

**HORIBA**  
Medical

**Installation Qualification, Performance,  
Qualification and Operational  
Qualification**

**YUMIZEN H500**

(Serial no: **802YOXH01328**)

Five Part Hematology Analyzer

For

**MEDRAY CLINICS PVT LTD**

**# 962 12th main Rd, opp. to Lakmé Salon,  
Doopanahalli, Indiranagar,  
Bengaluru 560008**

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**General Instructions:**

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H500, Five Part Hematology Analyzer, at MEDRAY CLINICS PVT LTD, BENGALURU as per the attached protocol.
- An authorized HORIBA India Pvt. Ltd., representative will physically check the system and proceed for the installation.
- This installation protocol will be followed as specified by the manufacturer.
- Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.
- After the installation of the system, Instrument calibration & QC will be performed by the authorized HORIBA India Pvt. Ltd. representative.
- An authorized HORIBA India Pvt. Ltd. representative will also perform the precision check on the system to check if it is as per the claim of the manufacturer.
- The results obtained for Calibration, QC & Precision checks will be verified by the qualified trained employee of MEDRAY CLINICS PVT LTD, BENGALURU along with an authorized HORIBA India Pvt. Ltd., representative.
- On completion of the Installation all the necessary documents of the System checks will be used to evaluate the instrument installation in accordance with the manufacturer's protocol and intended use.
- An authorized HORIBA India Pvt. Ltd., representative will verify the documents of the system checks and approve the same.
- Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage.

**Report Sign Off**

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Yeshwanth Padashetty		
Title:	Sign:	Date: 18/07/2023	
ENGINEER-CUSTOMER SUPPORT			
Reviewed by:	MEDRAY CLINICS PVT LTD, BENGALURU		
Name:	A. Jayudu Prasarath.		
Title:	Sign:	Date: 18/07/23	
Lab Incharge			
Approved by:	MEDRAY CLINICS PVT LTD, BENGALURU		
Name:	A. Jayudu Prasarath		

**HORIBA**  
Medical

HORIBA India Private Limited

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YUMIZEN H500

(Serial no: **802YOXH01328**)

Five Part Hematology Analyzer

**Installation Qualification**

For

**MEDRAY CLINICS PVT LTD**

**# 962 12th main Rd, opp. to Lakmé Salon,  
Doopannahalli, Indiranagar,**

**Bengaluru 560008**

**#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.**

Visit us: <http://www.horiba.com/in/>

**A. Installation Qualification****1. Installation Requirement:**

Sr. No.	Description	Compliance (Yes/No)	Verified by & Date
1.	Environmental conditions: Indoor Location not exposed to sunlight, water and vibration free platform. Temperature of 16°C to 34°C and maximum relative humidity of 80%.	Yes	18/07/2023
2.	Physical Space Requirement: 36(W) x 36(D) x 53(H)cm with at least 20 cm space at the back of the instrument from the wall.	Yes	
3.	Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 165 VA with earth less than 3 V.	Yes	
4.	UPS connection available.	Yes	

**2. The instrument has been checked for the following:**

Sr. No.	Verification	Provided (Yes/No)	Verified by & Date
1.	Instrument is identified Instrument Serial No.:802YOXH01328	Yes	18/07/2023
2.	Manufacturer's specifications: Technical and Physical Requirement	Yes	
3.	Accessories / consumables are listed as per checklist (Provided along)	Yes	
4.	System checked for any External / physical damage.	Yes	
5.	Instrument User Manual (Soft Copy)	Yes	

**2. Equipment Description:**

YUMIZEN H500, Five Part Hematology Analyzer

<b>Instrument Identification</b>	<b>Verified Yes/No</b>	<b>Verified by / Date</b>
Equipment Type: Hematology Analyzer	YES	<b>18/07/2023</b>
Model: YUMIZEN H500	YES	
Manufacturer: HORIBA Medical, France	YES	
Marketed By: HORIBA Medical - HORIBA India Pvt. Ltd.	YES	
Equipment #: One	YES	
Serial Number : <b>802YVOXH01328</b>	YES	
Dimensions :33 (W) x 66,8(D) x 62.1(H) Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz Power Consumption: 165 VA	YES	

**4. Accessories/Consumables:**

The accessories were supplied with the instrument as per the check list. Check & verified in case they are found to be in order.

<b>Qualified Trained employee name</b>	<b>Verified By</b>	<b>Date</b>
<b>Rajesh A</b>		
Yeshwanth Padashetty		
Sreesagar Deepak. B. N		
Mithun Krishna C U		

**3. Preventive Maintenance:**

The routine preventive maintenance of the system will be carried out by an authorized HORIBA India Pvt. Ltd., engineer at a specified time interval as recommended by the manufacturer.

**4. Spare Parts:**

HORIBA India Pvt. Ltd strongly recommends the end user to maintain a basic consumable parts onsite to minimize down time due to minor failures. Spare parts as provided in the installation kit.

**B. Installation Procedure:**

1. Putting the system at the predefined and pre inspected location (Having suitable Working Conditions).
2. Removal of the internal packing material of the system.
3. Place the Instrument on the bench top (Vibration free).
4. Connect the Power cord to the YUMIZEN H500.
6. Turn on the inbuilt Printer.
7. All the operating software has been loaded in to YUMIZEN H500.
8. Now from backside of the instrument turn the power switch ON. YUMIZEN H500 goes through its power up and self-test sequence.
9. The YUMIZEN H500 login menu is displayed after the Start up cycle is completed. Enter the credentials.

## C. INSTALLATION CERTIFICATE:

Instrument Name : YUMIZEN H500.



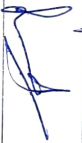
Serial Number : 802YOXH01328

Customer Details : MEDRAY CLINICS PVT LTD,

With complete address : # 962 12th main Rd, opp. to Lakmé Salon, Doopannahalli,  
Indiranagar, Bengaluru 560008

Installation Date : 14/05/2018

Warranty expires on : CMC

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Yeshwanth Padashetty		
Title:	Sign:	Date: 18/07/2023	
Customer Support Engineer			
Reviewed by:	MEDRAY CLINICS PVT LTD, BENGALURU		
Name:	A. Lourdu Prasanth		
Title:	Sign:	Date: 18/07/23	
Lab Incharge			
Approved by:	MEDRAY CLINICS PVT LTD, BENGALURU		
Name:	A. Lourdu Prasanth.		
Title:	Sign:	Date: 18/07/23	
Lab Incharge			

**Conclusion:** Instrument has been qualified for Installation. Hence it has been taken for Operational Qualification.



**HORIBA**  
Medical

HORIBA India Private Limited

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Medical

YUMIZEN H500

(Serial no: **802Y0XH01328**)

Five Part Hematology Analyzer

**Operational Qualification**

For

**MEDRAY CLINICS PVT LTD**

**# 962 12th main Rd, opp. to Lakmé Salon,  
Doopanahalli, Indiranagar,  
Bengaluru 560008**

**#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.**  
Visit us: <http://www.horiba.com/in/>

**A. Operational Qualification****1. Instrument Identification:**

Instrument Name : YUMIZEN H500  
Serial Number : 802YOXH01328

**2. Following is the list of actions performed and verified for running the system routinely.**

Sr. No.	Test Name	Test Purpose	Method	Observation	Verified Sign/Date
1.	SYSTEM SWITCH ON	TO CHECK THE ERROR FREE POWER UP.	Switch on the main, switch on the system. Login into yumizen Application software. Start up cycle is performed. Login in as User and check for the Screen Errors.	Done	18/07/2023
2.	STARTUP CYCLE	TO CHECK THE BACK GROUND IS OK.	Run a startup cycle from the main menu: check if the background is in the acceptable range.	Done	
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	Done	
4.	REAGENT STATUS	TO CHECK ADEQUATE REAGENT IS AVAILABLE FOR ANALYSIS	Manually check in the reagent bottles or else change the reagent from the Status Menu.	Done	
5.	SAMPLE ANALYSIS	TO CHECK PROPER FUNCTIONING OF SAMPLE ANALYSIS	1. To run Stat/ Manual sample, press on sample identification and enter the sample ID and press on validate.	Done	
6.	ARCHIVE AND CURRENT REPORTS	TO RECOVER THE SAMPLE RESULT FROM ARCHIVE AND CURRENT REPORTS	Press on Results History icon and view the current results. To view archived reports, Select Archive results and select the date of the reports and view the report.	Done	

7.	QUALITY CONTROL DATA	TO RECOVER QUALITY CONTROL DATA AND LJ GRAPH	Press on QC Icon from the Main Menu and select the Lot No. and press on Print Icon to print LJ graph. To view on QC Runs ,Click on Datas .	Done	18/07/2023
8.	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.	Done	

**B. Operational Training Record**

**Operator Training:** The users responsible for the operation of this instrument will be trained on the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filled as indicated below:

Sr. No.	Operators	Designation	Name & Sign of the Trainer	Date
1.	A Jayadev Pragasath	Lab Engineer	A. Jayadev	22/09/22
2.	Trivedi	Lab Tech	A. Jayadev	22/09/22
3.	Supritka	Lab Tech	A. Jayadev	01/10/22
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
16.				

**C. Operator Maintenance Protocol**

**Maintenance and Troubleshooting:** Perform Concentration Cleaning as advised by the HORIBA Medical Representative. Run a Shutdown cycle before switching off the analyzer.

## D. OPERATIONAL CERTIFICATE:

Instrument Name : YUMIZEN H500.


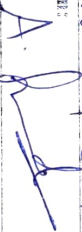

Serial Number : 802Y0XH01328

Customer Details : MEDRAY CLINICS PVT LTD,

With complete address : # 962 12th main Rd, opp. to Lakme Salon, Doopannahalli,  
Indiranagar, Bengaluru 560008

Installation Date : 14/05/2018

Warranty expires on : CMC

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Yeshwanth Padasubety		
Title:	Sign:	Date: 18/07/2023	
Customer Support Engineer			
Reviewed by:	MEDRAY CLINICS PVT LTD, BENGALURU		
Name:	A Jeurdu Prasanth		
Title:	Sign:	Date: 18/07/23	
Lab Incharge			
Approved by:	MEDRAY CLINICS PVT LTD, BENGALURU		
Name:	A Jeurdu Prasanth		
Title:	Sign:	Date: 18/07/23	
Lab Incharge			

Conclusion: Instrument has been qualified for Operational. Hence it has been taken for Performance Qualification.

# HORIBA

Medical

YUMIZEN H500

(Serial no: **802YOXH01328**)

Five Part Hematology Analyzer

**Design Qualification**

For

**MEDRAY CLINICS PVT LTD**

**# 962 12th main Rd, opp. to Lakmé Salon,**

**Doopanahalli, Indiranagar,**

**Bengaluru 560008**

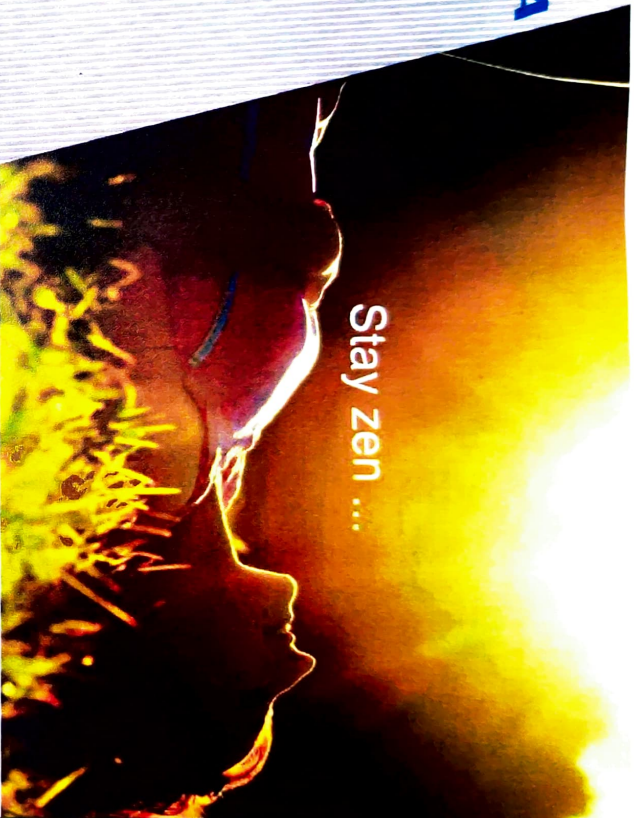
**A. Design Qualification**

This is to certify that Hematology analyzer specially designed for perform the following parameters:

1. WBC = White Blood Cell Count
2. RBC = Red Blood Cell Count
3. HGB = Hemoglobin Concentration
4. HCT = Hematocrit
5. MCV = Mean Corpuscular Volume
6. MCH = Mean Corpuscular Hemoglobin
7. MCHC = Mean Cellular Hemoglobin Concentration
8. PLT = Platelet Count
9. RDW-CV = Red Cell Distribution Width (Coefficient of Variation)
10. RDW-SD = Red Cell Distribution Width (Standard Deviation)
11. PDW = Platelet Distribution Width
12. MPV = Mean Platelet Volume
13. PCT = Plateletcrit
14. P-LCC # = Platelet Large Cell Concentration
15. P-LCR % = Platelet Large Cell Ratio
16. NEUT# = Neutrophil Count
17. LYMPH# = Lymphocyte Count
18. MONO# = Monocyte Count
19. EOSI# = Eosinophil Count
20. BASO# = Basophil Count
21. NEUT% = Neutrophil Percent
22. LYMPH% = Lymphocyte Percent
23. MONO% = Monocyte Percent
24. EOSI% = Eosinophil Percent
25. BASO% = Basophil Percent
26. LIC# = Large Immature Cells Count
27. LIC% = Large Immature Cells Percent



**HORIBA**  
Medical



Stay zen ...

