510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K260781

B Applicant

Horiba ABX Sas

C Proprietary and Established Names

Yumizen H550

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GKZ	Class II	21 CFR 864.5220 - Automated Differential Cell Counter	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Clearance of a New device

B Measurand:

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, MPV, LYM (%/#), MON (%/#), NEU (%/#), EOS (%/#), BAS (%/#), IMG (%/#).

C Type of Test:

Quantitative test for complete blood counts (CBC) with 6-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:

Yumizen H550 analyzer classifies and enumerates the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, MPV, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%.
Yumizen H550 analyzer provides information for in vitro diagnostic use in clinical laboratories.
Yumizen H550 analyzer is used for screening a physiological state (quantitative or qualitative hematology abnormality detection) or a pathological state of patient populations found in clinical laboratories.
Yumizen H550 analyzer is quantitative for parameters measurement and qualitative for alarms detection.
Yumizen H550 is intended to perform tests on the following specimens:

- Venous blood
- Capillary blood collected in K2-EDTA and K3-EDTA anticoagulant.

Yumizen H550 is intended to perform tests on the following specimens:

- Pediatrics
  - New born: from birth to 28 days
  - Infant: from 29 days to 2 years
  - Children: from 2 years to 12 years
  - Adolescent: from 12 years to 21 years
- Adult population
  - Above 21 years

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The Yumizen H550 device is a quantitative multi-parameter fully automated hematology analyzer intended for in-vitro diagnostic use in clinical laboratories by qualified healthcare professionals for the screening of patient populations. Quantitative determination of blood cells is performed on venous and capillary whole blood samples collected in K2 or K3 EDTA anticoagulant. The Yumizen H550 model provides Complete Blood Count (CBC) and Differential (DIFF) counts.

The Yumizen H550 device consists of the following:

- An analytical module that aspirates, dilutes and analyzes whole blood samples
- An integrated computer workstation that controls the instrument, provides primary user interface with the instrument and manages the data produced by the instrument

- An auto sampler that automatically loads, mixes, identifies and presents the samples for processing,

B Principle of Operation:

Yumizen H550 uses impedance variation, optical and fluorescence flow cytometry, hydrodynamic focusing, and absorption spectrophotometry technologies to measure, count, and calculate hematological parameters in samples.

- Impedance variation consists in measuring the proportional signal response to the volume of the particle generated by its passage through a calibrated micro aperture concurrent with an electric current to measure RBC and PLT in whole blood samples.
- Optical and fluorescence flow cytometry is a process used to count and measure the properties of cells or particles as they are carried by fluid through a sensing zone. The cells are counted with impedance variation technology and physical and chemical characteristics of cells or particles are measured via light absorbency response from a light beam. The Yumizen H550 device uses double hydrodynamic sequential system (DHSS) flow cytometry to focus and align cells into a single-file micro aperture through the sensing zone. Two cell-free liquid sheaths surround the diluted sample and move with it in a laminar flow. The laminar flow prevents any mixing between the two liquid sheaths and the diluted sample. Flow cytometry technology is used to make the differential white blood cell formula with absorbency measurement.
- Absorption spectrophotometry is based on the linear relationship between the amount of light that a well-mixed, nonflowing sample absorbs at a particular absorption band and the concentration of an absorbing entity in the sample (Beer-Lambert Law). To perform absorption spectrophotometry, the system uses the hemoglobin dilution as the sample and a specific reagent which result in RBC lysis and release of hemoglobin. The reagent then oxidizes and stabilizes all heme iron from erythrocytes. The resulting complexes are quantified by spectrophotometry at a wavelength of 555 nm. Absorption spectrophotometry is used to measure the HGB concentration. All the other hematological parameters are calculated or derived from these different measurements.

C Instrument Description Information:

1. Instrument Name:

   Yumizen H550

2. Specimen Identification:

   Specimen identification can be performed manually by an operator using an external keyboard or the virtual keyboard or barcode labels can be affixed to the sample tubes and racks to enable automatic reading of the ID using the integrated barcode reader or an external barcode reader.

3. Specimen Sampling and Handling:

The Yumizen H550 operates in two sampling modes:

- Automatic sampling (auto mixer and auto loader – Rack mode)
- Manual sampling (STAT mode)

4. Calibration:

   Calibration is a procedure that is performed during specific situations such as installation, maintenance or service intervention. It ensures that the precision and accuracy of the analyzer are acceptable, so that accurate measurements are performed by the analyzer. Calibration is performed using materials with assigned values that are traceable to standard reference methods. It is recommended that the laboratory calibrate using ABX Minocal, which is a commercial whole blood calibrator.

5. Quality Control:

   ABX Difftrol is a tri-level control intended for in vitro use in monitoring the accuracy and precision of HORIBA Medical hematology blood cell counters using HORIBA Medical reagents.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Yumizen H2500

B Predicate 510(k) Number(s):
K232946

C Comparison with Predicate(s):

Device & Predicate Device(s):	K260781	K232946
Device Trade Name	Yumizen H550	Yumizen H2500
General Device Characteristic Similarities		
Intended Use/Indications For Use	Yumizen H550 analyzer classifies and enumerates the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, MPV, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, IMG#, IMG%. Yumizen H550 analyzer provides information for in vitro diagnostic use in clinical laboratories.	The Yumizen H2500 is a quantitative multiparameter fully automated hematology analyzer intended for in-vitro diagnostic use in clinical laboratories by qualified healthcare professionals for the screening of patient populations. The Yumizen H2500 is intended to perform tests on the following specimens: • Anticoagulated whole blood specimens • Body fluids (synovial fluids,

