5	0.0	0.3	0.0	0.0	0.1	0.9	0.11	1.8
HGB (g/dL)	Low	90	6.3	0.2	2.6	0.0	0.0	0.0	0.6	0.1	1.5	0.2	3.1
	Med	90	13.2	0.2	1.9	0.0	0.1	0.0	0.3	0.2	1.3	0.3	2.3
	High	90	19.1	0.5	2.4	0.0	0.0	0.0	0.2	0.1	0.6	0.5	2.4
HCT (%)	Low	90	17.2	0.2	1.3	0.0	0.0	0.1	0.5	0.0	0.1	0.2	1.4

Parameter (units)	Level	n	Mean	Within-Run		Between-Run		Between-Day		Between-Site		Total	
				SD	CV%	SD	CV%	SD	CV%	SD	CV %	SD	CV%
	Med	90	35.7	0.3	0.8	0.0	0.0	0.1	0.4	0.0	0.0	0.3	0.9
	High	90	53.5	0.4	0.7	0.1	0.2	0.1	0.1	0.0	0.1	0.4	0.8
MCV (fL)	Low	90	80	2.0	2.0	0.5	0.6	0.0	0.0	0.0	0.0	2.0	2.1
	Med	90	85	1.0	1.5	0.2	0.2	0.0	0.0	1.0	1.3	2.0	2.0
	High	90	88	1.0	1.5	0.0	0.0	0.4	0.5	1.0	1.1	2.0	1.9
MCH (pg)	Low	90	29.2	1.0	3.4	0.0	0.0	0.1	0.2	0.5	1.7	1.1	3.8
	Med	90	31.5	0.7	2.2	0.3	0.9	0.1	0.3	0.0	0.0	0.8	2.4
	High	90	31.6	0.8	2.6	0.0	0.0	0.0	0.0	0.0	0.0	0.8	2.6
MCHC (g/dL)	Low	90	36.4	1.1	3.0	0.0	0.0	0.0	0.0	0.7	1.9	1.3	3.6
	Med	90	37.0	0.8	2.1	0.0	0.0	0.2	0.5	0.4	1.1	0.9	2.4
	High	90	35.7	0.8	2.4	0.0	0.0	0.0	0.0	0.3	0.8	0.9	2.5
PLT (x 10^3/µL)	Low	90	78	2.0	3.2	0.0	0.0	0.0	0.0	1.0	1.2	3.0	3.4
	Med	90	251	.05	1.8	0.0	0.0	0.0	0.0	7.0	2.9	9.0	3.4
	High	90	588	10	1.7	0.0	0.0	0.0	0.0	13.0	2.1	16.0	2.7
NEUT (%)	Low	90	35.8	2.6	7.3	1.4	3.8	0.0	0.0	2.1	5.9	3.6	10.2
	Med	90	56.6	1.7	3.1	0.0	0.0	0.0	0.0	1.0	1.8	2.0	3.6
	High	90	75.1	1.3	1.7	0.0	0.0	0.0	0.0	0.0	0.0	1.3	1.7
NEUT # (x 10^3/µL)	Low	90	0.9	0.1	9.6	0.0	3.7	0.0	0.0	0.1	6.8	0.1	12.3
	Med	90	4.5	0.2	3.8	0.0	0.0	0.0	0.0	0.0	0.0	0.2	3.8
	High	90	12.9	0.4	2.7	0.1	0.5	0.0	0.0	0.2	1.4	0.4	3.1
LYMPH (%)	Low	90	33.5	2.6	7.9	0.0	0.0	0.0	0.0	1.6	4.7	3.1	9.1
	Med	90	31.8	1.6	4.9	0.0	0.0	0.0	0.0	1.7	5.3	2.3	7.2
	High	90	16.7	1.1	6.6	0.0	0.0	0.0	0.0	0.3	1.9	1.2	6.9
LYMPH# (x 10^3/µL)	Low	90	0.9	0.1	9.9	0.0	0.0	0.0	0.0	0.03	3.4	0.1	10.4
	Med	90	2.5	0.2	6.0	0.0	0.0	0.0	0.0	0.2	7.5	0.2	9.6
	High	90	2.9	0.2	7.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	7.0
Other WBC (%)	Low	90	30.7	2.1	7.0	0.9	2.8	0.0	0.0	0.4	1.3	2.3	7.6
	Med	90	11.6	0.8	7.1	0.0	0.0	0.0	0.0	0.7	5.8	1.1	9.2
	High	90	8.1	0.6	7.5	0.3	3.6	0.0	0.0	0.3	4.3	0.8	9.4
Other WBC # (x 10^3/µL)	Low	90	0.8	0.1	7.6	0.0	3.7	0.0	0.0	0.0	0.0	0.1	8.5
	Med	90	0.9	0.1	7.9	0.0	0.0	0.01	1.5	0.0	3.7	0.1	8.8
	High	90	1.4	0.1	8.1	0.1	3.6	0.0	1.5	0.1	5.3	0.1	10.4