The Yumizen effect !

- 6 Part Hematology Analyser
- Only 2 Reagents per Analyser
- DHSS & VCF
- Complete Platelet Indices
- Artificial Intelligence System
- Color Patient Report



**Yumizen**  
H500

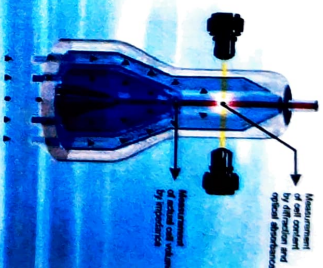
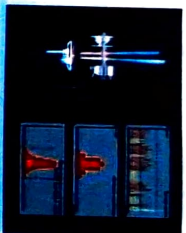
Follow us on 

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Automotive Test Systems | Process & Environmental | Medical | Semiconductor | Scientific

**HORIBA**

## Technologies VCF & DHSS



- Volume
- Cytochemistry
- Flow Cytometry
- DHSS® Double Hydrodynamic Sequential System

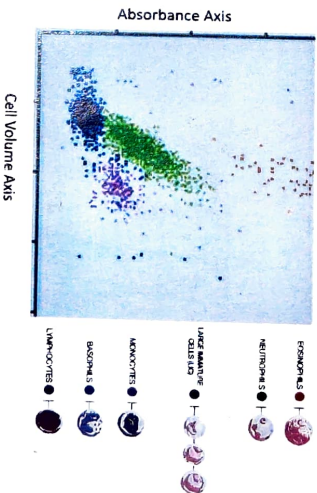
## DHSS (Double Hydrodynamic Sequential System) for Cytochemistry and Flow Cytometry:

### Cytochemistry

- Temperature controlled reagent cytochemistry produces excellent cell differentiation
- 48 hours post-draw stability

### Flow Cytometry

- Precise cellular identification by injecting the prepared sample into a double hydrofocusing cytometer; impedance (cell volume measurement) & optical (analysis of the internal cellular structure by measuring light absorbency).



## • Only 2 Reagents Per Analysis

- Artificial Intelligence System

- Only 2 Reagents Per Analysis

## 6 Part Hematology Analyzer

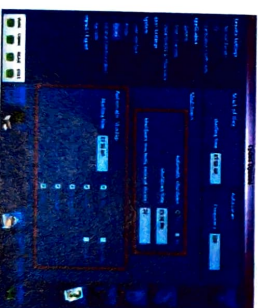


## Only 2 Reagents Per Analysis



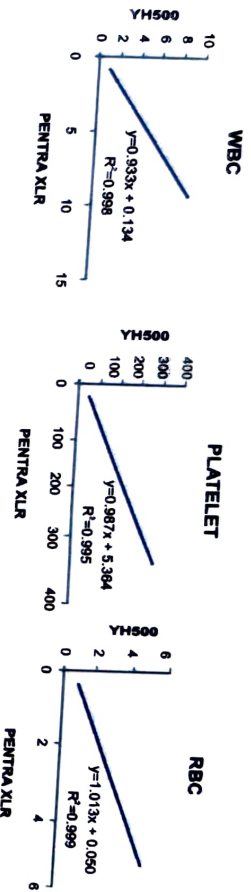
Whiteidif® TL

## Artificial Intelligence System





## Regression & Correlation Analysis



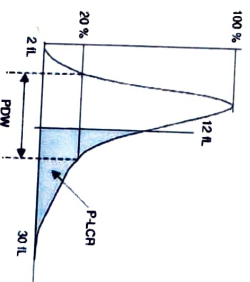
## Repeatability With 1:5 Dilution

	WBC	RBC	HGB	HCT	PLT	MCV	RDW
MEAN	1.03	1.05	3.4	9.1	8	86.6	13.4
SD	0.02	0.025	0.05	0.2	1	0.35	0.3
CV	1.78	2.16	2.06	2.23	13.2	0.41	2.38
MIN	1	1.03	3.4	8.9	6	86.1	12.9
MAX	1	1.11	3.6	9.6	9	87.4	13.9

\*Applicable For Even Low Platelet Count

## Extended Platelet Indices

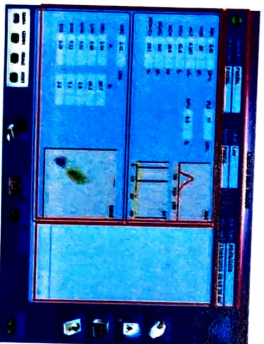
- ▶ P-LCC (#) : Count of Large Platelets with a Volume >12 fL.
- ▶ P-LCR (%) = P-LCC/PLT



## Quality Control

### • Complete Report

### Complete Report



### • Color Patient Report

### Quality Control

Uni-dimensional time progressive graph



Levey Jennings

Bi-dimensional multi-variable quantitative graph



Radar Graphs

# Yumizen H500



## PHYSICAL SPECIFICATIONS

Dimension & Weight:	Height	Width	Depth	Weight
Analyzer	48 cm	40 cm	48 cm	23 kg
	18 in	19 in	19 in	51 lbs

### Printer (optional):

- Compatible models
- Throughput: 50 sample/hour
- Sound level: OS 65db

### Operating Temperature & Humidity:

+15°C (+59°F) to +30°C (86°F)  
Relative Humidity of 30%-80% (maximum, without condensation)

Specimen Volume:

CEC mode: 20.µL

DFE mode: 20.µL

Power Requirements:

Power supply: 100 V to 240 V (+/-10%), 50 Hz to 60 Hz  
Power consumption: 160 VA  
Heat output: 348 kJ/h (830 BTU/h)

### Reagents:

- 2 reagents for analysis: ABX Diuret (20L Whitebird TL (openda line))
- 1 reagent for daily maintenance: ABX Cleaner / ABX Maintenance TL \*

## MEASUREMENT PRINCIPLES

WBC & Differential:

First Dilution: 1/51 with ABX Diuret  
First Dilution: 1/121 with Whitebird TL

Inoculation: 22 sec at 37°C

Method:

- Orientation: Double hydrodynamic Sequential System (DHS)\*
- Optical Reading: Absorbance
- Precipitation Method: Acetic Acid / Acetic Acid
- Counting: 11 x 1 sec

HGB Measurement:

First Dilution: 1/51 with ABX Diuret  
First Dilution: 1/121 with Whitebird TL

Inoculation: 125 sec at 37°C

Method:

- Spectrophotometry: at a wavelength of 555 nm
- Measurement: 10.µL 0.3 sec

RBC & PLT Detection:

First Dilution: 1/51 with ABX Diuret

First Dilution: 1/10251 with ABX Diuret \*

Method:

- Precipitation Method: Acetic Acid / Acetic Acid
- Auto-Focus Optical Counting: 12 x 1 sec
- RBC Measurement: 256 channels from 30 to 300 TL
- PLT Measurement: 256 channels from 2 to median threshold

HCT Measurement Method: optical integration

Calibration: MCV, MCH, MCHC, RDW-CV, RDW-SD, PCT, PLW, PLCTC, PLQR \*

## SOFTWARE SPECIFICATIONS

- Data Processing
- Color LCD touch screen: 12.1 in.
- Operating System: Linux™
- Connection: RS232, Ethernet, USB
- Communication: ASTM protocol
- Capacity: 1000 results \* graphs
- Options: top panel, monitor and bar code reader

\* Quality Control

3 controls levels (low, normal, high)

Target values download (USB)

QC results compatible with Horiba Medical Quality Control Program (QCQ)

Every-Alerting graphs

Full bar graphs

XB: 51 of 9 parameters, mean value of 20 yrs

## PARAMETERS & PERFORMANCE DATA

22 Parameters:

	RBC	PLT
WBC	HEH	MPV
NEH	& NEH%	HGB
LVM	& LVM%	PCT
MON	& MON%	MCV
ESG	& ESG%	MCW
BSM	& BSM%	P-LCR
LCF	& LCF%	MO-C
		RDW-CV
		RDW-SD*

Linearity:	Linearity Limits	Visible Range	Unit
RBC	0 - 300	300 - 600	10 <sup>9</sup> /L
HGB	0 - 18	6 - 18	10 <sup>9</sup> /L
HCT	0 - 54	0 - 300	PL
PLT	0 - 67	67 - 80	PL
PLT (compensated)	0 - 2500	2500 - 4000	10 <sup>9</sup> /L
PLT (uncompensated)	0 - 4000	4000 - 5000	10 <sup>9</sup> /L

Precisitation (Reproducibility):

Parameters	CV (%)	Range	Unit
WBC	<3.0	4 - 100	10 <sup>9</sup> /L
HGB	<2.0	3.8 - 6.2	10 <sup>9</sup> /L
HCT	<2.5	120 - 180	PL
PLT	<3.0	150 - 800	PL
PLT	<3.0	150 - 800	10 <sup>9</sup> /L

## CERTIFICATION

IS9718:2003	
EN ISO 15183	
IEC 60601-1	
IEC 61010-1	
IEC 61010-2-081	
IEC 61010-2-101	
EN 61326-1	
EN 61326-2-6	
IEC 61010-3-2	
IEC 61010-3-3	
EN 61010-1	
EN ISO 15183-2	
EN ISO 15183-3	
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EN ISO 15183-98	
EN ISO 15183-99	
EN ISO 15183-100	

\* PLQD parameters (Research Use Only)

# HORIBA

Medical

HORIBA India Private Limited

246, Okela Industrial Estate Phase III, New Delhi - 110020 India, Tel: +91 (11) 4646 5000 / 4669 5001 Fax: +91 (11) 4646 5020 / 4669 5010  
 HPD / www.horiba.com Toll Free No. 1800-103-4470, Email: [penetration.in@horiba.com](mailto:penetration.in@horiba.com)

FRANCE: +33 (0) 69 74 16 16 - BENELUX: +32 (0) 281 49 06 - ITALY: +39 (0) 51 59 27 21 - SPAIN: +34 (91) 351 91 10 - PORTUGAL: +351 (21) 24 72 17 70

UK: +44 (0) 160 542650 - POLAND: +48 (22) 6732022 - USA: +1 (349) 453 0500 - BRAZIL: +55 (11) 5505 1000 - THAILAND: +66 (2) 881 5936

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HORIBA Medical Centre <http://www.horiba.com/india>



Operating MS

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# HORIBA






NHN-VERT®

## B. DESIGN CERTIFICATE:

Instrument Name : YUMIZEN H500  
Serial Number : 802YOXH01328  
Customer Details : MEDRAY CLINICS PVT LTD,  
With complete address : # 962 12th main Rd, opp. to Lakmé Salon, Doopannahalli,  
Indiranagar, Bengaluru 560008

Installation Date : 14/05/2018

Warranty expires on : CMC

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Yeshwanth Padashetty		
Title:	Customer Support Engineer	Sign: 	Date: 18/07/2023
Reviewed by:	MEDRAY CLINICS PVT LTD, BENGALURU		
Name:	A. Lourdu Praerath		
Title:	Lab Decharge	Sign: 	Date: 18/07/23
Approved by:	MEDRAY CLINICS PVT LTD, BENGALURU		
Name:	A. Lourdu Praerath		
Title:	Lab Decharge	Sign: 	Date: 18/07/23

Conclusion: Instrument has been qualified for Operational. Hence it has been taken for Design Qualification.

# **HORIBA**

Medical

YUMIZEN H500

(Serial no: **802YOXH01328**)

Five Part Hematology Analyzer

**Performance Qualification**

For

**MEDRAY CLINICS PVT LTD**

**# 962 12th main Rd, opp. to Lakmé Salon,**

**Doopanahalli, Indiranagar,**

**Bengaluru 560008**

**A. Performance Qualification****A. Instrument Identification:**

Instrument Name : YUMIZEN H500.  
Serial Number : 802YQXHH01328

**B. Following is the list of test to be performed and verified**

- **Blank Reference cycle:** To verify the Startup Cycle of the instrument.

