

Results Run Date 04/11/2022 11:27:21 AM Operator PATHKIND **Last Name** Sample ID REPEAT 1 **First Name** Rack/Pos Gender Department Patient ID Physician Type Standard Birth Date Sample comments **Recommended actions** Range Slide review 3.83 106/μL 3.80 - 6.00 RBC Alarms 11.5 - 17.0 10.4 g/dL HGB Control failed RBC Draining alarm disabled 31.9 % 35.0 - 52.0 HCT WBC μm³ 76.0 - 100.0 83.1 MCV **Background Noise** 27.0 - 34.0 27.1 MCH pq LYM Interference g/dL 32.6 32.0 - 35.0 HC PLT RBC PLT Interference % 11.0 - 17.0 14.7 RDW-CV Susp. Pathologies μm^3 37.0 - 49.0 100 47.0 RDW-SD Macroplatelets Range PLT aggregate or NRBC ? 227 10³/μL 150 - 400 PLT; PLT 0.15 - 0.40 0.30 PCT * 13.1 μm³ 8.0 - 11.0 **H*** MPV μm³ 11.0 - 22.0 PDW 29.4 10³/μL 44 - 140 122 P-LCC 18.0 - 50.0 P-LCR 53.6 % Range DIE 3.50 - 10.00 9.99 103/µL WBC Range Range % 40.0 - 73.0 1.60 - 7.00 7.10 71.9 NEU h*1.00 - 3.00 15.0 - 45.0 2.20 22.2 LYM 0.43 0.20 - 0.804.3 4.0 - 12.0 MON * 0.00 - 0.50 0.5 - 7.0 0.13 1.4 * 35 0.2 0.0 - 2.0 0.02 0.00 - 0.15* BAS 0.00 - 0.10 0.0 - 1.0 1.2 h*0.11

Slide Review

Neutrophil	Myeloblast	Anysocytosis	
Lymphocyte	Promyelocyte	Hypochromia	
Monocyte	Myelocyte	Polychromasia	
Eosinophil	Metamyelocyte	Poikilocytosis	
Basophil	Blast	Microcytosis	
Atypical Lymphocyte	Target Cell	Macrocytosis	
Other	Sickle Cell	Platelet Clumps	
Reviewed on	by	Signature :	

LIC

h*

Results Run Date 04/11/2022 11:32:42 AM Operator PATHKIND **Last Name** Sample ID REPEAT 2 First Name Rack/Pos Gender Age Department Patient ID Physician Type Standard **Birth Date** Sample comments **Recommended actions** Range Slide review 3.77 106/μL 3.80 - 6.00 RBC Alarms g/dL 11.5 - 17.0 HGB 10.3 Control failed % 35.0 - 52.0 31.3 HCT Draining alarm disabled WBC 76.0 - 100.0 83.1 μm³ MCV **Background Noise** 27.5 27.0 - 34.0 MCH pg LYM Interference 32.0 - 35.0 33.0 g/dL AC. PLT **RBC PLT Interference** RDW-CV 14.3 % 11.0 - 17.0 Susp. Pathologies RDW-SD 46.2 μm³ 37.0 - 49.0 Macroplatelets Range PLT aggregate or NRBC? PLT; 10³/µL 150 - 400 217 PLT 0.29 0.15 - 0.40 PCT % 8.0 - 11.0 MPV 13.6 **H*** μm^3 PDW 31.6 μm³ 11.0 - 22.0 121 103/µL 44 - 140 P-LCC 55.9 18.0 - 50.0 P-LCR Range DIF 3.50 - 10.00 9.55 103/µL WBC Range % Range 6.88 1.60 - 7.00 72.9 40.0 - 73.0 NEU 2.04 1.00 - 3.00 15.0 - 45.0 LYM 21.6 * 3.8 0.36 0.20 - 0.804.0 - 12.0 MON |* 0.5 - 7.0 0.13 0.00 - 0.501.4 55 * 0.03 0.00 - 0.150.0 - 2.0BAS 0.3 * 0.00 - 0.10 LIC 0.11 1.2 h* 0.0 - 1.0