	Yumizen H550 analyzer is used for screening a physiological state (quantitative or qualitative hematology abnormality detection) or a pathological state of patient populations found in clinical laboratories. Yumizen H550 analyzer is quantitative for parameters measurement and qualitative for alarms detection. Yumizen H550 is intended to perform tests on the following specimens: - Venous blood - Capillary blood collected in K2-EDTA and K3-EDTA anticoagulant. Yumizen H550 is intended to perform tests on the following specimens: - Pediatrics • New born: from birth to 28 days • Infant: from 29 days to 2 years • Children: from 2 years to 12 years • Adolescent: from 12 years to 21 years - Adult population • Above 21 years	serous fluids and cerebrospinal fluids). The Yumizen H2500 classifies and enumerates the following parameters: • A complete blood count (CBC) consisting of TNC, WBC, RBC, HGB, calculated HCT, MCV, calculated MCH, calculated MCHC, RDW-SD, RDW-CV, PLT, PLT-Ox, LPF, MPV. • A leukocyte differential count consisting of LYM (%/#), MON (%/#), NEU (%/#), EOS (%/#), BAS (%/#), IMG (%/#) • A nucleated red blood cell count consisting of NRBC (%/#). • A reticulocyte analysis consisting of RET (%/#), calculated CRC, IRF, RHCC. • Quantitative determination of blood cells in synovial fluids, serous fluids (peritoneal, pericardial, pleural fluids) and cerebrospinal fluids consisting of BFWBC, BFRBC, BFPN (%/#), BFMN(%/#). Note: Venous and capillary whole blood should be collected in K2EDTA anticoagulant. Serous and synovial fluids should be collected without anticoagulant or in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with cerebrospinal fluid specimens is neither required nor recommended. Alternatively, Sodium Heparin or Lithium Heparin may be used for

		synovial fluid.
Test Principle	Performs analyses using the Double Hydrodynamic Sequential System, flow cytometry method (using a semiconductor laser and fluorescent dyes)	Same
Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, MPV, LYM (%/#), MON (%/#), NEU (%/#), EOS (%/#), BAS (%/#), IMG (%/#).	TNC, WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, MPV, LYM (%/#), MON (%/#), NEU (%/#), EOS (%/#), BAS (%/#), IMG (%/#), NRBC (%/#), BFWBC, BFRBC, BFPN (%/#), BFMN (%/#), PLT-Ox, LPF, RET (%/#), CRC, IRF, RHCC
Modes of operation	Automatic Rack mode Manual mode (Sample placed in tube holder position)	Same
Patient population	Adult and Pediatric	Same
Reagents	ABX DILUENT 10L (Diluent) ABX DILUENT 20L (Diluent) ABX CLEANER 1L (Cleaner) ABX MINOCLAIR 0.5L(Cleaner)	Same
Calibrator	ABX MINOCAL	Same
General Device Characteristic Differences		
Parameters	No equivalent parameter	TNC, PLT-Ox, LPF, NRBC (%/#), RET(%/#), CRC, IRF, RHCC, BFWBC, BFRBC, BFPN (%/#), BFMN (%/#).
Specimen types	Venous and Capillary Whole blood	Venous and Capillary Whole Blood, and body fluids
Anticoagulant	Whole blood: K2EDTA and K3EDTA	Whole blood: K2EDTA Body Fluids: • Serous: without anticoagulant/ K2EDTA. • Synovial: without anticoagulant/ K2EDTA/ Sodium Heparin/ Lithium Heparin. CSF: without anticoagulant.
Modes of operation	No equivalent analysis mode for the Body fluids parameters	Body Fluid Analysis Mode
Reagents	WHITEDIFF 1L (Lyse)	ABX BASOLYSE 5L (Lyse) NUCEDIFF 1L (Lyse) ABX LYSEBIO 1L (Lyse)

		ABX FLUOCYTE 0.5L (Stain)
Controls	ABX DIFFTROL (3 Levels)	Whole Blood: ABX MINOTROL RETIC (3 Levels) Body Fluid: BFTROL (2 Levels)
Throughput	60 samples per hour	120 samples/hour maximum depending on mode used.
Sample Aspiration Volume	20 µL	110 µL

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition
- CLSI EP06 2nd Edition, Evaluation of the Linearity of Quantitative Measurement Procedures.
- CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition.
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
- CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition
- CLSI EP07-A3, Interference Testing in Clinical Chemistry
- CLSI EP37 1st Edition, Supplemental Tables for Interference Testing in Clinical Chemistry
- CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard – Second Edition
- CLSI EP25 2nd Edition, Evaluation of Stability Of In Vitro Medical Laboratory Test Reagents
- CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers
- IEC 61326-2-6: Edition 3.0 2020-10, Electrical equipment for measurement control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- IEC 61326-1: Edition 3.0 2020-10, Electrical equipment for measurement control and laboratory use - EMC requirements - Part 1: General requirements
- IEC 60601 1-1-2: Edition 4.1 2020-09, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 14971: 2019, Medical devices − Application of risk management to medical devices
- ISO 15223-1: 2021, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

VII Performance Characteristics:

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability – Whole Blood

Repeatability studies were performed using a total of 43 residual K2EDTA whole blood samples to cover low, normal, high, and medical decision levels (MDLs). Each sample was measured in 12 replicates and the mean, SD, %CV, and the two-sided 95% Confidence Intervals (CIs) around the SD and %CV were calculated for each parameter. All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements. The results are summarized below.

Repeatability Whole Blood Samples

Measurand	Level	N	Result Range	Mean	CV% (max)	SD (max)
WBC ($10^3/mm^3$)	MDL	3	0.73 - 1.62	1.15	3.23	0.04
	Low	5	0.73 - 2.49	1.62	3.23	0.15
	Normal	20	4.09 - 9.76	6.3	2.94	0.20
	High	18	10.1 - 260.6	35.2	2.77	6.20
RBC ($10^3/mm^3$)	Low	17	1.17 - 3.58	2.7	1.32	0.04
	Normal	24	3.66 - 6.06	4.7	1.36	0.06
	High	2	6.65 - 7.10	6.9	0.75	0.05
HGB (g/dL)	MDL	4	4.3 - 7	5.90	0.91	0.05
	Low	20	4.3 - 11.8	8.7	0.93	0.12
	Normal	18	12.1 - 17.8	13.8	1.25	0.16
	High	5	18.2 - 22.0	19.2	1.13	0.21
HCT (%)	Low	19	10.8 - 34.2	25.6	1.55	0.41
	Normal	20	36.4 - 52.8	41.7	1.39	0.60
	High	4	54.3 - 66.3	58.0	1.10	0.61
MCV (fL)	Low	2	74.8 - 77.6	76.2	0.26	0.20
	Normal	40	81.8 - 99.9	90.6	0.38	0.34
	High	1	101.7 - 101.7	101.7	0.08	0.08
MCH (pg)	Low	2	23.6 - 25.2	24.4	1.32	0.31
	Normal	33	27.3 - 32.0	29.7	1.32	0.39
	High	8	32.1 - 36.4	33.6	1.36	0.50
MCHC (g/dL)	Low	3	28.9 - 31.8	30.7	1.28	0.40
	Normal	39	32.3 - 34.7	33.5	1.34	0.44
	High	1	39.4 - 39.4	39.4	1.42	0.56
RDWcv (%)	Low	2	11.7 - 11.9	11.8	2.42	0.28
	Normal	36	12.1 - 18.0	14.8	2.24	0.32
	High	5	18.0 - 21.6	19.4	1.23	0.22
RDWsd (fL)	Low	N/A	N/A	N/A	N/A	N/A
	Normal	37	37.1 - 53.4	46.6	2.19	1.07
	High	6	56.4 - 67.5	60.2	1.71	0.97
	MDL	2	19 - 28	24	8.29	2.35

