HORIBA

Affordable, Intelligent and Advanced Hematology Solutions

Analyzers with i-DoubleDiff and CoRA ESR

Yumizen H range

Yumizen H500 OT
Yumizen H500 CT
Yumizen H550
Yumizen H500E OT
Yumizen H500E CT
Yumizen H550E

Affordable hematology analyzers with i-DoubleDiff and CoRA ESR

World 1st

Delivering Safe Hematology Care

Comprehensive solutions for small to mid-throughput laboratories

Yumizen H500

Open Tube

Yumizen H500

Closed Tube

Yumizen H550

Auto Loader

Compact Hematology Solution

- Open Tube & Closed Tube versions
- CBC/DIFF Analysis
- 2 reagents use / Analysis
- 37 parameters menu

Full Walk Away Solution

- Auto loader version
- Integrated auto sampler
- Positive identification
- 40 tubes in continuous loading
- Urgent mode

Yumizen H500E

Open Tube

Yumizen H500E

Closed Tube

Yumizen H550E

Auto Loader

ESR Option

- Integrated ESR module
- No increase in instrument footprint
- Available on all models
- Result in 60 seconds

Flexible and adaptable solutions for Hematology Diagnosis

New applications, Configurable options, New instrument versions

Introduction

The compact instrument hematology range, started with the Yumizen H500, and was developed to meet the demand for an affordable and robust 5-population differential analyser that could fit into any laboratory, anywhere in the world

The worldwide success of that instrument sparked the further innovations of a small-footprint autoloading version, the Yumizen H550, plus screening for infectious diseases such as Malaria and Dengue

The next version increased the analytical capability from 27 to 37 parameters and introduced new connectability
This allowed the range to meet more needs in a larger range of laboratories, including oncology

Now the range has been expanded further to introduce new models combining CBC/Diff and ESR plus a software option dedicated to the quality of Blood Bank production

#1 Workflow Management — Dedicated to your laboratory needs

#2 Extended Parameters — Ensure effective diagnosis

#3 Infectious Screening — Cost effective flagging: Malaria & Dengue

#4 ESR Testing — ESR options for combined analysis

#5 Blood Bank Mode* — Dedicated software for RBC, platelet and WBC concentrates

#6 Connectivity — Connect with HELO 2.0
Connect the lab with Yumicare

* Available September 2024

#1 Workflow Management

Dedicated to your laboratory needs

Extensive Applications

Variety of clinical lab environments and clinical settings

Critical care
- Capillary Blood Compatibility
- Fast Testing
- Prediluted Mode

Oncology Care
- WBC Diff Separation
- WBC Immature Cells: IMG, IML, IMM
- Blasts Flagging

Infectious Care
- Malaria & Dengue Screening Flags
- Scoring Flags
- Neutrophils-To-Lymphocyte Ratio

Backup System
- Satellite Labs
- Night Shift Analysis
- Back up to HELO Solution

Health Centers
- Simplicity of use
- HL7 Combined ESR
- Infectious Screening Flags

Blood Banks
- Control of erythrocyte and platelet concentrates
- Control of Cell therapy products and leucocyte concentrates

Expand your analysis possibilities

Different analysis modes
- Standard Patient mode
- Prediluted mode with customized dilution ratio for micro sample volumes
- QC mode for dedicated Difftrol ® QC kits
- Options available – Blood Bank analysis profiles, Infectious screening, ESR

Safe blood testing against pathogens exposure with:
- Closed tube with the Yumizen H500 CT and Yumizen H500E CT
- Sample rack auto loading with the Yumizen H550 and Yumizen H550E

Capillary blood compatibility
Yumizen H500 CT/OT, Yumizen H550 and Yumizen H500E CT/OT, Yumizen H550E are suitable for capillary blood samples with correlation to venous blood

Ergonomic solution

High automation level
- Continuous loading (40 tubes) on autoloading models
- Automatic and scheduled start up and shutdown
- Secured reagent management with unique identification code

Usability
- Intuitive graphical interface with color-coded menus
- Only 2 reagents for hematology analysis
- All maintenance reagents on-board
- No additional reagents for ESR option

Data Management

Data Management options
- Yumizen P8000 Connection
- Data printout with optional printer
- Paperless patient reports results in PDF formats
- 10,000 patient data storage with easy USB export
- Bidirectional host communication: ASTM and HL7 standards
- Save & Restore database and settings

Quality Control Management

Embedded quality control indicators
- iQC indicators: Levey-Jennings flags, Radar Graphs view, XB means
- Overlapping QC when switching QC batches
- eQC testing in different modes
- Repeatability testing mode