Whole Blood Precision

Whole blood precision was evaluated using lithium-heparinized venous whole blood collected across five sites from the intended-use population with normal and abnormal analyte levels. For each test subject, eight replicates were measured across four instruments and two operators. The SD and CV% Precision estimates were calculated by pooling subject standard deviations and/or % CV for predefined Low, Medium or High sub-intervals selected to represent normal and abnormal regions of the analytical measuring range and

encompassing medical decision levels. Pooled imprecision is considered a representative estimate of reproducibility that includes variability of sites, instruments, operators, and repeatability. The pooled SD and pooled %CV meet the acceptance criteria for all reported parameters in the three sub-ranges (low, medium, high), as shown below.

Parameter (units)	Range	Subject (N)	Replicate (N)	Mean	SD	CV%
WBC ($x10^3/\mu L$)	Low: 1.0 – 4.0	10	76	3.5	0.18	5.3
	Med: 4.0 – 10.0	76	590	6.7	0.25	3.7
	High: 10 – 100	37	282	16.1	0.49	3.4
RBC ($x10^6/\mu L$)	Low: 1.0 – 4.0	53	412	3.5	0.11	3.0
	Med: 4.0 – 6.5	70	536	4.7	0.14	2.8
	High: 6.5 – 7.5	1	8	6.5	0.16	2.5
HGB (g/dL)	Low: 4.0 – 11.5	51	400	10.0	0.30	2.9
	Med: 11.5 – 15.5	65	503	13.4	0.35	2.7
	High: 15.5– 22.0	8	62	16.7	0.35	2.1
HCT (%)	Low: 15.0 – 30.0	15	112	25.9	0.46	1.9
	Med: 30.0 – 50.0	100	770	38.2	0.70	1.9
	High:50.0 – 60.0	2	16	52.7	0.38	0.7
PLT ($x10^3/\mu L$)	Low: 10 – 125	18	129	88	4.75	6.6
	Med: 125 – 500	99	763	264	13.40	4.6
	High: 500 – 1000	6	45	715	27.98	4.1
MCV (fL)	Low: 74 – 86	32	249	82	2.42	3.0
	Med: 86 – 90	40	306	88	2.44	2.8
	High: 90 – 106	45	343	96	2.61	2.7
MCH (pg)	Low: 21.0 – 28.0	30	232	26.2	0.89	3.4
	Med: 28.0 – 30.0	44	341	29.1	0.84	2.9
	High: 30.0 – 36.0	50	383	31.7	0.92	2.9
MCHC (g/dL)	Low: 28.0 – 32.0	34	258	31.1	0.90	2.9
	Med: 32.0 – 33.0	24	186	32.6	0.88	2.7
	High: 33.0 – 38.0	59	454	34.2	0.88	2.6
NEUT (%)	Low: 24.0 – 62.0	37	288	51.1	2.07	4.4
	Med: 62.0 – 74.0	43	335	68.2	1.69	2.5
	High: 74.0 – 91.0	43	324	81.4	1.47	1.8
NEUT# (x $10^3/\mu L$)	Low: 0.0 – 1.5	2	15	1.1	0.11	10.4
	Med: 1.5 – 7.0	83	645	4.1	0.21	5.5
	High: 7.0 – 100.0	38	287	11.6	0.55	4.2
LYMPH (%)	Low: 2.0 – 12.0	40	299	7.5	0.65	8.8
	Med: 12.0 – 23.0	41	322	17.7	1.21	7.0
	High: 23.0 – 59.0	42	326	34.3	1.66	5.1
LYMPH# ($x10^3/\mu L$)	Low: 0.0 – 1.0	42	311	0.7	0.07	11.3
	Med: 1.0 – 3.0	76	596	1.8	0.11	6.4
	High: 3.0 – 5.0	4	32	3.9	0.22	5.6
Other WBC(%)	Low: 2.0 – 9.0	34	264	7.5	0.90	12.6
	Med: 9.0 – 12.0	38	290	10.3	1.21	11.8
	High: 12.0 – 54.0	51	393	17.0	1.54	9.3