Measurand	Level	N	Result Range	Mean	CV% (max)	SD (max)
PLT (10^3/mm^3)	Low	13	19 - 157	77	8.29	4.8
	Normal	22	214 - 430	280	3.25	12.4
	High	8	527 - 3732	1208	2.33	28.0
MPV (fL)	Low	4	6.8 - 8.0	7.5	2.08	0.16
	Normal	35	8.2 - 11.9	9.6	2.82	0.31
	High	2	12.3 - 12.7	12.5	1.59	0.20
LYM% (%)	Low	12	10.9 - 22.9	16.8	4.45	0.66
	Normal	14	25.3 - 47.1	33.4	3.27	0.96
	High	1	54.5 - 54.5	54.5	1.49	0.81
MON% (%)	Low	4	3.7 - 4.9	4.3	8.73	0.33
	Normal	22	5.82 - 9.83	7.9	10.64	0.88
	High	9	10.2 - 31.0	14.6	7.84	0.96
NEU% (%)	Low	3	15.3 - 38.0	27.4	4.20	0.78
	Normal	28	47.9 - 79.1	62.8	2.09	1.31
	High	4	80.5 - 93.0	86.9	0.90	0.73
EOS% (%)	Low	N/A	N/A	N/A	N/A	N/A
	Normal	22	1.09 - 4.69	2.4	15.86	0.42
	High	3	5.67 - 6.23	5.9	6.24	0.36
BAS% (%)	Low	N/A	N/A	N/A	N/A	N/A
	Normal	35	0.10 - 1.70	0.5	39.41	0.19
	High	2	2.29 - 3.05	2.7	7.59	0.23
IMG% (%)	Low	N/A	N/A	N/A	N/A	N/A
	Normal	19	0.53 - 2.95	1.1	19.77	0.26
	High	8	3.38 - 27.8	14.1	8.70	0.83
LYM# (10^3/mm^3)	Low	N/A	N/A	N/A	N/A	N/A
	Normal	25	0.95 - 4.54	2.4	9.41	0.36
	High	3	5.10 - 5.80	5.4	2.41	0.14
MON# (10^3/mm^3)	Low	N/A	N/A	N/A	N/A	N/A
	Normal	21	0.19 - 0.96	0.5	11.05	0.11
	High	14	1.00 - 5.16	2.0	8.90	0.20
NEU# (10^3/mm^3)	Low	2	1.55 - 1.83	1.7	3.92	0.06
	Normal	21	2.78 - 7.16	4.1	2.84	0.14
	High	12	8.85 - 36.7	15.8	2.14	0.47
EOS# (10^3/mm^3)	Low	N/A	N/A	N/A	N/A	N/A
	Normal	23	0.05 - 0.36	0.1	24.12	0.03
	High	8	0.52 - 8.71	2.0	9.21	0.61
BAS# (10^3/mm^3)	Low	N/A	N/A	N/A	N/A	N/A
	Normal	32	0.01 - 0.22	0.0	39.15	0.03
	High	5	0.31 - 2.19	1.0	20.80	0.46
IMG# (10^3/mm^3)	Low	N/A	N/A	N/A	N/A	N/A
	Normal	25	0.02 - 0.17	0.1	19.53	0.02

Measurand	Level	N	Result Range	Mean	CV% (max)	SD (max)
	High	10	0.34 - 17.0	3.7	9.73	0.54

Repeatability- ABX Difftrol

Reproducibility studies were performed at one site to evaluate the repeatability of the Yumizen H550. Testing was performed using three levels of each control material (ABX Difftrol). Each level was run in duplicate twice each day for a minimum of 20 days using one reagent lot generating 80 measurements for each level. The results were analyzed in accordance with the CLSI EP05-A3 guidelines and met the acceptance criteria. Results are summarized below.

Measurand	Target Range	N	Result Range	Mean	%CV	SD
WBC $10^3/mm^3$	Low	80	2.77 - 3.27	2.98	3.10	0.09
	Normal	80	7.94 - 8.65	8.26	1.74	0.14
	High	80	17.04 - 18.20	17.57	1.21	0.21
RBC $10^6/mm^3$	Low	80	2.13 - 2.33	2.26	1.38	0.03
	Normal	80	4.42 - 4.64	4.52	1.07	0.05
	High	80	4.85 - 5.08	4.97	1.03	0.05
HGB g/dL	Low	80	6.10 - 6.40	6.31	0.79	0.05
	Normal	80	12.90 - 13.20	13.08	0.60	0.08
	High	80	15.40 - 15.80	15.59	0.61	0.09
HCT %	Low	80	17.70 - 19.60	18.89	1.62	0.31
	Normal	80	38.10 - 40.40	39.17	1.23	0.48
	High	80	45.60 - 47.90	46.77	1.11	0.52
MCV fL	Low	80	82.60 - 86.00	83.61	0.83	0.69
	Normal	80	86.00 - 87.50	86.62	0.45	0.39
	High	80	93.20 - 95.20	94.08	0.48	0.45
MCH pg	Low	80	27.20 - 28.90	27.99	1.30	0.36
	Normal	80	28.00 - 29.70	28.93	1.10	0.32
	High	80	30.80 - 32.00	31.36	0.96	0.30
MCHC g/dL	Low	80	32.00 - 34.70	33.48	1.67	0.56
	Normal	80	32.10 - 34.50	33.39	1.29	0.43
	High	80	32.50 - 34.20	33.34	1.10	0.37
RDW-CV %	Low	80	14.30 - 15.90	14.91	2.26	0.34
	Normal	80	13.20 - 14.30	13.67	1.63	0.22
	High	80	12.50 - 13.50	12.94	1.66	0.21
RDW-SD fL	Low	80	41.30 - 44.60	42.58	1.86	0.79
	Normal	80	39.00 - 41.30	40.27	1.58	0.64
	High	80	39.00 - 41.30	40.37	1.47	0.59
PLT $10^3/mm^3$	Low	80	58.00 - 78.00	67.73	5.89	3.99
	Normal	80	226.00 - 277.00	246.05	3.63	8.93
	High	80	455.00 - 508.00	479.79	2.46	11.82
MPV fL	Low	80	8.60 - 9.50	9.07	2.06	0.19
	Normal	80	9.00 - 9.50	9.31	1.14	0.11
	High	80	9.50 - 10.00	9.82	0.92	0.09