Comprehensive Quality Support

HORIBA Medical offers a Quality Program
- QAP - Documentation and support for laboratory accreditation
- QCP – Inter laboratory comparison of QC results
- Hematovision – online cytological atlas
- EQC Validation – list of validated EQC schemes

Report Results Faster

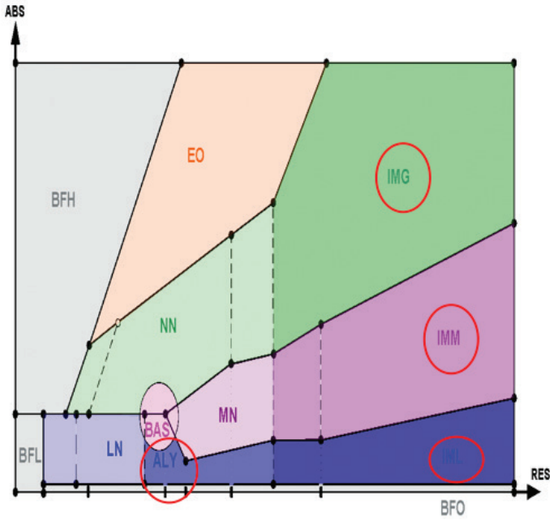
Efficient throughput
60 tests per hour:
- 3 models able to process whole blood samples on 20µL for CBC/Diff
- 3 models able to process whole blood samples on 20µL for CBC/Diff and 180 µL for ESR

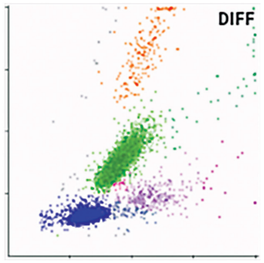
Optional ESR Models
Instruments with both CBC/Diff and ESR capability
Rapid ESR method – result in 60 seconds

Urgent mode
Yumizen H550 and Yumizen H550E able to manage urgent samples in real STAT mode to run closed, open tubes or micro-tubes during routine workflow

WBC: Double Diff* menu for Oncology Care

With the HORIBA patented double hydrodynamic flow-cytometry each WBC is individually mapped for volume and optical properties to provide an extended differential with 3 types of immature cell:
- **IML:** Immature cells of lymphoid lineage with large and granulocytic lymphocytes
- **IMM:** Immature cells of monocytic lineage which could include promonocytes or monoblasts
- **IMG:** Immature cells of granulocytic lineage with precursors cells of myelocytes, promyelocytes and metamyelocytes
- **ALY:** Atypical Lymphocytes as sub population of Lymphocytes for detecting activated lymphocytes, granulocytic lymphocytes, Sezary cells, tricholeucocytes,…



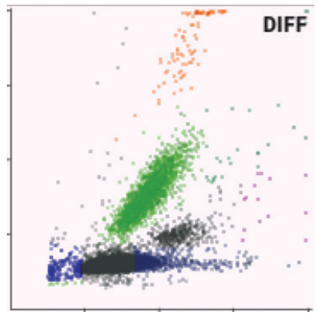


	%	10³/L		%	10³/L
NEU	56.5	4.54	IMG	0.7	0.05
LYM	34.3	2.75	IMM	0.1	0.01
MON	5.4	0.44	IML	0.0	0.00
EOS	3.3	0.26	ALY	1.4	0.12
BAS	0.5	0.04	LIC	0.9	0.08

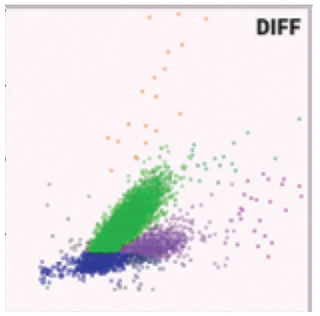
Mobile thresholds capture the populations, adapting to the pathological profile to provide the WBC differential and generate warning flags of any abnormalities
In addition, the matrix provides visual clues to aid diagnosis

*Double Diff = Normal WBC count + Abnormal WBC count

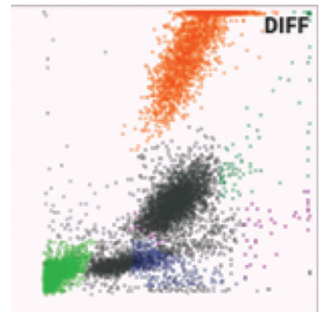
#2 Extended Parameters — Ensure effective diagnosis