Slide Review

Neutrophil	Myeloblast	Anysocytosis	
Lymphocyte	Promyelocyte	Hypochromia	
Monocyte	Myelocyte	Polychromasia	
Eosinophil	Metamyelocyte	Poikilocytosis	
Basophil	Blast	Microcytosis	
Atypical Lymphocyte	Target Cell	Macrocytosis	
Other	Sickle Cell	Platelet Clumps	
Reviewed on	by	Signature :	

Results Run Date 04/11/2022 11:36:58 AM Operator PATHKIND **Last Name** Sample ID REPEAT 3 First Name Rack/Pos Gender Department Age Patient ID Physician Type Standard **Birth Date** Sample comments Range **Recommended actions** Slide review 106/μL RBC 3.80 3.80 - 6.00 Alarms 10.4 g/dL 11.5 - 17.0 HGB Control failed 35.0 - 52.0 RBC Draining alarm disabled % 31.6 HCT WBC μm³ 76.0 - 100.0 83.3 MCV **Background Noise** 27.0 - 34.0 27.3 MCH pg LYM Interference 32.0 - 35.0 32.8 g/dL 'HC PLT RBC PLT Interference RDW-CV 14.4 % 11.0 - 17.0 Susp. Pathologies RDW-SD 47.0 μm³ 37.0 - 49.0 Macroplatelets Range PLT aggregate or NRBC? 10³/μL PLT; 216 150 - 400 PLT 0.15 - 0.40 0.29 * % PCT 8.0 - 11.0 μm^3 MPV 13.6 **H*** 11.0 - 22.0 PDW 31.0 μm^3 103/μL 44 - 140 122 P-LCC 56.3 % 18.0 - 50.0 P-LCR Range DIF 103/µL 3.50 - 10.00 9.94 WBC Range % Range 1.60 - 7.00 40.0 - 73.0 7.02 71.3 NEU 1.00 - 3.00 22.0 15.0 - 45.0 LYM 2.16 * 0.20 - 0.80 4.0 - 12.0 0.44 4.5 * MON 0.00 - 0.50 0.5 - 7.0 0.17 1.7 * 05 0.00 - 0.15 0.0 - 2.0 0.05 BAS 0.5 *

Slide Review

0.0 - 1.0

Neutrophil	Myeloblast	Anysocytosis	
Lymphocyte	Promyelocyte	Hypochromia	
Monocyte	Myelocyte	Polychromasia	
Eosinophil	Metamyelocyte	Poikilocytosis	
Basophil	Blast	Microcytosis	
Atypical Lymphocyte	Target Cell	Macrocytosis	
Other	Sickle Cell	Platelet Clumps	
Reviewed on	by	Signature :	

LIC

0.10

0.00 - 0.10

1.0

QC - Control Run Report

Run Date 03/08/2022 12:45:43 AM

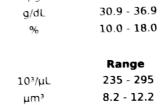
Name PX434N Level Normal Lot number PX434N

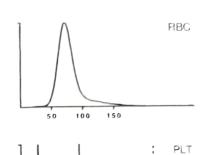
9.8

Operator PATHKIND

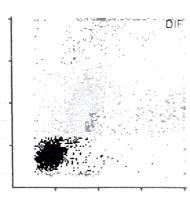
Sample ID PX434N Exp. date 05/05/2022

			Range
RBC	4.63	10°/µL	4.46 - 4.86
HGB	13.2	g/dL	13.1 - 14.1
нст	39.4	%	38.1 - 42.1 81.0 - 91.0
MCV	85.1 28.6	μm³ pg	27.2 - 31.2
MCHC MCHC	33.6	g/dL	30.9 - 36.9
RDW-CV	13.5	%	10.0 - 18.0
			Panga
PLT	248	10³/μL	Range 235 - 295