Parameter (units)	Range	Subject (N)	Replicate (N)	Mean	SD	CV%
Other WBC# (x10^3/µL)	Low: 0.0 – 1.5	99	762	0.8	0.09	12.8
	Med: 1.5 – 3.0	21	166	1.9	0.20	10.6
	High: 3.0 – 5.0	2	11	3.2	0.32	10.1

Lot-to-Lot Precision with Whole Blood

22 subjects consisting of 6 normal and 16 abnormal subjects were enrolled at a single point-of-care clinical site and tested on three lots of the Tru Hematology Test on three Tru Analyzers by two operators. A total of six replicates per subject participant, two replicates per lot, were tested by one of the two operators. All samples met acceptance criteria requirements, and the results are summarized below.

Parameter (units)	N*	Sample Range	Mean	Between-Lot /Instrument		Within-Run		Total	
				SD	CV%	SD	CV%	SD	CV%
WBC (x10^3/µL)	2	Low: 2.9 – 3.0	3.0	0.00	0.0	0.17	5.7	0.17	5.7
	18	Med: 4.0 – 8.6	6.3	0.00	0.0	0.32	5.1	0.32	5.1
	1	High: N/A	10.0	0.00	0.0	0.41	4.1	0.41	4.1
RBC (x10^6/µL)	3	Low: 3.9 – 4.0	4.0	0.05	1.3	0.09	2.2	0.10	2.5
	18	Med: 4.0 – 5.6	4.8	0.01	0.2	0.10	2.2	0.10	2.2
HGB (g/dL)	2	Low: 11.0 – 11.5	11.2	0.23	2.0	0.14	1.2	0.27	2.4
	18	Med: 11.8 – 15.0	13.3	0.00	0.0	0.25	1.9	0.25	1.9
	2	High: 15.6 – 16.3	15.9	0.06	0.4	0.19	1.2	0.20	1.3
HCT (%)	21	Med: 32.7 – 47.0	40.1	0.16	0.4	0.68	1.7	0.69	1.7
MCV (fL)	7	Low: 79 – 84	82	0.00	0.0	2.53	3	2.53	3.1
	7	Med: 85 – 89	87	0.00	0.0	1.78	2	1.78	2.0
	7	High: 89 – 92	90	0.47	0.5	2.84	3	2.88	3.2
MCH (pg)	8	Low: 23.8 – 28.6	27.3	0.00	0.0	0.64	2.3	0.64	2.3
	7	Med: 28.8 – 29.9	29.4	0.00	0.0	0.93	3.2	0.93	3.2
	6	High: 30.0 – 31.4	30.6	0.21	0.7	0.65	2.1	0.69	2.2
MCHC (g/dL)	7	Low: 30.0 – 32.8	32.2	0.00	0.0	0.50	1.5	0.50	1.5
	7	Med: 33.0– 33.9	33.4	0.14	0.4	0.57	1.7	0.59	1.8
	7	High: 33.9 – 35.8	34.8	0.25	0.7	0.98	2.8	1.01	2.9
PLT (x 10^3/µL)	3	Low: 39 – 68	55	1.12	2.0	2.07	3.7	2.35	4.3
	18	Med: 185 – 73	267	1.24	0.5	10.20	3.8	10.28	3.8
NEUT# (x 10^3/µL)	1	Low: N/A	1.0	0.03	3.3	0.04	4.5	0.06	5.6
	20	Med: 1.9 – 6.4	3.9	0.02	0.6	0.22	5.6	0.22	5.6
NEUT (%)	8	Low: 24.6 – 61.0	49.5	0.00	0.0	1.88	3.8	1.88	3.8
	6	Med: 61.8 – 63.7	62.8	0.05	0.1	1.86	3.0	1.86	3.0
	7	High: 64.4– 70.9	67.7	0.25	0.4	1.31	1.9	1.33	2.0
LYMPH# (x 10^3/µL)	2	Low: 0.7 – 0.8	0.8	0.00	0.0	0.06	8.6	0.06	8.6
	19	Med: 1.4 – 2.6	1.9	0.02	1.2	0.14	7.6	0.14	7.7
LYMPH (%)	7	Low: 21.6 – 24.6	22.8	0.26	1.1	1.13	5.0	1.16	5.1
	7	Med: 24.9 – 27.5	26.5	0.00	0.0	1.38	5.2	1.38	5.2
	7	High: 28.1 – 45.9	38.1	0.00	0.0	1.88	4.9	1.88	4.9