Chronic Lymphocytic Leukaemia with atypical and immature lymphoid cells



Myelodysplastic Syndrome Blood film shows hypochromic/ Hyposegmented neutrophils



Myeloproliferative Disorder with eosinophilia, nucleated RBCs and some myelocytes

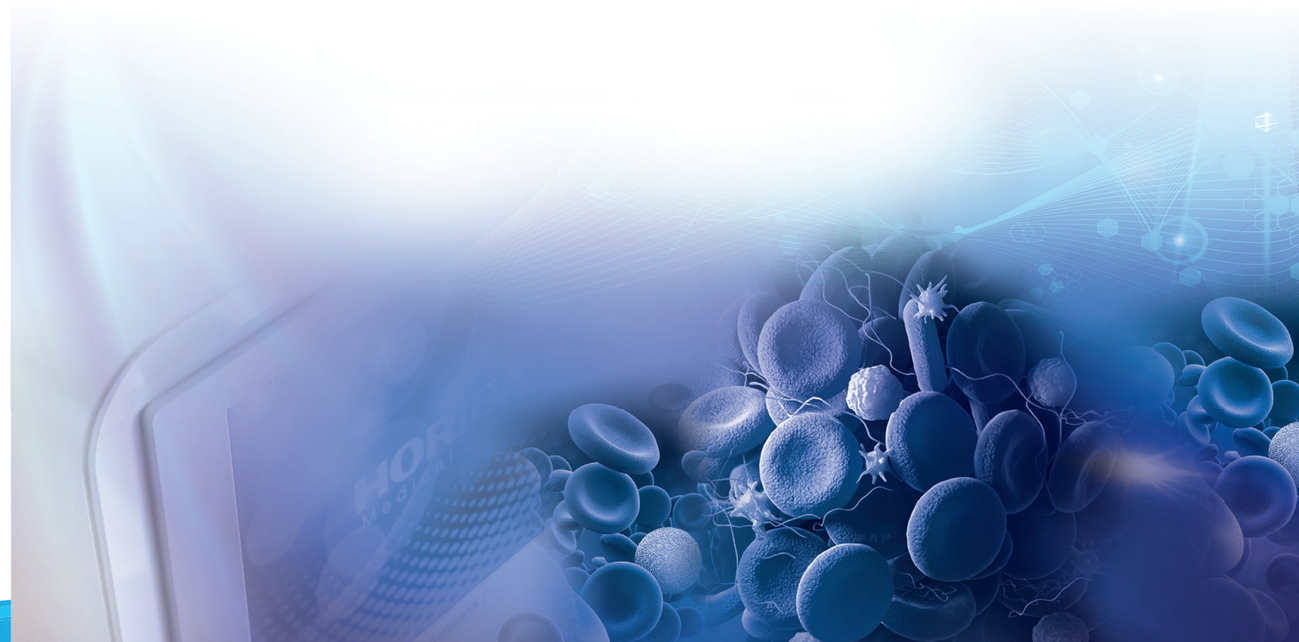
RBC and PLT

Extended parameters for Anemias and Thalassemia

The available parameters include both RDW-CV, RDW-SD plus MIC% and MAC% for further diagnosis of disorders. A comprehensive flagging system includes an assessment of Hypochromia, Anisocytosis, Poikilocytosis and Double populations of red cells

Specific Indices for Platelets Activation at no extra cost

P-LCC and P-LCR (Platelet Large Cells Count & Ratio) provide insight into immature platelets in cases of thrombocytopenia, reactive thrombocytosis or to highlight giant platelets either from inherited disorders or in myeloproliferative syndrome