Serial No: 802YQXHH01328

Parameters	Acceptable Range	Observed Value	Verified by Sign/Date
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.01	18/07/2023
RBC $10^6/\text{mm}^3$	$\leq 0.02 \times 10^6/\text{mm}^3$	0	
HGB g/dL	$\leq 0.3 \text{ g/dL}$	0	
PLT $10^3/\text{mm}^3$	$\leq 5 \times 10^3/\text{mm}^3$	1	

Conducted By: Verified By: 

# Logs - Blank

Date/Time	Operator	Status	WBC (10 <sup>3</sup> /μL)	RBC (10 <sup>6</sup> /μL)	HGB (g/dL)	PLT (10 <sup>3</sup> /μL)
07/10/2023 10:52:15 AM	MEDRAY2	●	0.01	0.00	0.0	0
07/11/2023 11:18:45 AM	MEDRAY2	●	0.00	0.00	0.0	0
07/12/2023 09:19:35 AM	MEDRAY2	●	0.01	0.00	0.0	0
07/13/2023 12:11:46 PM	MEDRAY2	●	0.01	0.00	0.0	0
07/14/2023 10:48:49 AM	MEDRAY2	●	0.01	0.00	0.0	0
07/15/2023 08:42:08 AM	MEDRAY2	●	0.01	0.00	0.0	2
07/16/2023 10:10:52 AM	MEDRAY2	●	0.01	0.00	0.0	4
07/16/2023 10:44:33 AM	MEDRAY2	●	0.01	0.00	0.0	1
07/17/2023 10:26:02 AM	MEDRAY2	●	0.01	0.00	0.0	0
07/18/2023 10:54:18 AM	MEDRAY2	●	0.01	0.00	0.0	1
07/18/2023 03:15:19 PM	MEDRAY2	●	0.01	0.00	0.0	1

Parameters: 0.01, 0.00, 0.0, 1

Status: PASSED

Comment:

**Add Comments**

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SYST

- Precision Study:** Precision is checked by running blood sample in 10 replicates & getting CV% in within acceptance.

Serial No: 80ZYOXH01328

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	0.82	PASS
HGB g/dL	< 1.5	0.74	PASS
HCT %	< 2.0	0.90	PASS
PLT $10^3/\text{mm}^3$	< 5.0	3.39	PASS
WBC $10^3/\text{mm}^3$	< 2.5	2.01	PASS

Conducted By:



Verified By:



### Repeatability

	WBC	RBC	HGB	HCT	PLT	MCV
Min	7.20	5.42	15.9	46.4	289	85.0
Max	7.66	5.57	16.2	47.7	315	85.7
Mean	7.41	5.50	16.0	47.0	304	85.5
Difference	0.46	0.15	0.4	1.3	26	0.7
2 SD	0.30	0.09	0.2	0.8	21	0.4
CV(%)	2.01	0.82	9.74	0.90	3.39	0.24

10/11

	Run Date & Time	WBC 10 <sup>3</sup> /μL	RBC 10 <sup>6</sup> /μL	HGB g/dL	HCT %	PLT 10 <sup>3</sup> /μL	MCV μm <sup>3</sup>
<input type="checkbox"/>	07/18/2023 03:29:17 PM	7.44	5.44	16.0	47.3	308	85.9
<input checked="" type="checkbox"/>	07/18/2023 03:30:49 PM	7.38	5.48	16.2	46.4	293	85.7
<input checked="" type="checkbox"/>	07/18/2023 03:32:06 PM	7.66	5.54	16.2	47.7	315	85.7
<input checked="" type="checkbox"/>	07/18/2023 03:33:32 PM	7.26	5.55	16.0	47.5	289	85.7
<input checked="" type="checkbox"/>	07/18/2023 03:36:08 PM	7.37	5.48	16.0	46.8	312	85.4
<input checked="" type="checkbox"/>	07/18/2023 03:37:25 PM	7.58	5.54	16.2	47.4	313	85.5
<input checked="" type="checkbox"/>	07/18/2023 03:39:12 PM	7.40	5.51	16.0	47.0	293	85.4
<input checked="" type="checkbox"/>	07/18/2023 03:40:29 PM	7.29	5.50	16.0	46.9	295	85.4
<input checked="" type="checkbox"/>	07/18/2023 03:43:14 PM	7.20	5.45	16.0	46.5	312	85.3

QUAL COMM REAG SYST



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07/18/2023 03:48 PM



### Repeatability

	WBC	RBC	HGB	HCT	PLT	MCV
Min	7.20	5.42	15.9	46.4	289	85.0
Max	7.66	5.57	16.2	47.7	315	85.9
Mean	7.42	5.50	16.0	47.0	304	85.5
Difference	0.46	0.15	0.4	1.3	26	0.9
2 SD	0.28	0.20	0.2	0.8	20	0.5
CV(%)	1.91	0.71	0.71	0.87	3.24	0.28

11/11

Run Date & Time	WBC 10 <sup>3</sup> /μL	RBC 10 <sup>6</sup> /μL	HGB g/dL	HCT %	PLT 10 <sup>3</sup> /μL	MCV μm <sup>3</sup>
<input checked="" type="checkbox"/> 07/18/2023 03:32:06 PM	7.66	5.57	16.2	47.7	315	85.7
<input checked="" type="checkbox"/> 07/18/2023 03:33:32 PM	7.26	5.53	16.0	47.5	289	85.7
<input checked="" type="checkbox"/> 07/18/2023 03:36:08 PM	7.37	5.48	16.0	46.8	312	85.4
<input checked="" type="checkbox"/> 07/18/2023 03:37:25 PM	7.58	5.54	16.2	47.4	313	85.5
<input checked="" type="checkbox"/> 07/18/2023 03:39:12 PM	7.40	5.51	16.0	47.0	293	85.4
<input checked="" type="checkbox"/> 07/18/2023 03:40:29 PM	7.29	5.50	16.0	46.9	295	85.4
<input checked="" type="checkbox"/> 07/18/2023 03:43:14 PM	7.20	5.45	16.0	46.5	312	85.3
<input checked="" type="checkbox"/> 07/18/2023 03:44:32 PM	7.55	5.51	16.0	46.8	306	85.0
<input checked="" type="checkbox"/> 07/18/2023 03:45:55 PM	7.45	5.50	16.1	47.0	313	85.5

QUAL COMM REAG SYST



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Technician

READY

07/18/2023 03:47 PM

# HORIBA

HORIBA India Private Limited

246, Okhla Industrial Estate Phase-III,  
New Delhi 110020, India  
Tel : +91 (11) 4646 5000 / 4669 5001  
https://www.horiba.com  
CIN : U73100DL2006PTC153232

Date: 18/07/2023

## CALIBRATION CERTIFICATE

This is to state that the hematology cell counter model **HORIBA Medical: YUMIZEN H500**, bearing **Serial no: 802YOXH01328** at Medray Clinics Pvt Ltd, Indiranagar, Bangalore was calibrated with Calibrator on **18<sup>th</sup> July 2023**.

Subsequently controls were processed and found them in respective range.

Calibrator Used: **ABX MINOCAL**

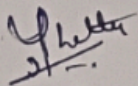
Lot No.: **CX 484**

Expiry Date: **05/08/2023**

Sr. No	Tested Parameter	Remarks
1	Repeatability/ Precision	Passed
2	Start up/Blank Cycle	Passed
3	Calibration	Passed
4	Quality Control	Passed

Next calibration cycle is due on **17<sup>th</sup> July 2024**.

Yeshwanth Padashetty



Customer Support Engineer,  
**Horiba Medical.**



- **Calibration:** To calibrate the Instrument using calibrator (ABX Minocal) and verify the same.

**Procedure:** Go to Quality Assurance icon on main screen and then Calibration icon. Run Calibrator (ABX Minocal) 6 times without taking the values of first run, calibrate the instrument using average of the last 5 runs.

**Lot:** CX 484; **Expiry:** 05/08/2023.

**Serial No:** 802YOXH01328

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.80	8.71	1.45	<2%	PASSED
RBC	4.57	4.53	1.00	<2%	PASSED
HGB	13.2	12.6	0.22	<1%	PASSED
HCT	38.6	36.2	1.03	<2%	PASSED
PLT	253	250	3.18	<5%	PASSED

**Conducted By:**

**Verified By:**

# Calibration

## Calibrator Information

Sample ID **CX484**

Lot number **CX484**

Exp. date **08/05/2023**

Modified on

Name **ABX MINOCAL**

Coefficients	WBC	RBC	HGB	HCT	PLT	MPV
New	1.051	0.968	0.943	1.081	0.992	1.010
Current	1.040	0.960	0.900	1.022	0.980	1.000
Target	8.80		13.2	38.6	253	10.4
Mean	8.71		12.6	36.2	250	10.3
CV(%)	1.45		0.22	1.03	3.18	1.50

Selected runs (5 minimum) **10/11**

Run Date & Time	WBC (10 <sup>3</sup> /µL)	HGB (g/dL)	HCT (%)	PLT (10 <sup>3</sup> /µL)	MPV (µm <sup>3</sup> )
<input checked="" type="checkbox"/> 07/18/2023 03:50:24 PM	8.56	12.7	36.0	262	10.2
<input checked="" type="checkbox"/> 07/18/2023 03:51:46 PM	8.55	12.6	36.5	252	10.4
<input checked="" type="checkbox"/> 07/18/2023 03:53:17 PM	8.60	12.5	36.1	253	10.1
<input checked="" type="checkbox"/> 07/18/2023 03:54:50 PM	8.67	12.6	35.7	255	10.4
<input checked="" type="checkbox"/> 07/18/2023 03:56:11 PM	8.74	12.6	35.8	249	10.2
<input checked="" type="checkbox"/> 07/18/2023 03:57:36 PM	8.53	12.6	36.3	245	10.6
<input checked="" type="checkbox"/> 07/18/2023 03:59:01 PM	8.81	12.6	36.1	260	10.4
<input checked="" type="checkbox"/> 07/18/2023 04:02:16 PM	8.64	12.7	36.1	261	10.4

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# Calibration

## Calibrator Information

Sample ID **CX484**  
 Lot number **CX484**

Exp. date **08/05/2023**  
 Modified on

Name **ABX MINOCAL**

	WBC	RBC	HGB	HCT	PLT	MPV
New	1.051	0.968	0.943	1.081	0.992	1.010
Current	1.040	0.960	0.900	1.022	0.980	1.000
Target	8.80	4.57	13.2	38.6	253	10.4
Mean	8.71	4.53	12.6	36.2	250	10.3
CV(%)	1.45	1.09	0.22	1.03	3.18	1.50

Selected runs  
 (5 minimum) 10/11

Run Date & Time	WBC (10 <sup>3</sup> /μL)	RBC (10 <sup>6</sup> /μL)	HGB (g/dL)	HCT (%)	PLT (10 <sup>3</sup> /μL)	MPV (μm <sup>3</sup> )
<input checked="" type="checkbox"/> 07/18/2023 03:54:50 PM	8.67	4.49	12.6	35.7	255	10.4
<input checked="" type="checkbox"/> 07/18/2023 03:56:11 PM	8.74	4.49	12.6	35.8	249	10.2
<input checked="" type="checkbox"/> 07/18/2023 03:57:36 PM	8.53	4.55	12.6	36.3	245	10.6
<input checked="" type="checkbox"/> 07/18/2023 03:59:01 PM	8.81	4.55	12.6	36.1	260	10.4
<input checked="" type="checkbox"/> 07/18/2023 04:02:16 PM	8.64	4.52	12.7	36.1	261	10.4
<input checked="" type="checkbox"/> 07/18/2023 04:03:35 PM	8.89	4.48	12.6	35.9	241	10.2
<input checked="" type="checkbox"/> 07/18/2023 04:05:00 PM	8.82	4.62	12.6	37.0	243	10.2
<input checked="" type="checkbox"/> 07/18/2023 04:07:41 PM	8.82	4.53	12.6	36.0	238	10.4

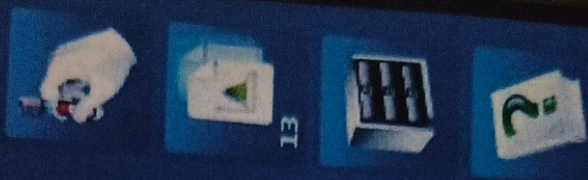
QUAL  
 COMM  
 REAG  
 SYST

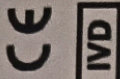
v 2.2.0.5

technician

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07/18/2023 04:09 PM





LOT

CX 484

Rev 1

CAL

(Exp.) 2023-08-05  
(YYYY-MM-DD)

PARAMETRES PARAMETERS	UNITES UNITS	WHITEDIFF				TOLERANCES TOLERANCE
		YUMIZEN V1.0 to V2.x		YUMIZEN since V3		
		H500	H500 OT H500 CT	H500 OT H500 CT	H500 CT H500	
GB WBC	$10^3/\text{mm}^3; 10^9/\text{l}$	8.80	8.80	8.80	8.80	$\pm 0.20$
GR RBC	$10^6/\text{mm}^3; 10^{12}/\text{l}$	4.57	4.57	4.54	4.54	$\pm 0.06$
	g/dl	13.2	13.2	13.3	13.3	$\pm 0.2$
HB HGB	g/l	132	132	133	133	$\pm 2$
	mmol/l	8.20	8.20	8.26	8.26	$\pm 0.12$
	%	38.6	38.6	36.9	36.4	$\pm 1.0$
HT HCT	l/l	0.386	0.386	0.369	0.364	$\pm 0.010$
PLA PLT	$10^3/\text{mm}^3; 10^9/\text{l}$	253	253	272	277	$\pm 10$
VMP MPV	$\mu\text{m}^3; \text{fl}$	10.4	10.4	N/A	N/A	$\pm 0.5$

Ref: TEMP-0387 Rev 49 BACK / VERSO 1300113555

# ABX Minocal

2018/07/06  
A01A00049MEN

**REF** 2032002

**CAL** 2 mL

**IVD** 

**HORIBA ABX SAS**  
Parc Euromédecine - Rue du Caducée  
B.P. 7290  
34184 MONTPELLIER Cedex 4  
FRANCE

- ABX Micros / Advia 60
- ABX Micros 60 / ABC Vet
- ABX Micros ES60 / ESV60
- ABX Micros CRP / CRP200
- ABX Pentra 60 / 60C+
- ABX Pentra 80 / XL80
- Pentra XLR
- Micros Care ST / Microsemi CRP
- ABX Pentra 120 / 120 Retic / DX120 / DF120
- scil Vet abc Plus+
- Pentra ES60 / MS60 / MS CRP-
- Pentra DX Nexus / DF Nexus
- Yumizen H500 OT / CT / H550
- Yumizen H1500 / H2500

## Hematology Devices (for *in vitro* diagnostic use)

### Intended Use <sup>a</sup>

**ABX Minocal** is a multiparameter blood calibrator intended for *in vitro* diagnostic use and designed for use in calibration of hematology blood cell counters. Refer to the **ABX Minocal** assay value data sheet for specific instrument models.