Measurand	Target Range	N	Result Range	Mean	%CV	SD
LYM# $10^3/mm^3$	Low	80	0.99 - 1.25	1.14	4.50	0.05
	Normal	80	2.90 - 3.41	3.20	2.57	0.08
	High	80	3.19 - 3.55	3.38	2.39	0.08
LYM %	Low	80	35.70 - 41.20	38.17	2.81	1.07
	Normal	80	36.60 - 40.20	38.79	1.66	0.64
	High	80	18.20 - 20.10	19.23	2.00	0.38
MON# $10^3/mm^3$	Low	80	0.19 - 0.27	0.23	7.44	0.02
	Normal	80	0.27 - 0.39	0.33	7.68	0.03
	High	80	0.50 - 0.63	0.57	5.42	0.03
MON %	Low	80	6.50 - 9.10	7.71	7.28	0.56
	Normal	80	3.30 - 4.70	4.04	7.58	0.31
	High	80	2.80 - 3.60	3.24	5.76	0.19
NEU# $10^3/mm^3$	Low	80	1.13 - 1.41	1.24	4.26	0.05
	Normal	80	4.12 - 4.54	4.30	2.04	0.09
	High	80	11.20 - 11.85	11.53	1.32	0.15
NEU %	Low	80	38.90 - 45.30	41.74	2.57	1.07
	Normal	80	50.50 - 54.10	52.10	1.27	0.66
	High	80	64.50 - 66.80	65.62	0.68	0.45
EOS# $10^3/mm^3$	Low	80	0.11 - 0.19	0.15	9.25	0.01
	Normal	80	0.19 - 0.29	0.24	8.57	0.02
	High	80	0.65 - 0.83	0.73	4.91	0.04
EOS %	Low	80	4.00 - 6.20	5.03	8.71	0.44
	Normal	80	2.40 - 3.50	2.95	7.76	0.23
	High	80	3.80 - 4.70	4.17	4.71	0.20
BAS# $10^3/mm^3$	Low	80	0.19 - 0.26	0.22	6.84	0.01
	Normal	80	0.15 - 0.21	0.18	7.01	0.01
	High	80	1.26 - 1.45	1.36	2.97	0.04
BAS %	Low	80	6.40 - 8.70	7.36	6.73	0.50
	Normal	80	1.80 - 2.50	2.12	7.43	0.16
	High	80	7.30 - 8.20	7.75	2.65	0.21
IMG# $10^3/mm^3$	Low	80	0.11 - 0.17	0.14	9.05	0.01
	Normal	80	0.44 - 0.62	0.51	6.87	0.04
	High	80	0.91 - 1.21	1.06	6.67	0.07
IMG %	Low	80	3.80 - 5.80	4.70	8.25	0.39
	Normal	80	5.40 - 7.20	6.18	6.40	0.40
	High	80	5.20 - 6.90	6.04	6.61	0.40

Reproducibility

Reproducibility studies were performed using three levels of each control material (ABX Difftrol) at three sites on three instruments (1 instrument/site) to evaluate the within-run, between-run, between-day, and total reproducibility of the Yumizen H550. Each level was run in three replicates, twice each day for five days using one reagent lot at each of the three testing sites, generating 90 measurements a day. The results were analyzed in accordance with CLSI EP05-A3 and met the acceptance criteria. Results are summarized below.

Measurand	Level	N	Mean	Within run		Between run		Between day		Between site		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC $10^3/mm^3$	L	90	2.87	0.07	2.56	0.05	1.72	0.02	0.76	0.09	3.03	0.13	4.39
	N	90	8.17	0.15	1.88	0.00	0.00	0.09	1.14	0.11	1.30	0.21	2.55
	H	90	18.01	0.23	1.29	0.09	0.50	0.11	0.59	0.14	0.79	0.31	1.70
RBC $10^6/mm^3$	L	90	2.32	0.03	1.32	0.00	0.00	0.02	0.68	0.00	0.00	0.03	1.49
	N	90	4.52	0.03	0.74	0.03	0.61	0.03	0.72	0.00	0.00	0.05	1.20
	H	90	5.06	0.05	0.92	0.02	0.30	0.05	0.95	0.00	0.00	0.07	1.36
HGB g/dL	L	90	6.25	0.06	0.98	0.02	0.26	0.00	0.00	0.07	1.04	0.09	1.46
	N	90	13.12	0.10	0.73	0.01	0.10	0.05	0.35	0.13	0.98	0.17	1.28
	H	90	15.74	0.14	0.92	0.00	0.00	0.07	0.47	0.16	1.00	0.23	1.44
HCT %	L	90	19.20	0.25	1.29	0.03	0.16	0.17	0.90	0.20	1.04	0.36	1.89
	N	90	39.36	0.31	0.79	0.26	0.67	0.41	1.03	0.32	0.82	0.66	1.68
	H	90	47.04	0.46	0.99	0.15	0.32	0.55	1.16	0.48	1.02	0.88	1.86
MCV fL	L	90	82.84	0.32	0.38	0.03	0.04	0.24	0.29	0.92	1.11	1.00	1.21
	N	90	87.04	0.28	0.32	0.11	0.13	0.25	0.28	0.82	0.94	0.91	1.04
	H	90	92.89	0.27	0.29	0.02	0.03	0.19	0.20	0.84	0.91	0.91	0.98
MCH pg	L	90	26.96	0.31	1.17	0.00	0.00	0.22	0.80	0.28	1.03	0.47	1.75
	N	90	29.03	0.24	0.84	0.12	0.42	0.21	0.73	0.25	0.85	0.43	1.47
	H	90	31.09	0.23	0.73	0.07	0.22	0.21	0.68	0.24	0.76	0.40	1.28
MCHC g/dL	L	90	32.56	0.39	1.18	0.00	0.00	0.33	1.01	0.00	0.00	0.51	1.56
	N	90	33.35	0.31	0.93	0.18	0.54	0.31	0.93	0.00	0.00	0.47	1.42
	H	90	33.48	0.28	0.83	0.07	0.22	0.28	0.82	0.03	0.10	0.40	1.20
RDW-CV %	L	90	15.15	0.24	1.59	0.00	0.00	0.18	1.20	0.56	3.71	0.64	4.21
	N	90	13.23	0.18	1.33	0.03	0.23	0.13	1.01	0.52	3.90	0.56	4.25
	H	90	12.84	0.17	1.33	0.06	0.45	0.13	1.01	0.51	3.95	0.55	4.31
RDW-SD fL	L	90	41.78	0.64	1.53	0.09	0.21	0.21	0.51	1.11	2.66	1.30	3.12
	N	90	39.67	0.38	0.97	0.27	0.68	0.13	0.33	0.94	2.37	1.06	2.67
	H	90	40.12	0.47	1.17	0.28	0.70	0.19	0.48	0.77	1.91	0.96	2.40
PLT $10^3/mm^3$	L	90	72.70	4.04	5.56	2.40	3.30	0.00	0.00	2.67	3.67	5.41	7.44
	N	90	238.64	6.93	2.91	1.96	0.82	1.22	0.51	5.55	2.33	9.18	3.85
	H	90	483.59	9.35	1.93	6.46	1.34	0.00	0.00	7.56	1.56	13.65	2.82
MPV fL	L	90	8.41	0.20	2.38	0.00	0.00	0.04	0.50	0.29	3.46	0.36	4.23
	N	90	8.15	0.10	1.23	0.00	0.00	0.01	0.18	0.26	3.23	0.28	3.46
	H	90	9.26	0.10	1.05	0.00	0.00	0.04	0.38	0.32	3.44	0.33	3.62
LYM# $10^3/mm^3$	L	90	1.08	0.04	3.94	0.01	1.15	0.02	2.30	0.02	2.14	0.06	5.17
	N	90	3.06	0.08	2.51	0.01	0.41	0.04	1.40	0.05	1.74	0.10	3.38
	H	90	3.54	0.08	2.35	0.04	1.21	0.00	0.00	0.04	1.08	0.10	2.86
LYM %	L	90	37.82	1.10	2.91	0.00	0.00	0.75	1.98	0.00	0.00	1.33	3.53
	N	90	37.48	0.62	1.65	0.00	0.00	0.18	0.48	0.15	0.41	0.66	1.77
	H	90	19.64	0.40	2.06	0.08	0.42	0.00	0.00	0.00	0.00	0.41	2.10