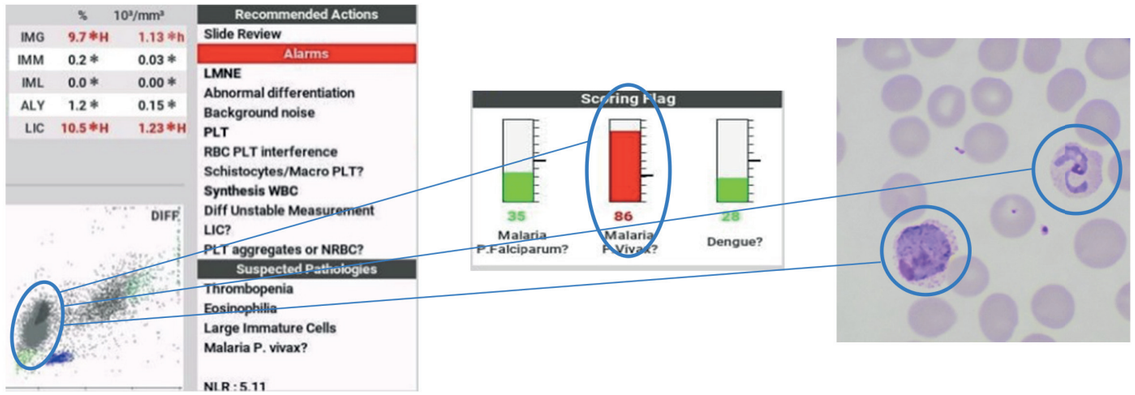
#3 Infectious Screening

Cost effective flagging
Malaria & Dengue

Infectious Screening Flags Combined with Full Blood Count

The Automated Suspicion Flags are available with an optional activation code for:
- Malaria Plasmodium falciparum
- Malaria Plasmodium vivax
- Dengue fever

Flag's methodology and efficiency
- Innovative **machine-learning** techniques
- **Multiple lab** assessment: India and Africa
- **Clinical accuracy:** 70 to 85%
- **S-Flags:** triggering levels & displaying relevancy
- **NLR:** marker of inflammation & infectious monitoring
- Corrected WBC in the case of malaria population in the differential channel



Main Screen
The NLR plus any specific flagging, is displayed on the main result screen under Suspected Pathologies

Expert Screen
S-flags - scoring detail is given for each pathology vs the detection cutoffs

- Flags available in routine use without the need for additional reagent or rerun cycles
- Suspicion of dual/concurrent infections
- Clarity of interpretation
- Improves the speed of diagnosis and reduces requirement for additional testing (cost-saving)

Infectious Screening Flags are optionally available on Yumizen H500 CT/OT, Yumizen H550 and Yumizen H500E CT/OT, Yumizen H550E upon request towards your HORIBA representative

#4 ESR Testing

ESR options for combined analysis

ESR Models

Analysers that combine testing for CBC/Diff with ESR are also available for each instrument type:
Yumizen H500E OT (Open tube sampling)
Yumizen H500E CT (Closed tube sampling)
Yumizen H550E (Autoloading)

Efficient laboratory testing
- Combination of CBC/Extended differential and ESR provide a comprehensive profile to assess inflammatory disease
- Combination of hematology and ESR in the same analyser saves laboratory space
- New CoRA* technology (Fig 1) – result in 60 seconds with under 180µl blood by tracking the early stages of red cell sedimentation
- Calibrated to reference Westergren method as part of the production version
- Less prone to interference and more precise than manual methods
- Graphical data (Syllectogram) plots the formation of rouleaux in the blood
- Detects anomalies in RBC deformability (poikilocytosis flag)