### Warnings and Precautions

- **ABX Minocal** is for professional *in vitro* diagnostic use only.
- It is the user's responsibility to verify that this document is applicable to the product use.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA approved method and found negative for the presence of HBsAg, HCV and antibody to HIV1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, the products should be treated like patient specimens as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (1, 2, 3).
- Observe the standard laboratory precautions for use and follow national or local health and safety guidelines.
- Please refer to the Material Safety Data Sheet (MSDS) associated with **ABX Minocal**.

### Waste Management <sup>b</sup>

Please refer to local legal requirements.

<sup>a</sup>Modification: new instrument added.

<sup>b</sup>Modification: modification of waste management.

This reagent contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

### Microbiological State

Not applicable.

### Description and Composition

#### Description:

**ABX Minocal** is similar in appearance to fresh whole blood. A light pink-tinted supernatant is normal.

#### Composition:

**ABX Minocal** contains mammalian leucocytes (WBC), erythrocytes (RBC) and thrombocytes (PLT) suspended in a plasma-like fluid.

### Storage and Stability

- **Storage condition (before opening):** 2-8°C (35-46°F). Do not freeze. Store the tubes vertically in their original packages when not in use. Storage in the door compartments of the refrigerator is not recommended.
- **Open stability:** **ABX Minocal** is stable for 1 day after the tube has been opened if it is properly handled and promptly refrigerated at 2-8°C (35-46°F) after use. **ABX Minocal** must be tightly capped after use.
- **Expiration date:** refer to "expiration date" reagent packaging label.

READY

Technician

v.2.2.0.5

QUAL-OA-TEMP-0866 Rev.5

## ABX Minocal

### Materials Required but not Provided

- Automated hematology analyzer.
- Standard laboratory equipment.

### Specimen

Not applicable.

### Procedure

**ABX Minocal** is ready to use.

The calibration on HORIBA Medical instruments is an important procedure, which may need to be performed during certain technical situations such as installation, maintenance and service interventions. Calibration should not be performed to compensate for a drift in results due to a blockage on the instrument.

Frequent re-calibration needs to be reported to HORIBA Medical Technical Support to determine the actual cause and appropriate remedy. After calibration, ensure the values for MCV, MCH and MCHC on patient samples agree with usual population means for these parameters.

1. Bring **ABX Minocal** to room temperature by rolling the tube between the palms of your hands until the red blood cell sediment is completely suspended. Do not shake.
2. Refer to the user manual to identify **ABX Minocal** using the barcode reader or manually.
3. Gently invert the tube 8 to 10 times immediately before sampling.
4. Run **ABX Minocal** according to the procedure described in the user manual.
5. Wipe threads and cap of the tube after use with lint-free gauze.
6. Recap and refrigerate the tube promptly after use.

Refer to the **ABX Minocal** assay value data sheet for specific instrument models.  
Refer to the instrument user manual for detailed analysis and control procedures.

### Methodology

**ABX Minocal** is a stable preparation used to calibrate blood cell counters. Calibration values have been obtained from replicate analyses on instruments which

have been whole blood calibrated to values obtained from reference methods. **ABX Minocal** is run on the instrument in the same way as a patient blood sample (resistivity, absorbance and spectrophotometry measurements) and is used to calibrate leucocytes (WBC), erythrocytes (RBC), hemoglobin, hematocrit and thrombocytes (PLT) values.

### Performance Characteristics and Limitations

Refer to the assay value data sheet for the target values and their tolerances regarding the instrument used. See paragraph Traceability of Calibrators and Control Materials.

### Calculation and Interpretation of Results

Refer to the instrument user manual for calibration procedure and interpretation of results.

### Changes in the Procedure and in the Performance

#### Packaging spoiling

In case of protective packaging spoiling, do not use **ABX Minocal** if the damages might have an effect on the product performance.

#### Signs of deterioration

In the event of any signs of physical or chemical deterioration (turbidity, change in colour etc.) **ABX Minocal** should be replaced.

#### Incorrect mixing

Incomplete mixing of the tube prior to use invalidates both the sample that is withdrawn and the remainder of **ABX Minocal** in the tube.

#### Temperature limits

Do not use **ABX Minocal** if it has been frozen or kept at excessive heat.  
Before using **ABX Minocal**, make sure it has reached the operating temperature conditions as described in the instrument user manual.



## ABX Minocal

### Internal Quality Control

HORIBA Medical control bloods must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.

HORIBA Medical offers an Online Interlaboratory Comparison Program (QCP) which provides internet access to:

- Submit Internal Quality Control results online.
- Monitor analytical performances and compare directly with hundreds of laboratories worldwide.
- Obtain real time peer group statistical reports from QCP

More informations are available at:

<http://qcp.horiba-abx.com>

### Traceability of Calibrators and Control Materials

HORIBA Medical controls and calibrators are traceable to standard reference methods.

Hematology analyzers in the Quality Assurance Laboratory are whole blood calibrated to values obtained using the following standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

The **White Blood Cells (WBC)** and **Red Blood Cells (RBC)** are analyzed on a Coulter Counter Z series instrument\*. All counts are corrected for coincidence.

**Hemoglobin** is measured using the Clinical Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method (4). Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations (4).

The **hematocrit** (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H7-A3 document (5). No correction is made for trapped plasma.

**Platelets** are assayed using a hemocytometer and phase contrast optics.

\* All brands and products are trademarks or registered trademarks of their respective companies:

### Reference Intervals

Not applicable.

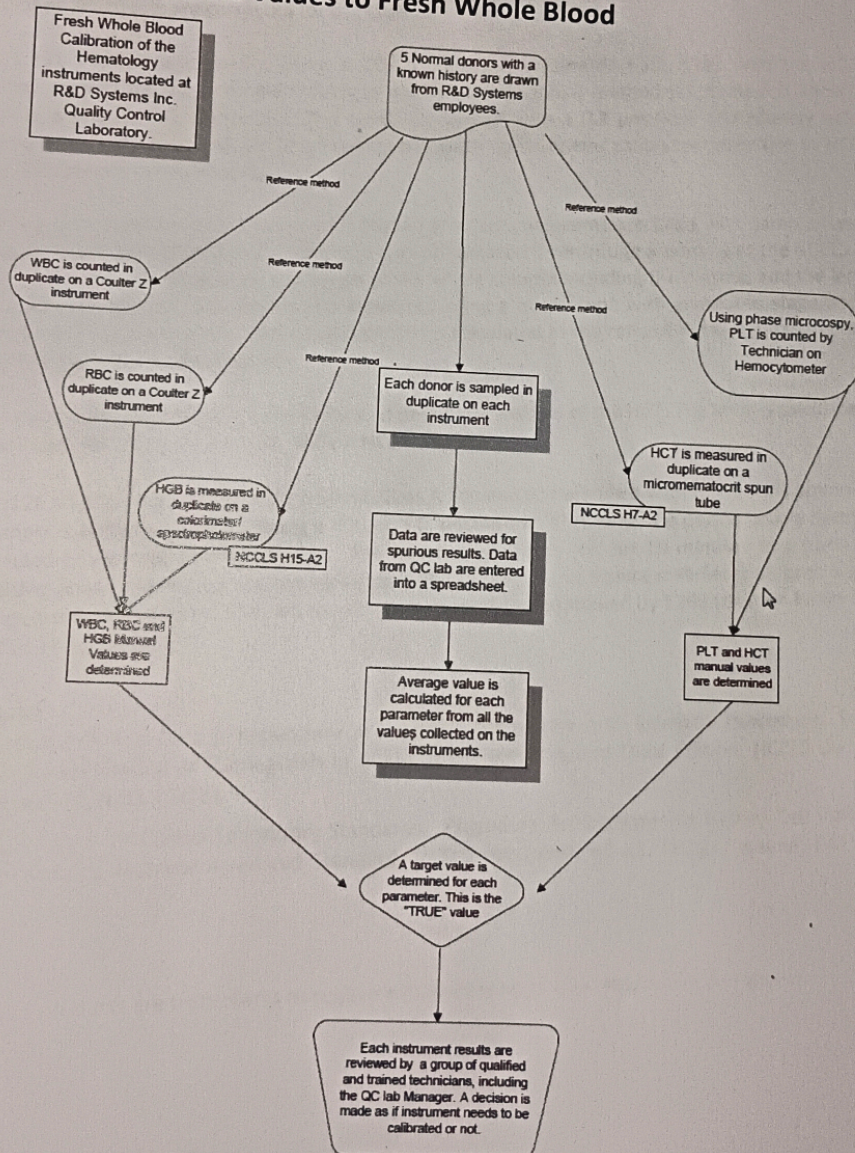
### Reference

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
2. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
3. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition. CLSI (NCCLS), document M29-A3 (2005) **25** (10).
4. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition. CLSI (NCCLS), document H15-A3 (2000) **20** (28).
5. Procedure for Determining Packed Cell Volume by Microhematocrit Method; Approved Standard - Third Edition. CLSI (NCCLS), document H7-A3 (2001) **20** (18).

**DECLARATION of TRACEABILITY and UNCERTAINTY**  
**HORIBA Medical calibrator**

The purpose of this document is to describe the metrological traceability of values assigned to HORIBA Medical calibrator: **ABX Minocal Ref 2032002** and to estimate the calibrator assigned value uncertainty component.

**Assignment of Reference Values to Fresh Whole Blood**



## Hematology Reference Methods

Hematology analyzers in R&D Systems' Quality Assurance Laboratory are whole blood calibrated to values obtained using these standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

**WBC:** A 1:500 dilution is prepared using a 200 mL Class A volumetric flask filled with isotonic diluent. 2.4 mL of diluent is removed. Sample is added to the flask using a 400  $\mu$ L T.C. micropipet, followed by 2.0 mL lysing agent. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

**RBC:** A 1:50,000 dilution is prepared using a 1000 mL Class A volumetric flask filled with isotonic diluent. Sample is added to the flask using a 20  $\mu$ L T.C. micropipet. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

**HGB:** A 1:251 dilution is prepared using a 100 mL Class A volumetric flask filled with the NCCLS recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method (1). Sample is added to the flask using a 400  $\mu$ L T.C. micropipet. The sample is filtered with a 0.2  $\mu$ m filter immediately before reading. Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to NCCLS H15-A3 and ICSH recommendations (1).

**HCT:** Plain glass microhematocrit tubes (not coated with anticoagulant) are filled with sample, sealed with sealing putty and centrifuged for 5 minutes in a microhematocrit centrifuge according to the NCCLS H7-A3 document (2). After centrifugation, the length of the whole column including the plasma, and the length of the red blood cell column, are viewed and measured using a microscope with graduated stage and an ocular micrometer. The hematocrit (packed cell volume) is calculated as the ratio of the two measurements. No correction is made for trapped plasma.

**MCV:** On some instruments MCV is the calibrated parameter instead of the HCT. The MCV is calculated from the HCT and RBC using the formula:  $MCV = HCT \times 10/RBC$

**PLT:** A 1:126 dilution is prepared using a 50 mL Class A volumetric flask filled with filtered 1% ammonium oxalate. Sample is added to the flask using a 400  $\mu$ L T.C. micropipet. The dilution is plated onto a clean, dry Neubauer ruled phase type hemocytometer. The hemocytometer is left for 10 minutes in a humidified chamber. Using phase contrast optics, the platelets in the entire central square millimeter on both sides of the hemocytometer are counted. The two counts are averaged and multiplied by 1260 (dilution factor 126  $\times$  volume factor 10 = 1260).

### BIBLIOGRAPHY

1. National Committee for Clinical Laboratory Standards. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood: Approved Standard-Third Edition. NCCLS document H15-A3. Wayne, PA: NCCLS, 2000.
2. National Committee for Clinical Laboratory Standards. Procedure for Determining Packed Cell Volume by the Microhematocrit Method: Approved Standard, NCCLS document H7-A3. NCCLS, Wayne, PA: NCCLS, 2001.