Measurand	Level	N	Mean	Within run		Between run		Between day		Between site		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
MON# $10^3/mm^3$	L	90	0.24	0.02	7.83	0.00	0.00	0.00	0.00	0.03	10.95	0.03	13.46
	N	90	0.42	0.03	5.96	0.01	2.68	0.00	0.00	0.02	5.27	0.04	8.40
	H	90	0.51	0.03	6.35	0.00	0.00	0.02	4.27	0.06	11.40	0.07	13.73
MON %	L	90	8.21	0.62	7.56	0.18	2.22	0.00	0.00	1.00	12.21	1.19	14.53
	N	90	5.17	0.29	5.62	0.14	2.70	0.00	0.00	0.35	6.75	0.47	9.19
	H	90	2.82	0.17	6.04	0.01	0.31	0.13	4.51	0.35	12.39	0.41	14.51
NEU# $10^3/mm^3$	L	90	1.30	0.05	4.00	0.02	1.63	0.01	1.12	0.06	4.43	0.08	6.29
	N	90	4.32	0.10	2.26	0.00	0.00	0.04	0.96	0.12	2.79	0.16	3.71
	H	90	12.78	0.18	1.41	0.00	0.00	0.10	0.80	0.30	2.32	0.36	2.83
NEU %	L	90	45.14	1.07	2.37	0.09	0.20	0.52	1.16	0.95	2.10	1.52	3.37
	N	90	52.92	0.70	1.33	0.06	0.11	0.05	0.10	0.75	1.42	1.03	1.95
	H	90	70.98	0.48	0.68	0.28	0.39	0.09	0.12	1.08	1.52	1.22	1.72
EOS# $10^3/mm^3$	L	90	0.12	0.01	11.62	0.01	8.31	0.00	0.00	0.01	9.32	0.02	17.06
	N	90	0.17	0.02	9.66	0.01	3.57	0.00	0.00	0.00	0.00	0.02	10.30
	H	90	0.59	0.03	5.66	0.03	5.28	0.00	0.00	0.02	3.29	0.05	8.41
EOS %	L	90	4.07	0.48	11.73	0.25	6.13	0.00	0.00	0.28	6.92	0.61	14.93
	N	90	2.12	0.19	9.09	0.08	3.98	0.00	0.00	0.00	0.00	0.21	9.93
	H	90	3.30	0.18	5.57	0.15	4.60	0.00	0.00	0.08	2.30	0.25	7.58
BAS# $10^3/mm^3$	L	90	0.14	0.01	9.53	0.00	0.00	0.00	0.00	0.00	3.12	0.01	10.03
	N	90	0.19	0.01	7.31	0.01	3.72	0.01	3.52	0.05	25.98	0.05	27.47
	H	90	0.59	0.02	4.09	0.02	2.90	0.02	3.68	0.16	26.63	0.16	27.35
BAS %	L	90	4.77	0.47	9.83	0.00	0.00	0.00	0.00	0.00	0.00	0.47	9.83
	N	90	2.31	0.16	7.12	0.07	3.18	0.10	4.47	0.64	27.58	0.67	29.00
	H	90	3.26	0.13	3.95	0.10	3.15	0.12	3.69	0.90	27.60	0.92	28.30
IMG# $10^3/mm^3$	L	90	0.17	0.01	7.36	0.01	4.22	0.00	1.07	0.01	8.82	0.02	12.28
	N	90	0.58	0.04	6.24	0.00	0.00	0.02	3.46	0.00	0.00	0.04	7.14
	H	90	1.21	0.07	5.51	0.00	0.00	0.01	0.82	0.02	1.62	0.07	5.81
IMG %	L	90	5.83	0.41	7.04	0.00	0.00	0.21	3.55	0.34	5.78	0.57	9.78
	N	90	7.07	0.40	5.69	0.08	1.14	0.16	2.31	0.18	2.55	0.48	6.74
	H	90	6.74	0.36	5.40	0.00	0.00	0.06	0.85	0.07	1.10	0.38	5.58

2. Linearity

The study was performed to validate the linear range of the Yumizen H550 analyzer reportable whole blood parameters (WBC, RBC, HGB, HCT, and PLT) according to CLSI EP06 2nd Edition. Testing was performed at one site on two instruments with two reagent lots of commercially available linearity kits (CBC-line linearity Kit, Biotechne, K942822). 10 levels were prepared for each measurand and tested in five replicates. All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements. The results are summarized below.