Parameter (units)	N*	Sample Range	Mean	Between-Lot /Instrument		Within-Run		Total	
				SD	CV%	SD	CV%	SD	CV%
Other WBC# (x10³/µL)	21	Low: 0.3 – 1.3	0.7	0.01	0.8	0.09	13.1	0.09	13.1
Other WBC (%)	7	Low: 6.7 – 8.6	7.7	0.51	6.6	0.88	11.5	1.02	13.3
	7	Med: 9.8 – 11.5	10.8	0.00	0.0	1.33	12.4	1.33	12.4
	7	High: 12.8 – 29.5	16.1	0.00	0.0	1.46	9.1	1.46	9.1

*Note: 1 subject was excluded from the calculation due to suppression by internal QC check.

Lot-to-Lot Precision with Control Material

To evaluate the lot-to-lot precision, three control samples (low, medium and high) were tested on three Tru Analyzers using three lots of the candidate test. Each sample level was tested with at least five replicates on one Tru Analyzer each day with each single use consumable kit lot over three days to achieve a minimum of 15 replicates per sample level and kit lot. All samples met acceptance criteria requirements, and the results are summarized below.

Parameter (unit)	N	Sample Range	Mean	Within-Run		Between-Lot/Instrument		Total	
				SD	CV%	SD	CV%	SD	CV%
HGB (g/dL)	34	Low: 7.2 – 11.4	10.0	0.29	2.9	0.12	1.2	0.31	3.1
	54	Med: 11.6 – 15.4	13.4	0.33	2.5	0.06	0.5	0.34	2.5
	4	High: 15.5 – 16.4	15.9	0.31	1.9	0.22	1.4	0.38	2.4
RBC (x10⁶/µL)	36	Low: 2.5 – 4.0	3.5	0.11	3.0	0.03	0.8	0.11	3.1
	56	Med: 4.0 – 5.8	4.6	0.12	2.6	0.02	0.4	0.12	2.6
WBC (x10³/µL)	10	Low: 2.2 – 4.0	3.4	0.19	5.5	0.00	0.0	0.19	5.5
	59	Med: 4.3 – 9.8	6.5	0.23	3.6	0.00	0.0	0.23	3.6
	22	High: 10.3 – 31.7	13.3	0.45	3.4	0.00	0.0	0.45	3.4
HCT (%)	9	Low: 19.3 – 29.5	26.1	0.46	1.8	0.00	0.0	0.46	1.8
	78	Med: 30.0 – 49.6	38.6	0.67	1.7	0.11	0.3	0.68	1.8
MCV (fL)	13	Low: 79 – 85	82	2.14	2.6	1.15	1.4	2.42	2.9
	28	Med: 85– 88	87	2.25	2.6	0.44	0.5	2.29	2.6