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### Determination of uncertainty (calibrator component)

The uncertainty associated with the calibration of the HORIBA Medical analyzer with the **ABX Minocal** calibrator has been estimated by adding the following sources of uncertainty:

-Uncertainty of the equipment used to determine the reference values: flask, pipette, single aperture impedance counter (WBC, RBC), hemocytometer by phase-contrast (PLT), spectrophotometer (HGB) and hematocrit measurement (ruler).

Uncertainty as an absolute value:

Parameter	Uncertainty
WBC (G/L)	0.09
RBC (T/L)	0.03
HGB (g / dL)	0.06
HCT (%)	0.45
PLT (G/L)	5.4

### Determination of total uncertainty

Total uncertainty is defined as the amount of error associated with reported patient results by the HORIBA Medical hematology analyzers to reference methods when the analyzers are calibrated using the **ABX Minocal** calibrator.

Three elements contribute to total uncertainty:

- the calibration system (working calibrators, primary and secondary calibrators, reference measurement procedures...)
- the procedure (reagents, instruments, laboratory staff ...)
- the sample

The overall expression of uncertainty is therefore:

$$u_{result} = \sqrt{u_{cal}^2 + u_{method}^2 + u_{sample}^2 + u_{other}^2}$$

- **Control Runs:** The quality of the analyzer is checked by running three levels of Controls & getting the values in the range as per the kit insert.

Lot: ABX DIFFTROL PX442; Exp: 05/09/2023.  
Serial No: 802YOXH01328  
Level I: Low Control

Parameters	Target	Tolerance	Observed Value Dated 18/07/2023	Comments
RBC 10 <sup>6</sup> /mm <sup>3</sup>	2.27	0.16	2.38	Passed
HGB g/dL	6.00	0.40	6.00	Passed
HCT %	18.4	1.50	18.7	Passed
MCV μm <sup>3</sup>	81.0	5.00	78.4	Passed
MCH pg	26.4	2.00	25.2	Passed
MCHC g/dL	32.6	3.00	32.2	Passed
RDW %	15.5	4.00	14.4	Passed
RDW #	45.5	8.00	43.4	Passed
PLT 10 <sup>3</sup> /mm <sup>3</sup>	77.0	20.0	87.0	Passed
MPV μm <sup>3</sup>	9.20	2.00	9.50	Passed
WBC 10 <sup>3</sup> /mm <sup>3</sup>	2.90	0.40	3.09	Passed
NEU %	43.4	10.0	44.0	Passed
NEU#	1.26	0.35	1.37	Passed
LYM%	40.4	12.0	35.7	Passed
LYM #	1.17	0.33	1.10	Passed
MON %	7.30	7.30	5.70	Passed
MON #	0.21	0.21	0.17	Passed
EOS%	6.70	6.70	10.3	Passed
EOS#	0.19	0.19	0.32	Passed
BAS%	2.20	2.20	4.30	Passed
BAS#	0.06	0.06	0.13	Passed

Level II: Normal Control

Parameters	Target	Tolerance	Observed Value Dated 18/07/2023	Comments
RBC 10 <sup>6</sup> /mm <sup>3</sup>	4.52	0.20	4.67	Passed
HGB g/dL	13.2	0.50	13.3	Passed
HCT %	40.2	2.00	41.5	Passed
MCV μm <sup>3</sup>	89.0	5.00	88.8	Passed
MCH pg	29.2	2.00	28.5	Passed
MCHC g/dL	32.8	3.00	32.1	Passed
RDW %	14.5	4.00	12.2	Passed
RDW #	49.0	8.00	42.5	Passed
PLT 10 <sup>3</sup> /mm <sup>3</sup>	261	30.0	253	Passed

Last Run : 07/18/2023 04:30:48 PM - DIF

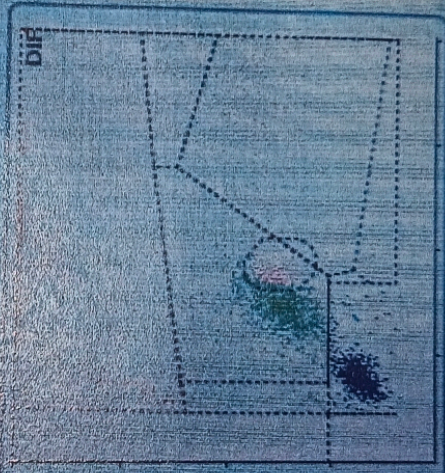
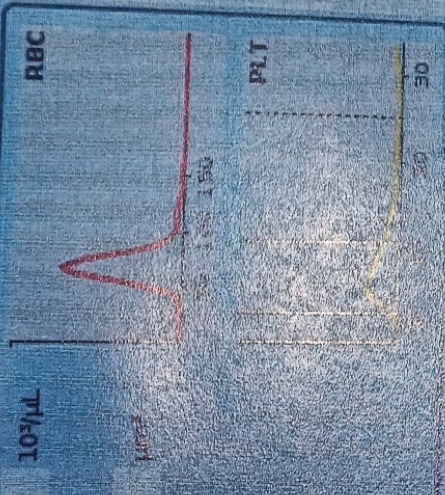
Sample ID PX442L  
 Lot number PX442L

Level Low  
 Name ABXdiffrol L

Exp. date 09/05/2023  
 Run date 07/18/2023 04:30:48 PM

RBC	2.38	10 <sup>12</sup> /μL	PLT	87	10 <sup>3</sup> /μL
HGB	6.0	g/dL	MPV	9.5	
HCT	18.7	%			
MCV	78.4	μm <sup>3</sup>			
MCH	25.2	pg			
MCHC	32.2	g/dL			
RDW-CV	14.4	%			
RDW-SD	43.4	μm <sup>3</sup>			

WBC	3.09	10 <sup>3</sup> /μL		
NEU	1.37	%	44.0	
LYM	1.10		35.7	
MON	0.17		5.7	
EOS	0.32		10.3	
BAS	0.13		4.3	



QUAL  COMM  REAG  SYST

v 2.2.0.5 technician

READY

07/18/2023 04:32 PM

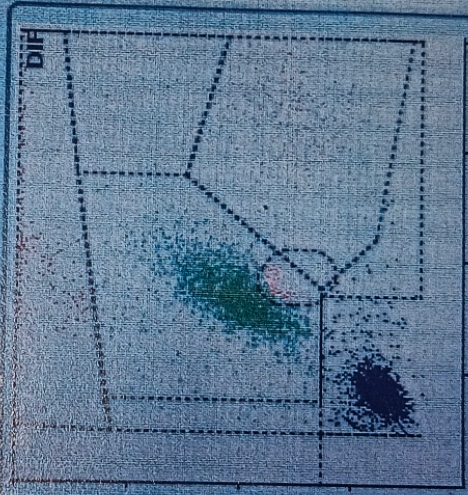
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Sample ID **PX442N**  
 Lot number **PX442N**

Level **Normal**  
 Name **ABXdiffrol N**

Exp. date **09/05/2023**  
 Run date **07/18/2023 04:20:02 PM**

RBC	4.67	10 <sup>6</sup> /μL	PLT	253	10 <sup>3</sup> /μL
HGB	13.3	g/dL	MPV	100.0	
HCT	41.5	%			
MCV	88.8	μm <sup>3</sup>			
MCH	28.5	pg			
MCHC	32.1	g/dL			
RDW-CV	12.2	%			
RDW-SD	42.5	μm <sup>3</sup>			



WBC	8.21	10 <sup>3</sup> /μL	
NEU	4.04	%	49.3
LYM	3.37	%	41.0
MON	0.43	%	5.2
EOS	0.27	%	3.3
BAS	0.10	%	1.2

QUAL  COMM  REAG  SYST

v 2.2.0.5      READY      technician

07/18/2023 04:27 PM

Sample ID PX442H

Lot number PX442H

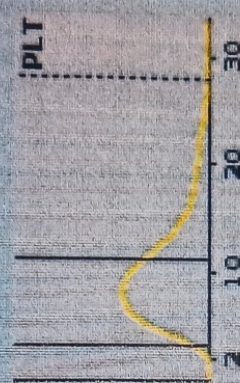
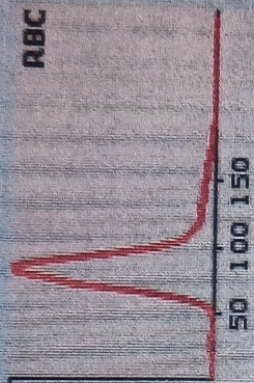
Level High

Name ABXdifftrol H

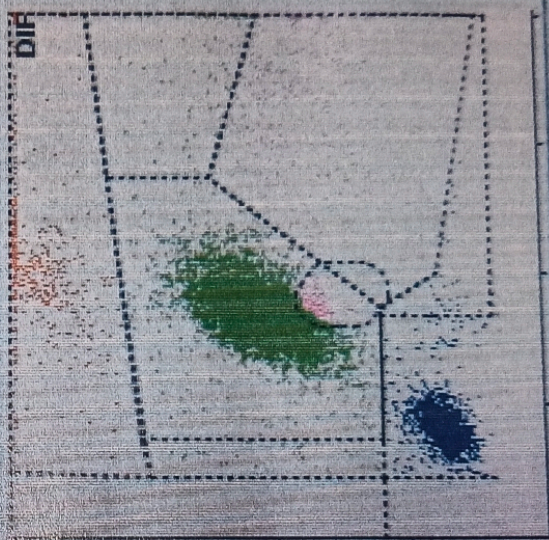
Exp. date 09/05/2023

Run date 07/18/2023 04:25:34 PM

RBC	5.34	10 <sup>3</sup> /μL	PLT	475	10 <sup>3</sup> /μL
HGB	16.6	g/dL			
HCT	51.0	%	MPV	9.7	μm <sup>3</sup>
MCV	95.5	μm <sup>3</sup>			
MCH	31.1	pg			
MCHC	32.6	g/dL			
RDW-CV	11.9	%			
RDW-SD	43.4	μm <sup>3</sup>			



WBC	17.64	10 <sup>3</sup> /μL	%	
NEU	13.06		74.0	
LYM	2.98		16.9	
MON	0.56		3.2	
EOS	0.82		4.7	
BAS	0.22		1.2	



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LOT

PX 442

Rev 1

CONTROL

(Exp.) 2023-09-05  
(YYYY-MM-DD)