Parameter	Reportable Range
WBC ($10^6/\mu L$)	0.2 – 300
RBC ($10^3/\mu L$)	0.2 – 8
HGB (g/dL)	1 – 24
HCT (%)	2 – 67
PLT ($10^3/\mu L$)	10 – 4000

3. Analytical Specificity/Interference:

The interference studies were performed to evaluate the effect of potential interferences on the Yumizen H550. The study was performed as per CLSI EP07-A3, CLSI EP37- 1st Edition, and CLSI H26-A2.

The susceptibility of the Yumizen H550 to interference of hemoglobin, triglycerides, total bilirubin, conjugated bilirubin, cholesterol, elevated WBCs, elevated RBCs, elevated PLTs,-microcytic RBCs were tested in whole blood samples collected in K2EDTA tubes. Varying concentrations of Hemoglobin, triglycerides, total bilirubin, conjugated bilirubin, cholesterol were spiked into whole blood samples to obtain concentrations. The potentially interfering substance was evaluated using the dose-response method with a single reagent lot on two Yumizen H550 instruments. The observed difference between the test sample (interferent added) and the control sample was compared to the pre-established allowable difference. Additionally, representative patient specimens and control samples (without interferent) were run in comparison to the comparative measurement instrument (K232946). A visual inspection of the difference plot of the test group and the control group is performed. All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements. The results are summarized below.

Interferent	**Up to Level**	**Affected Parameters**
Hemolysis	0.54 g/dL	MCHC
	0.74 g/dL	WBC
Lipemia	1.5g/dL	None
Unconjugated Bilirubin	40 mg/dL	None
Conjugated Bilirubin	40 mg/dL	None
Thrombocytosis (Elevated Platelets)	800 $\times 10^3/mm^3$	None
Leukocytosis (Elevated WBCs)	100 $\times 10^3/mm^3$	RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD
Microcytosis	75 fL	RDW-CV, PLT, MPV
Erythrocytosis	5.7 ×106/mm³	PLT

4. Reportable Range:

The upper limit of the assay reportable range for each of the parameters was determined by the linearity studies and lower limit were determined by the LoQ and linearity studies. All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements. The results are summarized below.

Parameter	**Reportable Range**
WBC ($10^6/\mu L$)	0.2 – 300
RBC ($10^3/\mu L$)	0.2 – 8
HGB (g/dL)	1 – 24
HCT (%)	2 – 67
PLT ($10^3/\mu L$)	10 – 4000 (HBG< 1.5 g/dL)

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

Whole Blood Sample Stability
A study was conducted to evaluate the stability of whole blood samples collected in K2EDTA when stored at room temperature and under refrigerated conditions. A total of 35 whole blood samples were analyzed at two sites on two Yumizen H550 analyzers. Following collection, samples were split into two sets, 15 samples stored at room temperature (20−24ºC) and 20 other samples stored under the refrigerated condition (2−8ºC). Room temperature samples were tested at T=0, 4, 10, 14, 16, 18, 20, 22, 24, and 27 hours and refrigerated samples were tested at T=0, 24, 28, 32, 40, 42, 44, 46, 48, and 50 hours in duplicate. The data supports sample stability of 24 hours at room temperature (20−24ºC) for all whole blood parameters and 48 hours at refrigerated conditions (2−8ºC) for all whole blood parameters.

6. Detection Limit:

Limits of Blank (LoB), Limit of Detection (LoD) and the Limit of Quantification (LoQ) were determined for WBC, TNC, RBC, HGB, HCT and PLT according to CLSI EP17-A2.

In LoB studies, testing was conducted over a minimum of five days using six blank samples (ABX DILUENT), with two different reagent lots on two different analyzers, each sample being run in ten replicates. The results obtained from all samples were used to calculate the LoB for each measurand.

In LoD studies, testing was conducted over a minimum of three days using six low concentration whole blood samples, with two different reagent lots on two different analyzers, each sample being run in ten replicates. The results obtained from all samples were used to calculate the LoD for each measurand.

In LoQ studies, testing was conducted over a minimum of three days using at least four low concentration whole blood samples, with two different reagent lots on two different analyzers, each sample being run in ten replicates. The results obtained from all samples were used to calculate the Mean, Total error, and LoQ for each measurand.

All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements. The results are summarized below.

Measurand	Results		
	LoB	LoD	LoQ
WBC (10^3/µL)	0.15	0.20	0.20
RBC (10^6/µL)	0.03	0.05	0.20
HGB (g/dL)	0.3	0.4	1.0
HCT (%)	0.1	0.3	2.0
PLT (10^3/µL)	5	8	10

7. Assay Cut-Off:
   Not applicable

8. Carry-Over:
   In accordance with CLSI H26-A2 guide, carryover was evaluated three times on three instruments by testing alternatively low, high and low WBC, RBC, HGB, PLT concentration samples at one test site. K2EDTA whole blood samples with low WBC, RBC, HGB and PLT counts were tested three consecutive times (LC1, LC2, LC3) followed immediately by testing samples with high target values consecutively three times (HC1, HC2, HC3). Finally, the low samples were processed another three times (LC4, LC5, LC6). The percentage of carry-over is calculated using the following formula:

   All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Method comparison studies were performed at three clinical sites (two sites in U.S. and one site in France) to assess the performance of the Yumizen H550 when compared to the predicate device, Yumizen H2500 (K232946). A total of 862 venous and/or capillary samples collected in K2EDTA from both pediatric (neonate to ≤21 years) and adult subjects including a wide variety of disease states/clinical conditions were tested across three clinical sites. Less than 4.9% of samples tested in study were contrived to cover the reportable range for various parameters. Each sample was tested within eight hours ambient or 24 hours refrigerated of collection in two replicates on both Yumizen H550 and Yumizen H2500. First replicate was used for analysis. Samples were tested on the Yumizen H550 and the Yumizen H2500 within three hours of each other.

   A Passing-Bablok regression analysis was performed. Bias at MDLs were also evaluated for all sites combined. All results were within the predefined acceptance criteria. Overall, the Yumizen H550 demonstrated comparable performance to the predicate device, Yumizen H2500 for its intended use.