	17	High: 89 – 92	90	1.85	2.0	0.00	0.0	1.85	2.0
MCH (pg)	31	Low: 23.2 – 28.6	26.7	0.90	3.4	0.12	0.4	0.91	3.4
	21	Med: 28.7 – 29.8	29.4	0.87	3.0	0.00	0.0	0.87	3.0
	23	High: 29.9 – 32.0	30.9	0.86	2.8	0.16	0.5	0.87	2.8
MCHC (g/dL)	36	Low: 29.3 – 32.8	31.8	0.82	2.6	0.41	1.3	0.92	2.9
	21	Med: 33.0 – 33.9	33.5	0.85	2.5	0.00	0.0	0.85	2.5
	28	High: 33.9 – 35.6	34.5	0.81	2.4	0.19	0.6	0.83	2.4
PLT (x 10³/µL)	12	Low: 42 – 119	76	5.88	7.8	0.00	0.0	5.88	7.8
	79	Med: 132 – 192	247	13.11	5.3	1.17	0.5	13.17	5.3
	1	High: N/A	635	15.69	2.5	0.00	0.0	15.69	2.5
NEUT# (x 10³/µL)	2	Low: 0.9 – 1.4	1.1	0.11	9.5	0.00	0.0	0.11	9.5
	66	Med: 1.6 – 6.8	3.7	0.20	5.4	0.00	0.0	0.20	5.4
	23	High: 7.1 – 28.5	10.5	0.44	4.2	0.00	0.0	0.44	4.2
NEUT (%)	31	Low: 24.7 – 59.7	51.4	2.06	4.0	0.27	0.5	2.08	4.0

Parameter (unit)	N	Sample Range	Mean	Within-Run		Between-Lot/Instrument		Total	
				SD	CV%	SD	CV%	SD	CV%
	8	Med: 61.3 – 63.4	62.6	1.96	3.1	0.00	0.0	1.96	3.1
	15	High: 64.1 – 71.0	68.1	1.64	2.4	0.16	0.2	1.65	2.4
LYMPH # (x 10^3/µL)	34	Low: 0.26 – 1.00	0.6	0.06	9.3	0.01	2.3	0.06	9.6
	54	Med: 1.0 – 2.9	1.7	0.10	5.8	0.02	1.2	0.10	5.9
	3	High: 3.4 – 4.3	3.8	0.21	5.4	0.00	0.0	0.21	5.4
LYMPH (%)	9	Low: 21.5 – 24.7	22.8	1.27	5.6	0.41	1.8	1.34	5.9
	5	Med: 24.8 – 27.6	25.98	1.37	5.3	0.00	0.0	1.37	5.3
	27	High: 28.0 – 45.5	36.1	1.67	4.6	0.00	0.0	1.67	4.6
Other WBC# (x10^3/µL)	80	Low: 0.3 – 1.5	0.7	0.08	11.8	0.01	1.4	0.08	11.9
	10	Med: 1.5 – 2.8	1.8	0.22	11.7	0.00	0.0	0.22	11.7
	1	High: N/A	3.3	0.23	7.1	0.27	8.2	0.35	10.9
Other (%)	29	Low: 6.9 – 9.3	8.1	0.96	11.8	0.00	0.0	0.96	11.8
	23	Med: 9.4 – 11.7	10.3	1.26	12.2	0.00	0.0	1.26	12.2
	33	High: 12.0 – 24.6	14.5	1.45	10.0	0.00	0.0	1.45	10.0