PARAMETRES PARAMETERS	UNITES UNITS	Whitediff																												
		CONTROL			L			TOLERANCES			CONTROL			N			TOLERANCES			CONTROL			H							
		YUMIZEN			H500 CT H500 CT Since V3			TOLERANCE			H500 OT H500 CT Since V3			YUMIZEN			H500 CT H500 CT Since V3			H500 OT H500 CT Since V3			YUMIZEN			H500 CT H500 CT Since V3				
		H500 OT V1.0 to V2.x	H500 CT	H500 CT	H500 OT	H500 CT	H500 CT	H500 OT	H500 CT	H500 CT	H500 OT	H500 CT	H500 CT	H500 OT	H500 CT	H500 CT	H500 OT	H500 CT	H500 CT	H500 OT	H500 CT	H500 CT	H500 OT	H500 CT	H500 CT	H500 OT	H500 CT	H500 CT	H500 OT	H500 CT
GB WBC	$10^3/mm^3; 10^9/l$	2.95	2.95	2.95	2.95	2.95	2.95	± 0.40	8.30	8.30	8.30	8.30	8.30	8.30	8.30	8.30	8.30	± 1.00	17.60	17.60	17.60	17.60	17.60	17.60	17.60	17.60	17.60	17.60	17.60	± 2.20
GR RBC	$10^6/mm^3; 10^{12}/l$	2.35	2.35	2.35	2.35	2.35	± 0.16	4.68	4.68	4.68	4.68	4.68	4.68	4.68	4.68	4.68	4.68	± 0.20	5.33	5.33	5.33	5.33	5.33	5.33	5.33	5.33	5.33	5.33	5.33	± 0.25
HB HGB	g/dl	6.0	6.0	6.0	6.0	6.0	± 0.4	13.5	13.5	13.5	13.5	13.5	13.5	13.5	13.5	13.5	13.5	± 0.5	16.6	16.6	16.6	16.6	16.6	16.6	16.6	16.6	16.6	16.6	16.6	± 0.6
HT HCT	%	3.73	3.73	3.73	3.73	3.73	± 0.25	8.38	8.38	8.38	8.38	8.38	8.38	8.38	8.38	8.38	8.38	± 0.31	10.31	10.31	10.31	10.31	10.31	10.31	10.31	10.31	10.31	10.31	10.31	± 0.37
VGM MCV	$\mu m^3; fl$	18.3	18.3	17.4	17.2	17.2	± 1.5	41.2	41.2	39.7	38.9	38.9	38.9	38.9	38.9	38.9	38.9	± 2.0	50.6	50.6	48.6	47.6	47.6	47.6	47.6	47.6	47.6	47.6	47.6	± 2.5
TGMH MCH	fmol	1.58	1.58	1.58	1.58	1.58	± 0.12	1.79	1.79	1.79	1.79	1.79	1.79	1.79	1.79	1.79	1.79	± 0.12	1.93	1.93	1.93	1.93	1.93	1.93	1.93	1.93	1.93	1.93	1.93	± 0.16
CCMH MCHC	g/dl	32.7	32.7	34.4	35.0	35.0	± 3.0	32.8	32.8	34.1	34.7	34.7	34.7	34.7	34.7	34.7	34.7	± 3.0	32.8	32.8	33.9	34.7	34.7	34.7	34.7	34.7	34.7	34.7	34.7	± 3.0
IDR-SD RDW-SD	%	20.31	20.31	21.36	21.74	21.74	± 1.86	20.37	20.37	21.18	21.55	21.55	21.55	21.55	21.55	21.55	21.55	± 1.86	20.37	20.37	21.05	21.55	21.55	21.55	21.55	21.55	21.55	21.55	21.55	± 1.86
IDR-CV RDW-CV	%	16.0	16.0	15.4	15.4	15.4	± 4.0	13.5	13.5	13.1	13.1	13.1	13.1	13.1	13.1	13.1	13.1	± 4.0	14.0	14.0	12.6	12.6	12.6	12.6	12.6	12.6	12.6	12.6	12.6	± 4.0
PLA. PLT	$10^3/mm^3; 10^9/l$	63	63	80	82	82	± 2.0	251	251	266	273	273	273	273	273	273	273	± 2.0	9.4	9.4	9.2	9.2	9.2	9.2	9.2	9.2	9.2	9.2	9.2	± 2.0
VMP MPV	$\mu m^3; fl$	8.8	8.8	10.4	10.3	10.3	± 2.0	9.4	9.4	9.3	9.2	9.2	9.2	9.2	9.2	9.2	9.2	± 2.0	12.58	12.58	12.30	12.30	12.30	12.30	12.30	12.30	12.30	12.30	12.30	± 1.90
NEU	$10^2/mm^3; 10^8/l$	1.36	1.36	1.31	1.31	1.31	± 0.35	4.08	4.08	3.93	3.93	3.93	3.93	3.93	3.93	3.93	3.93	± 0.35	71.5	71.5	69.6	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9	± 10.0
LYM	$10^2/mm^3; 10^8/l$	46.0	46.0	44.5	44.5	44.5	± 10.0	49.2	49.2	47.4	47.4	47.4	47.4	47.4	47.4	47.4	47.4	± 10.0	3.06	3.06	3.22	3.22	3.22	3.22	3.22	3.22	3.22	3.22	3.22	± 1.50
MON	$10^2/mm^3; 10^8/l$	1.09	1.09	1.12	1.12	1.12	± 0.33	3.27	3.27	3.36	3.36	3.36	3.36	3.36	3.36	3.36	3.36	± 0.33	17.4	17.4	18.3	18.3	18.3	18.3	18.3	18.3	18.3	18.3	18.3	± 8.0
EOS	%	37.1	37.1	38.0	38.0	38.0	± 12.0	39.4	39.4	40.5	40.5	40.5	40.5	40.5	40.5	40.5	40.5	± 12.0	0.53	0.53	0.63	0.63	0.63	0.63	0.63	0.63	0.63	0.63	0.63	± 0.53
BAS	$10^2/mm^3; 10^8/l$	0.19	0.19	0.20	0.20	0.20	± 0.19	0.45	0.45	0.48	0.48	0.48	0.48	0.48	0.48	0.48	0.48	± 0.19	3.0	3.0	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	± 3.0
IMG	%	6.4	6.4	6.7	6.7	6.7	± 6.4	5.4	5.4	5.8	5.8	5.8	5.8	5.8	5.8	5.8	5.8	± 6.4	0.79	0.79	0.81	0.81	0.81	0.81	0.81	0.81	0.81	0.81	0.81	± 0.79
	$10^2/mm^3; 10^8/l$	0.18	0.18	0.19	0.19	0.19	± 0.18	0.23	0.23	0.26	0.26	0.26	0.26	0.26	0.26	0.26	0.26	± 0.18	4.5	4.5	4.6	4.6	4.6	4.6	4.6	4.6	4.6	4.6	4.6	± 4.5
	%	6.2	6.2	6.5	6.5	6.5	± 6.2	2.8	2.8	3.1	3.1	3.1	3.1	3.1	3.1	3.1	3.1	± 6.2	0.63	0.63	0.63	0.63	0.63	0.63	0.63	0.63	0.63	0.63	0.63	± 0.63
	$10^2/mm^3; 10^8/l$	0.13	0.13	0.13	0.13	0.13	± 0.13	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27	± 0.13	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	± 3.6
	%	4.3	4.3	4.3	4.3	4.3	± 4.3	3.2	3.2	3.2	3.2	3.2	3.2	3.2	3.2	3.2	3.2	± 4.3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	± 1.11
	$10^2/mm^3; 10^8/l$	N/A	N/A	0.08	0.08	0.08	± 0.08	N/A	N/A	N/A	0.36	0.36	0.36	0.36	0.36	0.36	0.36	± 0.08	N/A	N/A	N/A	6.4	6.4	6.4	6.4	6.4	6.4	6.4	6.4	± 6.4
	%	N/A	N/A	N/A	N/A	N/A	± 2.6	N/A	N/A	N/A	4.3	4.3	4.3	4.3	4.3	4.3	4.3	± 2.6	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	± 4.3

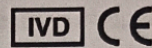
Ref: TEMP-0821 Rev/48 FRONT / RECTO

# ABX Difftrol

- ABX Pentra 60 / 60C+
- ABX Pentra 120 / 120 Retic
- ABX Pentra DX120 / DF120
- Pentra ES60 / MS60 / MS CRP
- Pentra DX Nexus / DF Nexus
- ABX Pentra 80 / XL80
- Pentra XLR
- Yumizen H500 OT / CT / H550
- Yumizen H1500 / H2500

2062011 (L)\*  
2062012 (N)\*  
**REF** 2062013 (H)\*  
2062203 (2N)\*  
2062207 (2L)\*  
2062208 (2H)\*

**CONTROL** 3 mL



**HORIBA ABX SAS**  
Parc Euromédecine - Rue du Caducée  
B.P. 7290  
34184 MONTPELLIER Cedex 4  
FRANCE

## Hematology Devices (for *in vitro* diagnostic use)

### Intended Use \*

**ABX Difftrol** is a tri-level multiparameter control intended for *in vitro* diagnostic use and designed for use in monitoring the accuracy and precision of HORIBA Medical hematology blood cell counters. Refer to the **ABX Difftrol** assay value data sheet for specific instrument models.

### Warnings and Precautions

- **ABX Difftrol** is for professional *in vitro* diagnostic use only.
- It is the user's responsibility to verify that this document is applicable to the product use.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N° 1272/2008.
- Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA approved method and found negative for the presence of HBsAg, HCV and antibody to HIV1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, the products should be treated like patient specimens as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (1, 2, 3).
- Observe the standard laboratory precautions for use and follow national or local health and safety guidelines.
- Please refer to the Material Safety Data Sheet (MSDS) associated with **ABX Difftrol**.

### Waste Management

Please refer to local legal requirements.

\*Modification: designation modification.

### Microbiological State

Not applicable.

### Description and Composition

#### Description:

**ABX Difftrol** is similar in appearance to fresh whole blood. A light pink-tinted supernatant is normal.

#### Composition:

**ABX Difftrol** contains mammalian leucocytes (WBC), erythrocytes (RBC) and thrombocytes (PLT) suspended in a plasma-like fluid.

### Storage and Stability

- **Storage condition (before opening):** 2-8°C (35-46°F). Do not freeze. Store the tubes vertically in their original packages when not in use. Storage in the door compartments of the refrigerator is not recommended.
- **Open stability:** **ABX Difftrol** is stable for 16 sampling events over a maximum of 16 days at 2-8°C (35-46°F) after opening and within the expiration limit. **ABX Difftrol** must be tightly capped after use.
- **Expiration date:** refer to "expiration date" reagent packaging label.

READY

Technician

V 2.2.0.5

## ABX Difftrol

### Materials Required but not Provided

- Automated hematology analyzer.
- Standard laboratory equipment.

### Specimen

Not applicable.

### Procedure

**ABX Difftrol** is ready to use.

An analysis of the control must be carried out on a daily basis at the same time as the patient samples, including each time a calibration or a maintenance is carried out. The frequency of the controls depends on the laboratory requirements. Each laboratory must establish the quality assurance procedures to be followed. These must conform to the current accreditation requirements and pertinent regulations.

1. Bring **ABX Difftrol** to room temperature by rolling the tube between the palms of your hands until the red blood cell sediment is completely suspended. Do not shake.
2. Refer to the user manual to identify **ABX Difftrol** using the barcode reader or manually.
3. Gently invert the tube 8 to 10 times immediately before sampling.
4. Run **ABX Difftrol** according to the procedure described in the user manual.
5. Wipe threads and cap of the tube after use with lint-free gauze.
6. Recap and refrigerate the tube promptly after use.

Refer to the **ABX Difftrol** assay value data sheet for specific instrument models.

Refer to the instrument user manual for detailed analysis and control procedures.

### Methodology

**ABX Difftrol** is a stable preparation used to monitor the accuracy and precision of blood cell counters. Reference values have been obtained from replicate analyses on instruments which have been whole blood calibrated to values obtained from reference methods. **ABX Difftrol** is run on the instrument in the same way as a patient blood sample (resistivity, absorbance and spectrophotometry measurements).

### Performance Characteristics and Limitations

The mean assay values of each **ABX Difftrol** parameter are obtained from replicated assays performed on analysers that have been calibrated using whole blood. The assays were performed using reagents recommended by HORIBA Medical. Values obtained with **ABX Difftrol** (if used before its expiry date) should fall within the expected range. The expected ranges are representative of estimates of the variation between different laboratories for each parameter. Inter-laboratory variations are the consequence of instrument calibration, maintenance, and operating technique. The reference results are therefore only indicative for control purposes and should not be used for calibration. At least five consecutive analyses, on a correctly calibrated analyser, are needed to establish the assay means and standard deviations for each **ABX Difftrol** parameter. See paragraph Traceability of Calibrators and Control Materials.

### Calculation and Interpretation of Results

Refer to the instrument user manual for control procedure and interpretation of results.

### Changes in the Procedure and in the Performance

#### Packaging spoiling

In case of protective packaging spoiling, do not use **ABX Difftrol** if the damages might have an effect on the product performance.

#### Signs of deterioration

In the event of any signs of physical or chemical deterioration (turbidity, change in colour etc.) **ABX Difftrol** should be replaced.

#### Incorrect mixing

Incomplete mixing of the tube prior to use invalidates both the sample that is withdrawn and the remainder of **ABX Difftrol** in the tube.

#### Temperature limits

Do not use **ABX Difftrol** if it has been frozen or kept at excessive heat.

## ABX Difftrol

Before using **ABX Difftrol**, make sure it has reached the operating temperature conditions as described in the instrument user manual.

### Internal Quality Control

ABX Difftrol must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.

HORIBA Medical offers an Online Interlaboratory Comparison Program (QCP) which provides internet access to:

- Submit Internal Quality Control results online.
- Monitor analytical performances and compare directly with hundreds of laboratories worldwide.
- Obtain real time peer group statistical reports from QCP

More informations are available at:  
<http://qcp.horiba-abx.com>

### Traceability of Calibrators and Control Materials

HORIBA Medical controls and calibrators are traceable to standard reference methods.

Hematology analyzers in the Quality Assurance Laboratory are whole blood calibrated to values obtained using the following standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

The **White Blood Cells (WBC)** and **Red Blood Cells (RBC)** are analyzed on a Coulter Counter Z series instrument\*. All counts are corrected for coincidence.

**Hemoglobin** is measured using the Clinical Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method (4). Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations (4).

The **hematocrit** (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H7-A3 document (5). No correction is made for trapped plasma.

**Platelets** are assayed using a hemocytometer and phase contrast optics.

\* All brands and products are trademarks or registered trademarks of their respective companies.

### Reference Intervals

Not applicable.

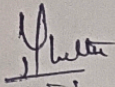
### Reference

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
2. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
3. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition. CLSI (NCCLS), document M29-A3 (2005) **25** (10).
4. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition. CLSI (NCCLS), document H15-A3 (2000) **20** (28).
5. Procedure for Determining Packed Cell Volume by Microhematocrit Method; Approved Standard - Third Edition. CLSI (NCCLS), document H7-A3 (2001) **20** (18).

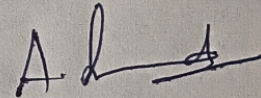
- **Carryover Study:** Carryover is checked by running quality controls (Low & high) in 3 replicates & getting CV% in within acceptance.
- Carry Over % =  $(L1-L3) * 100 / (H3-L3)$ .