   A summary of the regression analysis results for all sites combined is presented in table below.

Measurand	N	Range	Intercept [95%CI]	Slope [95%CI]	R
WBC	862	[0.42; 278.25]	0.049 [0.017; 0.085]	0.997 [0.991; 1.002]	0.999
RBC	861	[0.41; 7.55]	0.073 [0.054; 0.091]	0.975 [0.970; 0.980]	0.994
HGB	859	[1.10; 23.90]	0.443 [0.391; 0.505]	0.952 [0.947; 0.957]	0.988

Measurand	N	Range	Intercept [95%CI]	Slope [95%CI]	R
HCT	859	[3.50; 66.90]	0.752 [0.492; 1.013]	0.970 [0.962; 0.977]	0.989
MCV	861	[58.80; 130.60]	-0.400 [-1.291; 1.137]	1.000 [0.984; 1.010]	0.971
MCH	858	[18.30; 57.20]	1.006 [0.51; 1.45]	0.962 [0.947; 0.979]	0.950
MCHC	858	[29.20; 56.10]	-3.255 [-6.72; 0.00]	1.095 [1.000; 1.200]	0.315
RDW-SD	861	[27.40; 98.90]	8.508 [7.48; 9.53]	0.803 [0.781; 0.828]	0.917
RDW-CV	851	[10.60; 25.70]	2.400 [2.024; 2.780]	0.825 [0.800; 0.852]	0.912
PLT	860	[11.00; 3551.00]	2.733 [1.013; 4.468]	0.981 [0.974; 0.989]	0.996
MPV	860	[6.30; 13.70]	-0.733 [-0.980; -0.491]	1.074 [1.048; 1.100]	0.929
LYM#	766	[0.04; 215.40]	0.028 [0.012; 0.042]	1.030 [1.020; 1.039]	0.996
LYM%	766	[0.80; 94.30]	0.539 [0.352; 0.742]	1.017 [1.010; 1.026]	0.989
MON#	776	[0.00; 53.10]	0.000 [-0.017; 0.000]	1.000 [1.000; 1.034]	0.955
MON%	776	[0.10; 68.20]	0.435 [0.217; 0.636]	0.941 [0.918; 0.970]	0.946
NEU#	788	[0.02; 82.61]	0.030 [0.003; 0.051]	0.982 [0.975; 0.988]	0.996
NEU%	789	[1.10; 95.20]	-0.600 [-0.912; -0.114]	1.000 [0.992; 1.006]	0.992
EOS#	832	[0.00; 7.83]	-0.010 [-0.010; -0.010]	1.000 [1.000; 1.000]	0.973
EOS%	833	[0.00; 41.30]	-0.200 [-0.218; -0.100]	1.000 [1.000; 1.029]	0.979
BAS#	819	[0.00; 8.14]	0.001 [0.000; 0.003]	0.917 [0.727; 1.000]	0.898
BAS%	820	[0.00; 6.20]	0.067 [0.033; 0.100]	0.667 [0.538; 0.750]	0.512
IMG#	772	[0.00; 96.71]	-0.006 [-0.010; -0.003]	0.911 [0.836; 1.000]	0.914
IMG%	772	[0.00; 49.20]	-0.100 [-0.100; -0.096]	1.000 [0.986; 1.000]	0.929

2. Matrix Comparison:

K2EDTA vs K3EDTA

A study was conducted to evaluate the equivalence of K2EDTA and K3EDTA anticoagulants on Yuzimen H550 hematology analyzer, using 131 paired whole blood samples (including 13 contrived) collected from two US sites analyzed in duplicate via DIF mode. First run was used for the analysis. A Passing-Bablok (non-parametric) regression was used for all measured and reported parameters, excepted for BAS and IMG parameters. The slope, intercept, and the two-sided 95% CIs around the slope and intercept were calculated. Predicted absolute and relative bias and their 95% CIs were calculated at MDLs. Acceptance criteria were met for all parameters at all results.

Venous versus Capillary Whole Blood
A study was conducted to evaluate the comparability of matrices (venous versus capillary) using whole blood samples tested on the Yumizen H550. A total of 79 normal and pathological paired capillary and venous whole blood samples collected in K2EDTA were tested in the study. The samples from donors covered all relevant MDLs and AMR. The study was performed in DIF mode. The slope, intercept, and the two-sided 95% CI around the slope and intercept were calculated. The predicted bias and % bias, as well as the two-sided 95% CI around the bias and % bias, were calculated around the MDLs. All reportable parameters that were evaluated met the predefined acceptance criteria, demonstrating the equivalency between the two matrices (K2EDTA capillary and K2EDTA venous whole blood) on the Yumizen H550.

C Clinical Studies:

1. Clinical Sensitivity:

Clinical sensitivity/specificity studies were conducted to evaluate the flagging capabilities of the Yumizen H550 using the flagging results obtained from the samples in the method comparison study. The study was conducted at three clinical sites as per CLSI H20-A2 guidelines using a total of 250 residual whole blood samples (102 normal samples with no flags, marked as negative and 148 flagged abnormal samples). Three peripheral blood smears were prepared for each sample for manual microscopy counts. A 2x2 table was constructed to determine sensitivity and specificity for both distributional and morphological abnormalities. The sample size (N), number of true positives (TP), false positives (FP), true negative (TN), false negatives (FN), sensitivity, specificity, and overall percent agreement are presented in the following table.