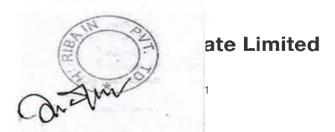
		Range	
7.39	10³/μL	6.20 - 8.20	
#	Range	%	Range
3.57	3.03 - 4.83	48.2	44.6 - 64.6
2.81	1.74 - 3.14	38.1	25.9 - 41.9
0.41	0.00 - 0.80	5.6	0.0 - 11.0
0.38	0.00 - 0.64	5.1	0.0 - 8.8
0.22	0.00 - 0.24	3.0	0.0 - 3.2
	# 3.57 2.81 0.41 0.38	# Range 3.57 3.03 - 4.83 2.81 1.74 - 3.14 0.41 0.00 - 0.80 0.38 0.00 - 0.64	# Range % 3.57 3.03 - 4.83 48.2 2.81 1.74 - 3.14 38.1 0.41 0.00 - 0.80 5.6 0.38 0.00 - 0.64 5.1



Alarms

Slide Review

Neutrophil	Myeloblast	Anysocytosis
Lymphocyte	Promyelocyte	Hypochromia
Monocyte	Myelocyte	Polychromasia
Eosinophil	Metamyelocyte	Poikilocytosis
Basophil	Blast	Microcytosis
Atypical Lymphocyte	Target Cell	Macrocytosis
Other	Sickle Cell	Platelet Clumps
Reviewed on	by	Signature :



HIN/MED/2021-2022/100410

05/10/ 2021

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **YumizenH550** bearing serial number: **910YAXH02141** installed at **PATHKIND LABS**, **VARANASI** as calibrated on 10st SEPT 2021.

Calibrator : ABX MINOCAL

Lot No. : CX462.

Expiry Date : 5th OCT 2021

The reports of Blank Cycle, Repeatability and Calibration Values were all found in acceptable range.

Next calibration cycle is due on 9th SEPT 2022.



Shrish Dixit

(Head- Products & Marketing) For **Horiba India Pvt. Ltd.**

Calibration Report

Sample ID 1 Lot number CX468		Na	me MINOCAL		Exp. date Modified on	05/05/2022
Coefficient	WBC	RBC	HGB	нст	PLT MPV	
New	1.096	0.865	0.977	1.028 0.	911 1.051	
Current	1.110	0.916	0.999	1.001 0.	793 1.070	
Target	8.90	4.60	13.4	38.6 2	263 10.9	
Mean	9.01	4.87	13.7	39.8 2	229 11.1	
CV(%)	2.32	0.96	0.48	1.18 2	.49 0.82	
Number of calibration run sele	ected for coeff	icient calculati	ion (minimum	5) 5/7		
Sel. Run Time	WBC (10³/µL)	RBC (106/µL)	HGB (g/dL)	HCT (%) (1	PLT MPV 10³/μL) (μm³)	
04/10/2022 10:05:05 AM	8.95	4.84 h	13.9 h	39.7 h 2	213 l 11.3	
✓ 04/10/2022 10:07:25 AM	9.27 h	4.90 h	13.7 h	40.3 h 2	32 11.2	
✓ 04/10/2022 10:09:45 AM	9.11 h	4.89 h	13.7 h	40.1 h 2	36 I 11.1	
04/10/2022 10:14:34 AM	8.97	5.71 h	13.5	46.8 h 2	70 11.2	
✓ 04/10/2022 10:16:54 AM	8.70 I	4.79 h	13.6 h	39.1 2	24 11.1	
✓ 04/10/2022 10:19:14 AM	9.00	4.87 h	13.7 h	39.7 h 2	30 11.0	
✓ 04/10/2022 10:21:33 AM	8.98	4.89 h	13.8 h	40.0 h 2	22 I 11.0	

Printed by : technician



HORIBA

Installation Qualification, Performance, Qualification and Operational Qualification

YUMIZEN H550

(Serial no:902**YAXH02141**)
Fully Automated Hematology Analyzer

For

PATH KIND LANKA VARANASI

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

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



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- III. Operator Maintenance Protocol.
- IV. Operational Certificate.