2. Linearity:
Linearity studies were performed to validate the linear range of the Tru Hematology Test reportable whole blood parameters (WBC, RBC, HGB, HCT, and PLT). Nine sample dilutions were prepared including one level below and one level above the claimed linearity range. Testing was performed in replicates of four using one single-use consumable kit lot on 12 Tru Analyzers at one internal site. All results met predefined acceptance criteria and were determined to be acceptable.

Parameter	Linear Range
WBC (x10^3/µL)	1.0 – 100.0
RBC (x10^6/µL)	1.00 – 7.50
HGB (g/dL)	4.0 – 22.0
HCT (%)	15.0 – 60.0
PLT (x10^3/µL)	15 – 1000

3. Analytical Specificity/Interference:
Interfering studies were conducted for conjugated bilirubin, unconjugated bilirubin, chyle, D-Glucose, hemoglobin, hemolysis, intralipid, elevated WBC, excess and insufficient lithium-heparin, platelet aggregates, and yeast to determine the concentration that impact parameters on the Tru Hematology Test on the Tru Analyzer. Lithium heparin whole blood samples were collected from donors for this study and varying concentrations of interferent were added to obtain test concentrations. The measurements were tested in replicates of five on the Tru

Analyzer at one testing site with three lots of reagents. The results of the interference study demonstrated that:

Substance	Max Concentration without Interference				
	WBC	**RBC**	**Hemoglobin**	**Hematocrit**	**Platelets**
Conjugated Bilirubin (mg/dL)	38.1	38.1	38.1	19.1	38.1
Unconjugated Bilirubin (mg/dL)	28.6	38.1	38.1	9.5	28.6
Chylomicrons (mg/dL)	440.6	440.6	440.6	440.6	55.1
D-Glucose (mg/dL)	952.4	952.4	952.4	952.4	952.4
Hemoglobin mg/dL	476.2	714.3	N/A	476.2	119.1
Hemolysis (mg/dL) (Cell Lysis)	N/A	N/A	No Interference	N/A	N/A
Lipemia (mg/dL) (Intralipid)	1,363.7	1,818.2	1,818.2	454.6	1,363.7
PLT Aggregates	Interference Observed	No Interference	No Interference	No Interference	Interference Observed
Yeast (mg/dL) (Saccharomyces cerevisiae)	4.8	4.8	4.8	4.8	4.8
Leukocytosis (Elevated WBCs)	No Interference	No Interference	No Interference	No Interference	No Interference
Lithium-heparin Over blood draw or short blood draw	No Interference	No Interference	No Interference	No Interference	No Interference

4. Detection Limit and Assay Reportable Range:

A Limit of Blank (LoB) study was determined in accordance with the classical approach provided in section 5.3 of CLSI EP17-A2 for WBC, HGB, and PLT. Limit of Detection (LoD) and Limit of Quantitation (LoQ) were determined for WBC, RBC, HGB, HCT, and PLT.

For LoB testing, four blank samples were measured in replicates of five, over a period of three days using two reagent lots, to yield 120 total measurements per parameter across four Tru Analyzers.

For LoD and LoQ testing, five low concentration samples were measured in replicates of eight over a period of five days using two reagent lots, to yield 200 total measurement results per parameter across four Tru Analyzers. All results met the predefined acceptance criteria and were determined to be acceptable. The maximum observed LoB, LoD, and LoQ values for whole blood parameters are summarized below:

Parameter (units)	LoB	LoD	LoQ
WBC (x 10^3 /µL)	0.1	0.2	0.2
RBC (x 10^6 /µL)	N/A	0.22	0.3
Hemoglobin (g/dL)	0.2	0.3	0.4
Hematocrit (%)	N/A	0.9	2.0
Platelets (x 10^3 /µL)	7	9	15

Assay Reportable Range:
The reportable range was determined and validated by the method comparison study, linearity study, precision study, and limit of quantitation study.