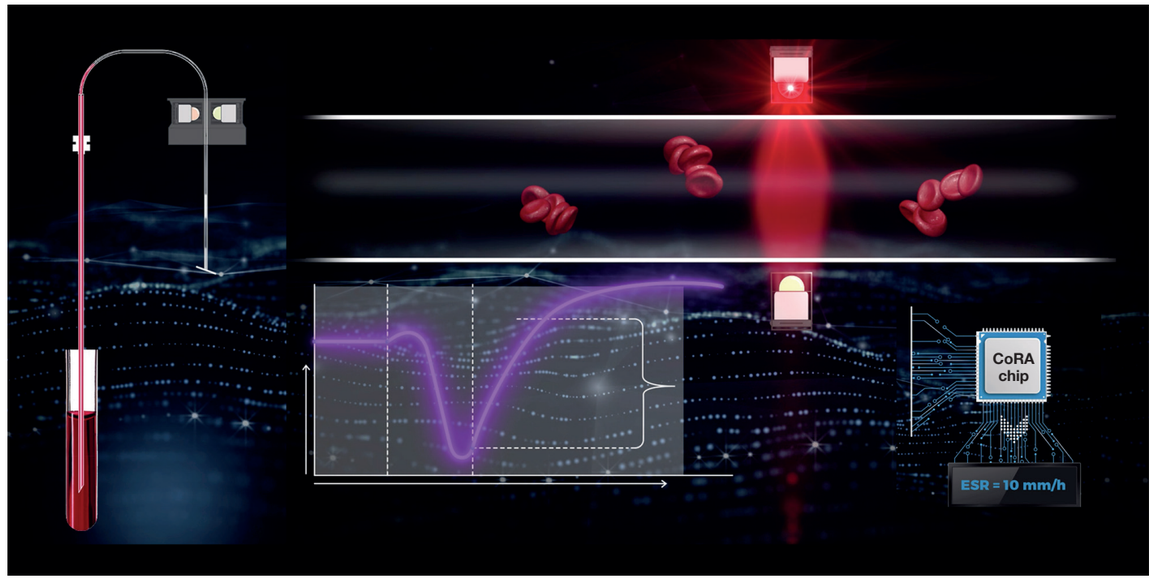


Fig 1: CoRA* Technology process

*CoRA = Correlated Rouleaux Analysis

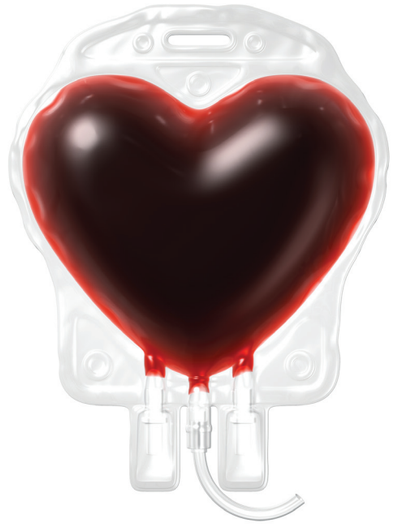
#5 Blood Bank Mode

Dedicated software for RBC, platelet and WBC concentratese

Blood Bank Profiles (optional) Available on Yumizen H550 only

To meet the specific needs of blood transfusion laboratories, HORIBA has developed 3 analysis profiles with specific settings for each type of sample assayed in blood bank quality control and preparation laboratories:

- **Platelet concentrate**
- **Red blood cell concentrate**
- **Concentrated white blood cells**



Easy and affordable:

- Suitable (price/throughput, for low to medium activity)
- No additional reagents (only 3 reagents to manage)
- Standard whole blood profiles still available

Advantages:

The first analyzer for low- to medium- activity laboratories with specific profiles for the analysis of concentrated product: developed to meet the needs of blood bank laboratories

Measurement ranges adapted to the specific characteristics of concentrated blood products => saving of technical time due to a significant reduction in the need for dilutions, rerun, check with another technique

Performances are correlated with reference methods (CD45+ (WBC), microcentrifugation (HCT), etc.)

Thanks to clinical validation done by HORIBA, reducing method validation to a simple verification of system performance

Reduces product losses due to incompatible high values that can occur on an analyzer without specific profiles for analyzing concentrated products

Compatible with Specific quality controls who are titrated controls designed to monitor, respectively, the performance of high blood platelet counting methods and the performance of high haematocrit and haemoglobin measurement methods

#6 Connectivity

Connect with HELO
Connect the lab with Yumicare

Connect with Yumizen P8000

Yumizen Data Management solution

- Links analyser with High-throughput systems Yumizen H2500 and Yumizen H1500
- Allows consolidation of results from satellite labs to the main laboratory
- Facilitates management of satellite laboratories and clinics
  - Quality Control Consolidation
  - Remote validation of results
  - Troubleshooting
- Allows analyser to be used as a 'STAT' analyser in the main laboratory with HELO 2.0
- Connects the ESR parameter of the Yumizen H500E OT/CT or Yumizen H550E
  - Consolidate patient results
  - Avoid a separate interface to LIS

Connect with Yumicare

- Remote technical support tool for compact hematology analysers

Increasing Analyzer Up-time

- Remote Software Update
- Remote troubleshooting by service teams

Managing Quality Control

- Remote QC target values
- Automated QC results transfer to QCP
- Facilitating Analyser Activity
- Managing reagent deliveries

Specifications

PHYSICAL SPECIFICATIONS

Dimensions & Weight:
Height Width Depth Weight

Yumizen H500 OT / Yumizen H500E OT
39.7 x 47.7 x 48.3 cm 22 kg
15.63 x 18.78 x 19.02 in. 49 lbs

Yumizen H500 CT / Yumizen H500E CT
39.7 x 47.7 x 48.3 cm 23.5 kg
15.63 x 18.78 x 19.02 in. 51 lbs

Yumizen H550 / Yumizen H550E
53 x 66.8 x 62.1 cm 35 kg
20.87 x 26.3 x 24.45 in. 78 lbs

Printer (optional):
Compatible models with Linux drivers

Throughput:
60 samples/hour all sampling modes

Sample Management (Yumizen H550):
Autonomy of 40 tubes in 1 hour
Continuous Loading
STAT Mode
Rack Automatic Mixing
Tubes Positive Identification