Section 4 Performance Qualifications

- I. Performance Qualification.
- II. Performance Certificate.

Section 5 Attachments



General Instructions:

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H550, Fully 6 part Part Automated Hematology Analyzer, at Sankalpo clinic pvt ltd. 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.
- 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
- PATHKIND DIAGNOSTIC PVT LTD ,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	HORIBA Medical - HORIBA India Pvt. Ltd.			
Name: ARUN PRAKASH					
Title:Executive support	Customer	Sign: Arun frakash	Date: 24/04/2019		
Approved by:	PATHK	IND DIAGNOSTIC PVT L	TD		
Name:		SH KUMAR SINGH			
Title:LAB in cha	rge	Sign: Production	Date: 24/04/2019		



YUMIZEN H550

(Serial no: 902YAXH02141)
Fully Automated Hematology Analyzer

Installation Qualification

For

PATH KIND LANKA VARANASI

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

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A. Installation Qualification

1. Installation Requirement:

Sr. No.	Description	Compliance (Yes/No)
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
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 150VA 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)
1.	Instrument is identified Instrument Serial No.: 902YAXH02141	yes
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



3. Equipment Description:

YUMIZEN H550, Fully Automated Hematology Analyzer

Instrument Identification	Verified Yes/No	
Equipment Type : Hematology Analyzer	Yes	
Model : YUMIZEN H550	Yes	
Manufacturer : HORIBA Medical, France	Yes	
Marketed By :HORIBA Medical - HORIBA India Pvt. Ltd.	Yes	
Equipment # : One	Yes	
Serial Number: 902 YAXH02141	Yes	
Dimensions: 36(W) x 36(D) x 53(H)	Yes	
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz Power Consumption: 150 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.

5. 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.

6. 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 H550.
- 6. Turn on the inbuilt Printer.
- 7. All the operating software has been loaded in to Yumizen H550.
- 8. Now from back side of the instrument turn the power switch ON. Yumizen H550 goes through its power up and self-test sequence.
- The Yumizen H550 login menu is displayed after the Start up cycle is completed. Enter the credentials.



C. INSTALLATION CERTIFICATE:

Instrument Name

: YUMIZEN H550

Serial Number

: 902YAXH02141

Customer Details

: PATHKIND DUIAGNOSTIC PVT LTD,

with complete address

RASMI NAGAR LANKA

VARANASI221005

Installation Date

: 24/04/2019

Warranty expires on

: RR (Reagent Rental).

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.			
Name:	ARUN PRA	ARUN PRAKASH		
Title:Executive C	Customer Sig	hakash	Date:24/04/2019	
Approved by:	PATHKIND	LANKA VARANA	ASI	
Name:	PRADESH I	PRADESH KUMAR SINGH		
Title:LAB Incharge	Sig	gn: rodesh SheL	Date:24/04/2019	

Deviation:

<u>Conclusion:</u> Instrument has been qualified for Installation. Hence it has been taken for Operational Qualification.



HORIBA

YUMIZEN H550

(Serial no: 902YAXH02141)

Fully Automated Hematology Analyzer

Operational Qualification

For

PATHKIND DIAGNOSTIC PVT LTD

VARANASI



#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 H550

Serial Number

902YAXH02141

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

Sr. No.	Test Name	Test Purpose	Method	Observation	
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.	Ok	
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.		
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	Ok	
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.	Ok	
5.	SAMPLE ANALYSIS	TO CHECK PROPER FUNCTIONING	To run Stat/ Manual sample, press on sample identification and enter the sample ID and	ok	



		OF SAMPLE ANALYSIS	press on validate.	
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.	ok
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. To view on QC Runs, Click on Dates.	ok
8	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.	ok

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:

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 H550.