Serial No: 802YOXH01328

Parameters	WBC $10^3/\text{mm}^3$	RBC $10^6/\text{mm}^3$	HGB g/dL	PLT $10^3/\text{mm}^3$
Carry Over (%)	-1.23	-1.0	0.0	0.3
Manufacturer acceptable CV%	<2%	<2%	<2%	<2%
Status	Passed	Passed	Passed	Passed



Conducted By:



Verified By:

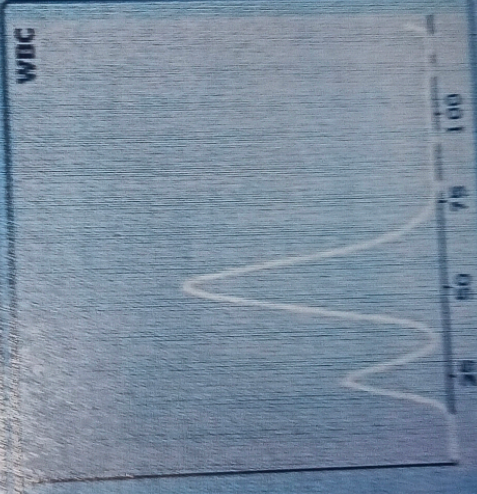
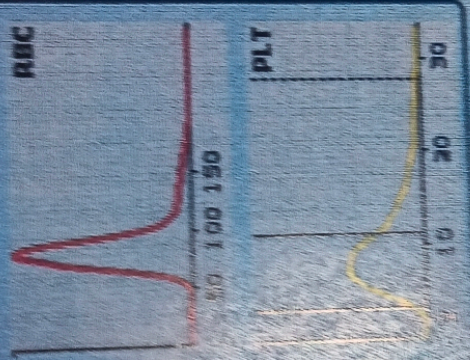
Sample ID **High**  
 Last Name

Gender  
 First Name

Age

Run Date  
 07/18/2023 04:33:09 PM

RBC	5.37	10 <sup>12</sup> /L	PLT	476	h	10 <sup>9</sup> /L
HGB	15.6	g/dL	PCT	0.47	h	%
HCT	51.4	%	MPV	9.8		fL
MCV	95.8	fL	PDW	15.4		%
MCH	30.9	pg	P-LCC	155		%
MCHC	32.2	g/dL	P-LCF	31.7		%
RDW-CV	12.2	%				
RDW-SD	44.4	fL				



WBC **13.23** **Wb** 10<sup>9</sup>/L

Recommended Actions

Slide review

Alarms

Technician

WBC

Background Noise

LYM Interference

Suspected Pathologies

NRBC ?

Leukocytosis

QUAL COMM READ SYST

READY

Technician

V.2.2.6.6

07/18/2023 04:37 PM

# Results

Sample ID **High**

Last Name

Gender

First Name

Age

Run Date  
07/18/2023 04:41:03 PM

### Recommended Actions

Slide review

**Alarms**

Technician

**WBC**

Background Noise

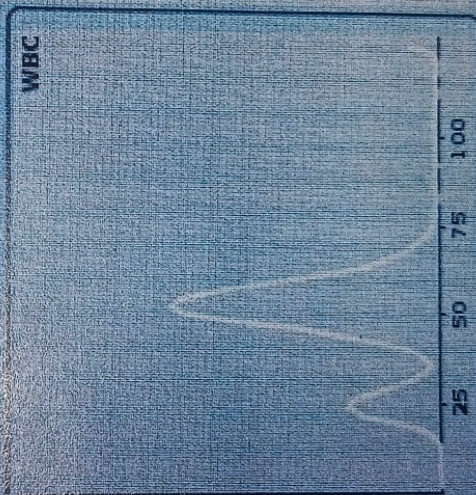
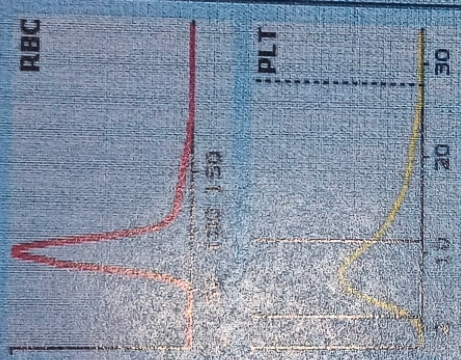
LYM Interference

### Suspected Pathologies

NRBC ?

Leukocytosis

RBC	5.38	10 <sup>6</sup> / $\mu$ L	PLT	485	10 <sup>3</sup> / $\mu$ L
HGB	16.6	g/dL	PCT	0.47	%
HCT	51.6	%	MPV	9.8	fL
MCV	96.0	$\mu$ m <sup>3</sup>	PDW	15.5	%
MCH	30.8	pg	P-LCC	157	%
MCHC	32.1	g/dL	P-LCR	32.3	%
RDW-CV	12.2	%			
RDW-SD	44.4	$\mu$ m <sup>2</sup>			



WBC **13.54 H\*** 10<sup>3</sup>/ $\mu$ L

QUAL  COMM  REAG  SYST

v 2.2-0.5

technician

READY

07/18/2023 04:47 PM

# Results

Sample ID **High**

Last Name

Gender

First Name

Age

Run Date  
07/18/2023 04:44:17 PM

### Recommended Actions

Slide review

### Alarms

Technician

WBC

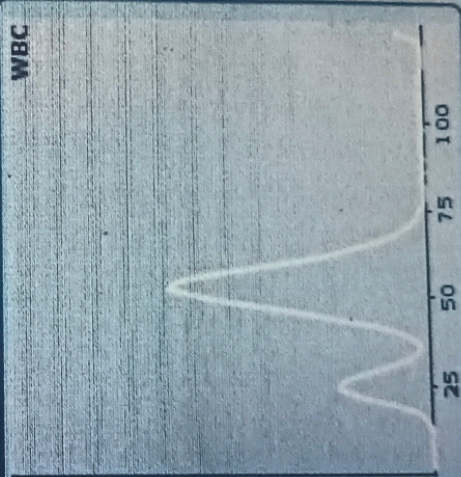
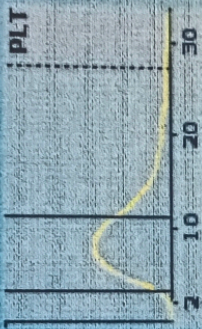
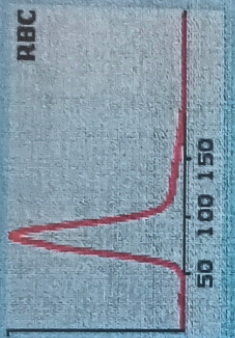
Background Noise

LYM interference

### Suspected Pathologies

NRBC ?

RBC	5.36	$10^9/\mu\text{L}$	PLT	448	$10^9/\mu\text{L}$
HGB	16.4	g/dL	PCT	0.43	%
HCT	51.0	%	MPV	9.6	$\mu\text{m}^3$
MCV	95.3	$\mu\text{m}^3$	PDW	14.6	$\mu\text{m}^3$
MCH	30.7	pg	P-LCC	137	$10^9/\mu\text{L}$
MCHC	32.2	g/dL	P-LCR	30.5	%
RDW-CV	11.8	%			
RDW-SD	42.5	$\mu\text{m}^3$			



WBC 12.91  $10^9/\mu\text{L}$

QUAL  COMM  REAG  SYST

v 2.2.0.5 technician

READY

07/18/2023 04:47 PM



# Results

Sample ID **LOW.**

Last Name

Gender

First Name

Age

Run Date  
07/18/2023 04:34:53 PM

## Recommended Actions

Slide review

**Alarms**

Technician

WBC

Background Noise

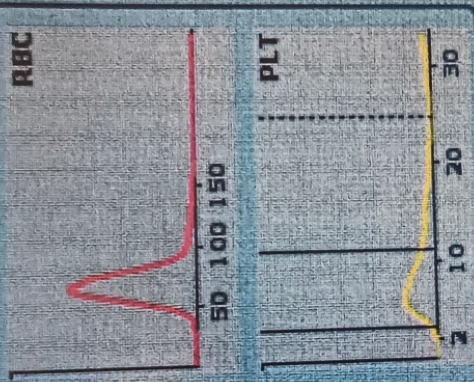
LYM interference

## Suspected Pathologies

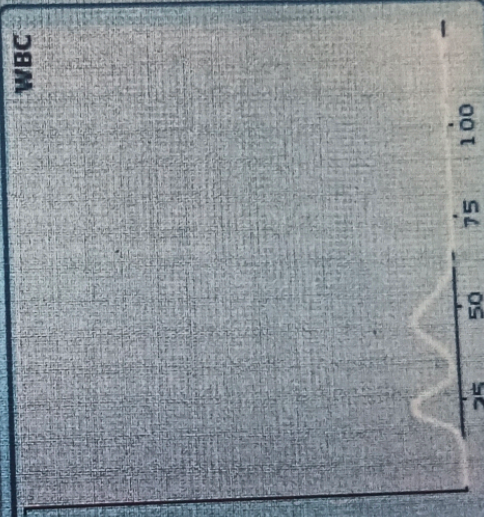
Pancytopenia

Anemia

PLT aggregate or NRBC ?



RBC	2.39	L*	10 <sup>3</sup> /μL	PLT	77	L*	10 <sup>3</sup> /μL
HGB	6.0	L	g/dL	PCT	0.07	%	
HCT	18.9	L*	%	MPV	9.5	* μm <sup>3</sup>	
MCV	78.8	* μm <sup>3</sup>		PDW	17.8	* μm <sup>3</sup>	
MCH	25.0	f	pg	P-LCC	25	10 <sup>3</sup> /μL	
MCHC	31.8	L	g/dL	P-LGR	31.8	%	
RDW-CV	14.1	%					
RDW-SD	42.5	μm <sup>3</sup>					



WBC 1.87 L\* 10<sup>3</sup>/μL

QUAL  COMM  REAG  SYST

Technician

v 2.2.0.5

READY

07/18/2023 04:47 PM

Sample ID LOW

Last Name

First Name

Gender

Age

Run Date  
07/18/2023 04:39:16 PM

Recommended Actions

Slide review

Alarms

Technician

WBC

Background Noise

LYM Interference

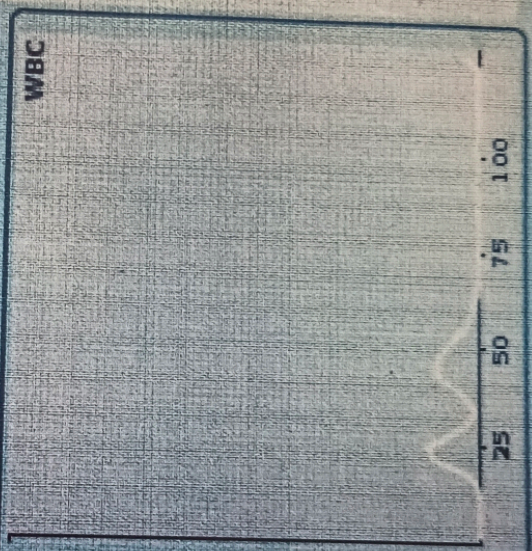
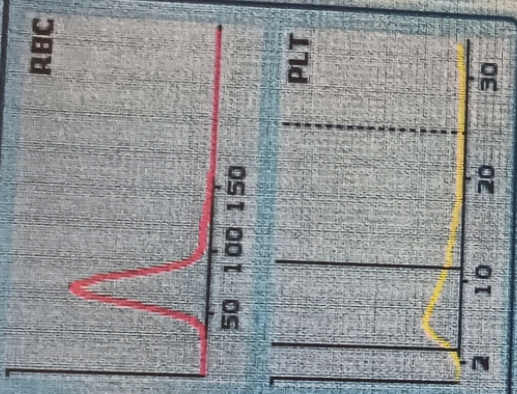
Suspected Pathologies

Pancytopenia

Anemia

PLT aggregate or NRBC ?