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

Parameter (Units)	Reportable Range
WBC (x 10^3/µL)	1.0–100.0
RBC (x 10^6/µL)	1.00–7.50
Hemoglobin (g/dL)	4.0–22.0
Hematocrit (%)	15.0–60.0
Platelets (x 10^3/µL)	15–1000
Neutrophils # (x 10^3/µL)	0.0–100.0
Lymphocytes # (x 10^3/µL)	0.0–100.0
Other WBC # (x 10^3/µL)	0.0–100.0

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

Sample Stability:
The evaluation of lithium-heparin venous whole blood was conducted at two Point-of-care sites using 105 samples and eight Tru Analyzers. For each time point, the results were compared to the baseline results, and the mean percentage difference and CV% were calculated to meet the predefined acceptance criteria. The sample stability study results demonstrate that samples measured on the candidate test are stable for 60-minutes post-collection.

Consumable Kit Shelf-Life:
A real-time stability study was conducted to establish shelf-life stability for the Single-Use Consumable Kit when stored at the recommended storage conditions. Three lots of cartridges were tested. Each cartridge lot was stored both at refrigerated and room temperature and tested at defined time points and then evaluated using three samples. Based on the study results, the shelf-life stability of the Tru Hematology Test is six months at refrigerated storage condition (2–8°C) and 14 days at room temperature (15–25°C).

6. Assay Cut-Off:

Not Applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:
   A method comparison study was performed to evaluate the performance of the Tru analyzer compared to the comparative method, Sysmex XN-11 Automated Hematology Analyzer (K141681). A total of 423 subjects (214 female and 209 male) were included in the study. Each subject has a lithium heparin (analyzed on the Tru Analyzer) and K2EDTA (analyzed on the Sysmex) venous whole blood sample collected. Samples were analyzed by 22 operators across six Point-of-care sites in the US. Statistical analyses for the method comparison were performed based on correlation plots with Passing-Bablok regression. For each reported parameter, the slope, intercept, and correlation coefficient from the regression analysis, are shown in the table below.

Parameter (units)	N	Range	Slope (95% CI)	Intercept (95% CI)	R
WBC (x 10^3/µL)	383	1.3 – 91.4	0.96 (0.94, 0.97)	0.04 (-0.05, 0.15)	0.993
RBC (x 10^6/µL)	392	1.8 – 6.8	0.94 (0.92, 0.95)	0.22 (0.14, 0.29)	0.971
Hemoglobin (g/dL)	399	4.0 – 20.2	0.95 (0.94, 0.97)	0.67 (0.46, 0.89)	0.973
Hematocrit (%)	373	17.6 – 56.3	0.96 (0.94, 0.98)	1.14 (0.35, 1.98)	0.975
MCV (fL)	373	71 – 109	1.04 (0.97, 1.11)	-3.11 (-9.78, 2.54)	0.826
MCH (pg)	391	16.5 – 38.1	1.00 (0.95, 1.04)	0.50 (-0.69, 1.87)	0.887
MCHC (g/dL)	372	16.4 – 39.5	1.56 (1.40, 1.75)	-17.76 (-24.11, -12.67)	0.555
Platelets (x 10^3/µL)	370	19 – 996	0.94 (0.91, 0.97)	5.09 (-2.49, 10.90)	0.966
Neutrophils# (x 10^3/µL)	274	0.0 – 14.4	0.96 (0.93, 0.98)	-0.04 (-0.11, 0.04)	0.975
Neutrophils (%)	274	0.5 – 91.6	0.99 (0.97, 1.03)	-0.05 (-1.99, 1.77)	0.971
Lymphocytes# (x 10^3/µL)	274	0.1 – 34.4	0.94 (0.92, 0.97)	0.04 (0.00, 0.08)	0.996
Lymphocytes (%)	274	2.9 – 81.2	1.00 (0.98, 1.01)	0.30 (0.00, 0.78)	0.987
Other# (x 10^3/µL)	274	0.2 – 11.1	0.78 (0.71, 0.85)	0.13 (0.08, 0.17)	0.870
Other (%)	274	1.7 – 32.1	0.92 (0.83, 1.03)	0.91 (-0.23, 1.75)	0.702