Serial Number

: 902YAXH02141

Customer Details

: PATHKIND DIAGNOSTIC PVT LTD

with complete address

RASMINAGAR LANKA VARANASI 221005

Installation Date

: 24/04/2019

Warranty expires on

: RR (Reagent Rental).

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.					
Name:	ARUN	ARUN PRAKASH				
Title:Customer su	upport	Sign: De Rakersh	Date:24/04/19			
Approved by: PATH		IKIND DIAGNOSTIC Pvt Ltd				
Name:	PRAD	DESH KUMAR SINGH				
Title:		Sign: fradesh Cn	Date:24/04/2019			

Deviation:



<u>Conclusion:</u> Instrument has been qualified for Operational. Hence it has been taken for Performance Qualification.

HORIBA Medical

YUMIZEN H550

(Serial no:902YAXH02141)

Fully Automated Hematology Analyzer

Performance Qualification

For

PATHKIND DIAGNOSTIC PVT LTD

VARANASI



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

A. Performance Qualification

A. Instrument Identification:

Instrument Name

: YUMIZEN H550

Serial Number

902YAXH02141

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: 902YAXH02141

Parameters	Acceptable Range	Observed Value
WBC 10 ³ /mm ³	≤ 0.3 ×10³/ mm³	0.0
RBC 106/mm3	≤ 0.02× 10 ⁶ /mm ³	0.00
HGB g/dL	≤ 0.3 g/dl	0.0
PLT 103/mm3	≤ 10×10³/mm³	0



Conducted By: Jocher

Verified By:

- 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 Minotrol CX456; Exp: 05/05/2019.

Serial No: 902YAXH02141

LEVEL	STATUS	
LOW (PX 426L)	OK	
NORMAL (PX426N)	ОК	
HIGH (PX426H)	OK	

Conducted By: John

Veriffed By:



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

Serial No: 902YAXH02141

Parameters	CV % Acceptance	CV % Observed	Comments
RBC 106/mm³	< 2.0	0.6	
HGB g/dL	< 1.5	0.5	
HCT %	< 2.0	0.7	
PLT 10 ³ /mm ³	< 5.0	3.9	
WBC 10³/mm³	< 2.5	1.2	
GRA %	<4	2.0	
LYM%	<10	1.3	
MON%	<20	6.4	



Conducted By: Asch

Verified By:

- <u>Carryover Study:</u> Carry over 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: 902YAXH02141

Parameters	WBC 10 ³ /mm ³	RBC 106/mm³	HGB g/dL	нст %	PLT 10 ³ /mm ³
Carry Over (%)	0.5	0.9	0	0.6	0.2
Manufacturer acceptable CV%	<1%	<1%	<1%	<1%	<1%
Status	Passed	Passed	Passed	Passed	Passed

Conducted By: frefer

Verified By:



B. PERFORMANCE CERTIFICATE:

Instrument Name

: YUMIZEN H550

Serial Number

: 902YAXH02141.

Customer Details with complete address

: PATHKIND DIAGNOSTIC PVT LTD , RASMINAGAR LANKA VARANASI

Installation Date

: 24/04/2019

Warranty expires on

: RR (Reagent Rental).

Prepared by:	HORIBA	HORIBA Medical - HORIBA India Pvt. Ltd.				
Name:	ARUN P	PRAKASH				
Title:Executive Customer support		Sign: A Prokash	24/04/2019			
Approved by:	PATHK	IND DIAGNOSTIC Pvt Lt	d			
Name: PRADE		SH KUMAR SINGH	The same of the sa			
Title:LAB in char	ge	Sign: page	Date:24/04/2019			

HORIBA			HORIBA India Private Lim		
Medical					
Deviation:					

Conclusion: Instrument has been qualified for Performance.

ATTACHMENTS

Attachment No	Document Title	Page Nos.	Verified By Sign/Date
		7 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	