Distributional Classification		**Manual**		
		Positive (Abnormal)	**Negative (Normal)**	**Total**
YH550	**Positive (Abnormal)**	137	2	139
	Negative (Normal)	8	103	111
	Total	145	105	250
Positive Agreement: 98.6% (95% CI: 94.91% – 99.60%)				
Negative Agreement: 92.8% (95% CI: 86.37% – 96.34%)				
Sensitivity: 94.5% (95% CI: 89.41% – 97.20%)				

Specificity: 98.1% (95% CI: 93.35% – 99.47%)
Efficiency: 96.0% (95% CI: 92.83% – 97.80%)

Morphological		Manual		
		Positive (Abnormal)	**Negative (Normal)**	**Total**
YH550	**Positive (Abnormal)**	90	17	107
	Negative (Normal)	11	132	143
	Total	101	149	250
Positive Agreement: 84.11% (95% CI: 76.01% – 89.87%)				
Negative Agreement: 92.31% (95% CI: 86.72% – 95.67%)				
Sensitivity: 89.11% (95% CI: 81.65% – 93.79%)				
Specificity: 88.59% (95% CI: 82.55% – 92.74%)				
Efficiency: 88.80% (95% CI: 84.34% – 92.12%)				

Morphological or Distributional Overall		Manual		
		Positive (Abnormal)	**Negative (Normal)**	**Total**
YH550	**Positive (Abnormal)**	137	2	139
	Negative (Normal)	11	100	111
	Total	148	102	250
Sensitivity: 92.6% (95% CI: 87.18% – 95.80%)				
Specificity: 98.0% (95% CI: 93.13% – 99.46%)				
Efficiency: 94.8% (95% CI: 91.31% – 96.94%)				
Positive agreement (PPV): 98.6% (95% CI: 94.91% – 99.60%)				
Negative agreement (NPV): 90.1% (95% CI: 83.12% – 94.38%)				

2. Clinical Specificity:
   See clinical sensitivity.

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

D Clinical Cut−Off:
Not applicable

E Expected Values/Reference Range:

Reference range studies were performed according to CLSI EP28-A3.

Adult Whole Blood Reference Range
The reference validation study was conducted at two clinical sites located in U.S. using venous K2EDTA whole blood samples collected from a total of 55 apparent healthy adults (>21 years of age) comprising of 31 males and 24 females. Each sample was tested in one replicate on Yumizen H550. The lower and upper limits of the 95% reference intervals were determined based on the 2.5^{th} and 97.5^{th} percentiles of all valid measurements for each sex group, respectively. The results are summarized below.

Parameter	Female	Male
WBC ($10^3/mm^3$)	3.78-11.42	4.05-11.00
RBC ($10^6/mm^3$)	3.93-5.19	4.28-5.79
HGB (g/dL)	11.50-15.10	13.40-16.70
HCT (%)	34.40-44.60	39.20-48.60
MCV (fL)	74.70-95.60	79.60-97.00
MCH (pg)	26.40-32.60	27.30-32.80
MCHC (g/dL)	31.90-35.80	32.40-36.30
RDW-CV (%)	12.00-18.00	12.00-18.00
RDW-SD (fL)	37.00-56.00	37.00-56.00
PLT ($10^3/mm^3$)	185.00-445.00	161.00-398.00
MPV (fL)	7.50-10.90	7.40-10.80
LYM% (%)	15.00-45.00	15.00-45.00
MON% (%)	4.00-13.00	4.00-13.00
NEU% (%)	40.00-75.00	40.00-75.00
EOS% (%)	0.50-7.00	0.50-7.00
BAS% (%)	0.00-2.00	0.00-2.00
IMG% (%)	0.00-2.00	0.00-2.00
LYM# ($10^3/mm^3$)	1.24-3.97	1.24-3.92
MON# ($10^3/mm^3$)	0.19-0.71	0.23-0.77
NEU# ($10^3/mm^3$)	1.69-7.50	1.78-6.95
EOS# ($10^3/mm^3$)	0.04-0.55	0.04-0.55
BAS# ($10^3/mm^3$)	0.00-0.09	0.00-0.10
IMG# ($10^3/mm^3$)	0.00-0.10	0.00-0.10

Pediatric Reference Range
The pediatric reference range study was conducted at two clinical sites located in U.S. The study was performed using 98 pediatric venous or capillary whole blood samples collected in K2EDTA from apparent healthy pediatric patients in subcategories neonates (20 samples), infants (30 samples), children (28 samples) and adolescents (21 samples). Each of the samples was analyzed on one Yumizen H550 device for all parameters. The study was conducted

using CLSI EP28-A3c recommendations using the robust method to determine the most appropriate weighed mean and calculate the desired reference interval of all valid measurements for each age group. The results are summarized below.

Parameter	Neonate / Infant	Child / Adolescent
WBC ($10^3/mm^3$)	6.12 - 19.38	4.35 – 10.40
RBC ($10^6/mm^3$)	3.04 - 5.30	3.92 - 5.39
HGB (g/dL)	9.2 – 19.1	10.7 – 16.1
HCT (%)	28.2 – 58.0	32.6 - 46.9
MCV (fL)	69 – 126	64 - 97
MCH (pg)	23.0 – 40.3	21.0 – 32.7
MCHC (g/dL)	31.2 - 34.7	32.6 - 34.8
RDW-CV (%)	12.8 – 19.7	11.1 – 16.8
RDW-SD (fL)	37.7 – 79.7	30.4 - 47.8
PLT ($10^3/mm^3$)	114 - 582	165 - 463
MPV (fL)	7.8 – 12.0	7.0 - 12.3
LYM% (%)	5.22 – 84.7	16.9 – 68.4
MON% (%)	0.17 – 20.0	5.12 – 15.4
NEU% (%)	10.8 – 80.6	20.9 – 72.2
EOS% (%)	0.10 – 10.5	0.15 – 16.4
BAS% (%)	0.03 - 1.67	0.00 - 0.88
IMG% (%)	0.20 – 4.75	0.02 – 1.01
LYM# ($10^3/mm^3$)	0.44 – 15.5	1.23 – 5.01
MON# ($10^3/mm^3$)	0.02 – 3.20	0.32 – 1.07
NEU# ($10^3/mm^3$)	1.12 – 7.79	1.11 – 6.75
EOS# ($10^3/mm^3$)	0.01 – 1.28	0.01 - 0.99
BAS# ($10^3/mm^3$)	0.00 - 0.22	0.00 - 0.07
IMG# ($10^3/mm^3$)	0.02 - 0.84	0.00 - 0.10

F Other Supportive Instrument Performance Characteristics Data:

Auto mode vs manual mode

The study was performed to evaluate the comparability between automatic rack mode versus manual (STAT) mode when testing whole blood samples on the Yumizen H550 device. A total of 79 normal and pathological residual whole blood samples collected in K2EDTA covering the relevant MDLs and the analytical measuring range, were tested in automatic rack mode versus manual mode on the Yumizen H550 device at one clinical site. A Passing-Bablok (non-parametric) regression was used for all measured and reported parameters. The results show comparable performance characteristics for all Yumizen H550 modes. The slope and interception of the regression line, and the two-sided 95% CI around the slope and interception were calculated. Predicted absolute and relative bias and their 95% CIs were calculated at MDLs. All results were within the predefined acceptance criteria.

VIII Proposed Labeling:

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