2. Matrix Comparison:

   Not applicable

C Clinical Studies:

1. Clinical Sensitivity:
   A flagging study was performed at six Point-of-care sites including near-patient clinics, urgent care, primary care clinics and hospitals to evaluate the flagging agreement between the Tru Hematology Test on the Tru Analyzer against manual microscopy. 324 subjects had

one lithium heparin and one K2EDTA venous whole blood sample collected. The lithium-heparin sample was tested on the Tru Hematology Test on the Tru Analyzer in a single replicate, while the K2EDTA blood was used to prepare four blood smears and evaluated with manual microscopy by qualified professionals. 2x2 tables were constructed to determine flagging capabilities of Tru Analyzer for distributional and morphological abnormalities. The flagging results met the predefined acceptance criteria and are presented in the following table.

Category	N	TP	FP	TN	FN	Sensitivity (95% CI)	Specificity (95% CI)	Efficiency (95% CI)
Any Distribution Flag	324	110	29	175	10	91.7 (85.3, 95.4)	85.8 (80.3, 89.9)	88 (84, 91.1)
Any Morphology Flag	324	25	70	226	3	89.3 (72.8, 96.3)	76.4 (71.2, 80.8)	77.5 (72.6, 81.7)
Any Flag (combined)	324	116	43	154	11	91.3 (85.2, 95.1)	91.3 (85.2, 95.1)	91.3 (85.2, 95.1)

Sensitivity = 100 * TP / (TP+FN)
Specificity = 100 * TN / (TN+FP)
Efficiency = 100 * (TP+TN) / (TP+TN+FP+FN)

2. Clinical Specificity:

   Refer to Clinical Sensitivity

3. Clinical Cut-Off

   Not applicable

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

   Not Applicable

D Expected Values/Reference Range:

A reference interval study was performed to determine the reference intervals of adults on the Tru Hematology Test performed on the Tru Analyzer. Healthy subjects were enrolled at one internal site, including 256 adults (128 male, 128 female). One lithium-heparin venous whole blood sample was collected from each subject and tested. For the adult group (over 21 years old), reference intervals are established by nonparametric method following CLSI EP28-A3c.

Parameters (units)	Adult Female	Adult Male
WBC ($\times 10^3/\mu L$)	3.9–10.2	3.4–10.1
RBC ($\times 10^6/\mu L$)	3.9–5.3	4.1–5.5
HGB (g/dL)	10.6–15.0	12.2–16.3
HCT (%)	33.9–44.5	37.9–46.9

Parameters (units)	Adult Female	Adult Male
MCV (fL)*	77–97	81–96
MCH (pg)*	23.6–34.0	27.1–32.8
MCHC (g/dL)*	31.1–36.4	31.6–36.1
PLT (×10³/µL)	174–401	141–388
NEUT # (×10³/µL)	1.8–7.6	1.7–7.0
LYMP # (×10³/µL)	1.1–3.3	1.1–3.1
Other WBC # (×10³/µL)	0.4–1.0	0.4–1.2
NEUT (%)*	40.5–73.4	40.5–75.6
LYMPH (%)*	19.9–46.6	17.4–45.7
Other WBC (%)*	5.5–16.7	7.1–17.3

**Asterisk indicates calculated value*

VIII Proposed Labeling:

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

IX Conclusion:

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