RBC	2.40	L	$10^9/\mu\text{L}$	PLT	83	L*	$10^9/\mu\text{L}$
HGB	6.1	L	g/dL	PCT	0.08	L*	%
HCT	18.9	L	%	MPV	9.4	*	$\mu\text{m}^3$
MCV	78.9		$\mu\text{m}^3$	PDW	16.4	*	$\mu\text{m}^3$
MCH	25.3	L	pg	P-LCC	27	L	$10^9/\mu\text{L}$
MCHC	32.0		g/dL	P-LCR	32.2		%
RDW-CV	14.6		%				
RDW-SD	44.4		$\mu\text{m}^3$				



WBC 1.78 L\*  $10^9/\mu\text{L}$

QUAL  COMM  REAG  SYST

v 2.2.0.5

technician

READY

07/18/2023 04:47 PM

# Results

Sample ID **LOW.**

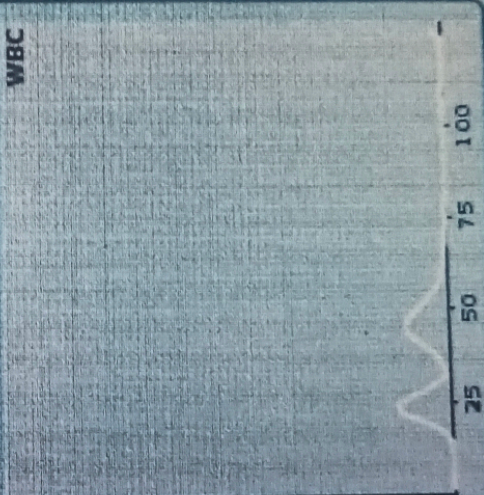
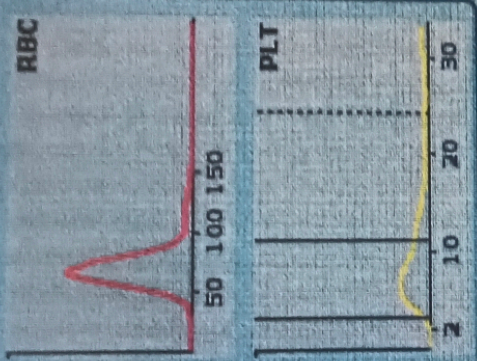
Last Name

Gender

First Name

Age

RBC	2.36	L	10 <sup>9</sup> /μL	PLT	78	L*	10 <sup>9</sup> /μL
HGB	6.0	L	g/dL	PCT	0.07	L*	%
HCT	18.6	L	%	MPV	9.6	*	μm <sup>3</sup>
MCV	78.5		μm <sup>3</sup>	PDW	16.2	*	μm <sup>3</sup>
MCH	25.3	L	pg	P-LCC	25	L	10 <sup>9</sup> /μL
MCHC	32.2		g/dL	P-LCR	32.4		%
RDW-CV	14.6		%				
RDW-SD	43.4		μm <sup>3</sup>				



WBC **L-69** L\* 10<sup>9</sup>/μL

Run Date  
07/18/2023 04:42:40 PM

### Recommended Actions

Slide review

**Alarms**

Technician

WBC

Background Noise

LYM Interference

### Suspected Pathologies

Pancytopenia

Anemia

PLT aggregate or NRBC ?

QUAL  COMM  REAG  SYST

v 2.2.0.5

Technician

READY

07/18/2023 04:47 PM

# Medray Clinics Pvt Ltd, Bengaluru

YH 500			Sr No: 802YOXH01328																						
CARRYOVER STUDY																									
<b>18.07.2023</b>																									
HB	H1	16.4		L1	6.0																				
	H2	16.6		L2	6.1																				
	H3	16.6		L3	6.0																				
RBC	H1	5.36		L1	2.4																				
	H2	5.38		L2	2.4																				
	H3	5.37		L3	2.4																				
PLATELETS	H1	448		L1	78.0																				
	H2	485		L2	83.0																				
	H3	476		L3	77.0																				
WBC	H1	12.91		L1	1.7																				
	H2	13.54		L2	1.8																				
	H3	13.23		L3	1.9																				
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Parameter s</th> <th style="text-align: center;">WBC 10<sup>3</sup>/mm<sup>3</sup></th> <th style="text-align: center;">RBC 10<sup>6</sup>/mm<sup>3</sup></th> <th style="text-align: center;">HGB g/dL</th> <th style="text-align: center;">PLT 10<sup>3</sup>/mm<sup>3</sup></th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Carry Over (%)</td> <td style="text-align: center;">-1.23</td> <td style="text-align: center;">-1.0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0.3</td> </tr> <tr> <td style="text-align: center;">Manufact urer acceptable CV%</td> <td style="text-align: center;">0.5</td> <td style="text-align: center;">1</td> <td style="text-align: center;">1</td> <td style="text-align: center;">0.5</td> </tr> <tr> <td style="text-align: center;">Status</td> <td style="text-align: center;">Passed</td> <td style="text-align: center;">Passed</td> <td style="text-align: center;">Passed</td> <td style="text-align: center;">Passed</td> </tr> </tbody> </table>						Parameter s	WBC 10 <sup>3</sup> /mm <sup>3</sup>	RBC 10 <sup>6</sup> /mm <sup>3</sup>	HGB g/dL	PLT 10 <sup>3</sup> /mm <sup>3</sup>	Carry Over (%)	-1.23	-1.0	0	0.3	Manufact urer acceptable CV%	0.5	1	1	0.5	Status	Passed	Passed	Passed	Passed
Parameter s	WBC 10 <sup>3</sup> /mm <sup>3</sup>	RBC 10 <sup>6</sup> /mm <sup>3</sup>	HGB g/dL	PLT 10 <sup>3</sup> /mm <sup>3</sup>																					
Carry Over (%)	-1.23	-1.0	0	0.3																					
Manufact urer acceptable CV%	0.5	1	1	0.5																					
Status	Passed	Passed	Passed	Passed																					
Source: User Manual , Summary of performance data, Carryover																									

### 3. Summary of Performance Data



The documentation media (USB flash drive) includes the latest version of the "Performance and Reference: Tools for Accreditation" document, which details necessary references and requirements relating to quality management, technical requirements and performance of the analyzer including obtained data results.

#### 3.1. Precision: Reproducibility Claims

Expected Precision (Reproducibility) on control samples

Parameter	Low level (%CV)	Normal level (%CV)	High level (%CV)
WBC	5	4	3
RBC	3	2.5	2.5
HGB	2.5	2	1.8
HCT	5	4	3
MCV	3	2.5	2
MCH	2.5	2.5	2.5
MCHC	3	3	3
RDW-CV	5	5	5
PLT	15	10	7
MPV	6	5	5
LYM%	8	8	8
MON%	40	25	25
NEU%	8	6	4
EOS%	30	25	15
BAS%	40	40	40

#### 3.2. Precision: Repeatability Claims

Based on ten consecutive runs without alarm of the same fresh whole blood sample:

Parameter	%CV	Nominal Values
WBC	< 3	4 - 100 10 <sup>9</sup> /L
RBC	< 2	3.6 - 6.2 10 <sup>12</sup> /L
HGB	< 1.5	120 - 180 g/L

Parameter	%CV	Nominal Values
HCT	< 2	
MCV	< 1.5	0.36 - 0.54 L/L
RDW-CV	< 4	80 - 100 fL
RDW-SD	< 4	10 - 16%
PLT	< 5	37 - 49 fL
P-LCR	< 15	180 - 500 10 <sup>9</sup> /L
LYM%	< 5	15 - 35% and PLT > 50000
MON%	< 15	25 - 50%
NEU%	< 3.5	5 - 10%
EOS%	< 20	45 - 80%
BAS%	< 40	2 - 5%
		1 - 2%

### 3.3. Linearity Limits

**Linearity limits:** maximum and minimum values within which the instrument returns no dilution alarm.

**Visible range:** range values given by the instrument. These values (above linearity limits) are given as an indication. They are associated with a "D" alarm. This visible range is outside manufacturer range.

**Linearity kits:** linearity was tested using commercially available "Low Range" and "Full Range" linearity test kits. The test kits were analyzed and data was computed according to the manufacturer instructions.

**Human blood:** linearity was also performed on human blood, using a minimum of five dilution points. The results of this study are as follows:

Parameter	Linearity Limits	Visible Range	Error Limit <sup>1</sup>
WBC (10 <sup>9</sup> /L)	0 - 300	300 - 999	+/- 0.3 or +/- 7.5%
RBC (10 <sup>12</sup> /L)	0 - 8	8 - 18	+/- 0.07 or +/- 3%
HGB (g/L)	0 - 240	240 - 300	+/- 3 or +/- 3%
HCT (L/L)	0 - 0.67	0.67 - 0.80	+/- 0.02 or +/- 3%
PLT (10 <sup>9</sup> /L) for HGB ≥ 15 g/L	0 - 2500	2500 - 4000	+/- 10 or +/- 12.5%
PLT (10 <sup>9</sup> /L) for HGB < 15 g/L	0 - 4000	4000 - 5000	+/- 10 or +/- 12.5%

<sup>1</sup>: Whichever is greater

### 3.4. Carry-over

The following table shows carry-over for WBC, RBC, HGB and PLT. Carry-over is determined by running whole blood specimens with high target values of WBC, RBC, HGB and PLT. Each specimen is run in triplicate followed by three aspirations of whole blood specimens with low target values.

	WBC (10 <sup>9</sup> /L)	RBC (10 <sup>12</sup> /L)	HGB (g/L)	PLT (10 <sup>9</sup> /L)
Mean low level	1.24	1.11	37	24
Mean high level	97.3	8.26	249	1495
Maximum actual carry-over (%)	0.25%	0.54%	0.50%	0.37%
Claimed carry-over (%)	< 0.5%	< 1%	< 1%	< 0.5%

### 3.5. Reference Values

Parameter	Male	Female
WBC (10 <sup>9</sup> /L)	3.5 - 10	3.5 - 10
RBC (10 <sup>12</sup> /L)	4.2 - 6	3.8 - 5.2
HGB (g/L)	130 - 170	115 - 152
HCT (L/L)	0.39 - 0.52	0.35 - 0.46
MCV (fL)	76 - 100	77 - 97
MCH (pg)	26 - 34	26 - 34
MCHC (g/L)	320 - 350	320 - 355
RDW-CV (%)	11 - 16	11 - 17
RDW-SD (fL)	37 - 49	37 - 49
PLT (10 <sup>9</sup> /L)	150 - 400	150 - 400
MPV (fL)	8 - 11	8 - 11
PCT (L/L)	0.0015 - 0.0040	0.0015 - 0.0040
PDW (fL)	11 - 22	11 - 22
P-LCR (%)	18 - 50	18 - 50
P-LCC (10 <sup>9</sup> /L)	44 - 140	44 - 140
LYM (%)	15 - 45	15 - 45
LYM (10 <sup>9</sup> /L)	1 - 3	1 - 3
MON (%)	4 - 12	4 - 12
MON (10 <sup>9</sup> /L)	0.2 - 0.8	0.2 - 0.8
NEU (%)	40 - 73	40 - 73
NEU (10 <sup>9</sup> /L)	1.6 - 7	1.6 - 7
EOS (%)	0.5 - 7	0.5 - 7
EOS (10 <sup>9</sup> /L)	0 - 0.5	0 - 0.5
BAS (%)	0 - 2	0 - 2
BAS (10 <sup>9</sup> /L)	0 - 0.15	0 - 0.15

Parameter	Male	Female
LIC (%)	0 - 1	0 - 1
LIC (10 <sup>9</sup> /L)	0 - 0.1	0 - 0.1

### Study Conditions

The study was performed on four analyzers during several days at HORIBA Medical. Analyzers calibration was daily checked.

189 whole blood samples from a population of apparently healthy, Caucasian, male and female adults (>18 years of age) from Southern France. The genders and ages were recorded.

The samples were kept at room temperature between sampling and analysis.



Expected values will vary according to sample population and/or geographical location. It is highly recommended that each laboratory establishes its own normal ranges based on the local population.

## 3.6. Accuracy

The data show a good correlation between the results obtained on Yumizen H500 OT and the reference system:

Parameters	R (comparison of means)
WBC	> 0.97
LYM%	> 0.97
MON%	> 0.89
NEU%	> 0.97
EOS%	> 0.95
EAS%	> 0.2
RBC	> 0.97
HGB	> 0.97
HCT	> 0.97
MCV	> 0.84
RDW-CV	> 0.45
RDW-SD	> 0.70
PLT	> 0.97
MPV	> 0.84



### 3.7. Analytical Sensitivity

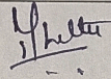
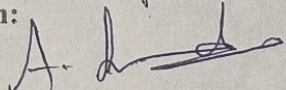
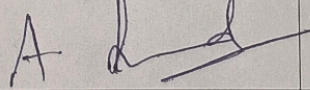
The instrument analytical sensitivity is defined with the following limits:

- LoB (Limit of Blank) is the highest apparent analyte concentration expected to be found when a blank sample containing no analyte is tested.
- LoD (Limit of Detection) is the lowest analyte concentration likely to be reliably distinguished from the LoB and at which detection is feasible.
- LoQ (Limit of Quantitation) is the lowest concentration at which the analyte cannot only be reliably detected but at which some predefined goals for bias and imprecision are met.

Parameter	LoB Conventional Units	LoD Conventional Units	LoQ Conventional Units
WBC	0.1	0.3	0.5
RBC	0.03	0.05	0.5
HGB	0.3	0.4	1.5
HCT	0.1	0.5	1.5
PLT	5	10	20

**B. PERFORMANCE CERTIFICATE:**

Instrument Name : YUMIZEN H500.  
Serial Number : 802YOXH01328  
Customer Details : MEDRAY CLINICS PVT LTD,  
With complete address : # 962 12th main Rd, opp. to Lakmé Salon, Doopanahalli,  
Indiranagar, Bengaluru 560008  
Installation Date : 14/05/2018  
Warranty expires on : CMC

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. YESHWANTH PADASHETTY		
Title: Deputy Service Manager	Sign: 	Date: 18/07/2023	
Reviewed by:	MEDRAY CLINICS PVT LTD, BENGALURU		
Name:	A Lourdu Prasanth		
Title: Lab Incharge	Sign: 	Date: 18/07/23	
Approved by:	MEDRAY CLINICS PVT LTD, BENGALURU		
Name:	A. Lourdu prasanth		
Title: Lab In charge	Sign: 	Date: 18/07/23	

**Conclusion:** Instrument has been qualified for Performance.