Analysis Mode:
Patient, Prediluted, iQC (Difftrol),
eQC (External)

Sound Level: 60 dBa

Operating Temperature & Humidity:
+15°C (+59°F) to + 30°C (+86°F)
Relative humidity up to 80% maximum,
without condensation

Specimen Type & Volume:
Human venous and capillary blood
EDTA K2, EDTA K3 anticoagulant
CBC mode: 20µL
DIF mode: 20µL
ESR mode: up to 180 µL depending
on sample viscosity

Power Requirements:
Power Supply: AC/DC adapter (external) 24 Vdc
Power consumption: 180 VA
Heat output: 378 KJ/h

Reagents:
2 reagents for analysis :
ABX Diluent (10L or 20L)
Whitediff 1L (cyanide free)
1 reagent for daily shutdown : ABX Cleaner 1L

ECO FRIENDLY SOLUTION

LED light source
Cyanide free lysis reagent
Low reagents consumption: < 20 µL/test
WEEE Standard compliance

MEASUREMENT PRINCIPLES

WBC & Differential

Methods:
- Cytometry :
  Double Hydrodynamic Sequential System 'DHSS'
- Optical Reading : Absorbance
- Impedance Variation

HGB Measurement

Method:
- Spectrophotometry

RBC & PLT Detection

Methods:
- Impedance Variation
- Analogic Digital Conversion

HCT Measurement Method:
- Analogical integration

ESR Method:
- Optical measurement
of red cell agglomeration

SOFTWARE SPECIFICATIONS

- Data Processing
Color LCD touch screen: 12,1 in.
Operating System: Linux™
Connection: RS232, Ethernet, USB
Communication: ASTM & HL7 protocols
Capacity: 10 000 results + graphs
Options: keyboard, mouse and bar code reader

- Quality Control
ESR - 2 Controls levels (normal, high)

CBC/Dif - 3 controls levels (low, normal, high)
Target values download
QC results compatible with
HORIBA Medical Quality Control Program (QCP)
Levey-Jennings graphs
Radar graphs
XB on 3 or 9 parameters
Overlapping QC (Diff - 6 active QC files,
ESR - 4 active files)

- Yumicare®
Connected service option:
LAN, Wifi, 4G
Automatic QC management
(target values download and QC results
upload to QCP)
Analyzer activity monitoring
Consumption management
Remote software update
Predictive maintenance

PARAMETERS & PERFORMANCE DATA

37 Parameters:
(38 including ESR for Yumizen H500E (CT/OT) and
Yumizen H550E
WBC
NEU# & NEU%
LYM# & LYM%
MON# & MON%
EOS# & EOS%
BAS# & BAS%
IMG# & IMG%
IML# & IML%
IMM# & IMM%
ALY# & ALY%
LIC# & LIC%

RBC
HGB
HCT
MCV
MCH
MCHC
RDW-CV
RDW-SD
MIC
MAC

PLT
MPV
PCT
PDW
P-LCC
P-LCR

ESR

NLR (Neutrophil-To-Lymphocyte Ratio)

Infectious Screening Flags (Option)
Plasmodium falciparum, *Plasmodium vivax*, Dengue fever
Scoring flags

Analytical Measurements Range:

Linearity Limits	Visible Range	Unit
WBC 0 - 300	300 - 999	10^9/L
RBC 0 – 8	8 - 18	10^{12}/L
HGB 0 – 240	240 - 300	g/L
HCT 0 - 0.67	0.67 - 0.80	L/L
PLT 0 - 2500	2500 - 4000	10^9/L
PLT (concentrate)		
0 – 4000	4000 - 5000	10^9/L
ESR	0 – 120	mm/hr

Limit Of Quantification	Unit
WBC 0,2	10^9/L
RBC 0,2	10^{12}/L
HGB 10	g/L
PLT 10	10^9/L
ESR N/A	

Precision (Repeatability):

Parameters CV (%)	Range	Unit
WBC <3.0	4 – 10	10^9/L
RBC <2.0	3.6 – 6.2	10^{12}/L
HGB <1.5	120 – 180	g/L
HCT <2.0	0.36 – 0.54	L/L
PLT <5.0	180 – 500	10^9/L
ESR <10	0 - >20	mm/hr

CE IVD

Certified
ISO 9001 :2015
ISO 14001 :2015
ISO 13485 :2016
MDSAP – Medical Device Single Audit Program

HORIBA

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