



ate Limited

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 10<sup>st</sup> SEPT 2021.

Calibrator : ABX MINOCAL  
Lot No. : CX462.  
Expiry Date : 5<sup>th</sup> OCT 2021

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

Next calibration cycle is due on **9<sup>th</sup> SEPT 2022.**



Shrish Dixit

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



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

**YUMIZEN H550**

**(Serial no:902YAXH02141)**

Fully Automated Hematology Analyzer

For

**PATH KIND LANKA  
VARANASI**

## **Table of Contents:**

### **Section 1 General Instructions**

### **Section 2 Installation Qualification**

- I. Installation Qualification.
- II. Installation Procedure.
- III. Installation Certificate.

### **Section 3 Operational Qualification**

- I. Operational Qualification.
- II. Operational Training Record.
- 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**

<b>Prepared by:</b>	<b>HORIBA Medical - HORIBA India Pvt. Ltd.</b>		
<b>Name:</b>	<b>ARUN PRAKASH</b>		
<b>Title:Executive support</b>	<b>Customer</b>	<b>Sign:</b>	<b>Date: 24/04/2019</b>
<b>Approved by:</b>	<b>PATHKIND DIAGNOSTIC PVT LTD</b>		
<b>Name:</b>	<b>PRADESH KUMAR SINGH</b>		
<b>Title:LAB in charge</b>	<b>Sign:</b>	<b>Date: 24/04/2019</b>	

# YUMIZEN H550

(Serial no: **902YAXH02141**)

Fully Automated Hematology Analyzer

## **Installation Qualification**

For

**PATH KIND LANKA  
VARANASI**

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

<b>Sr. No.</b>	<b>Description</b>	<b>Compliance (Yes/No)</b>
1.	<b>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%.</b>	yes
2.	<b>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.</b>	yes
3.	<b>Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 150VA with earth less than 3 V.</b>	yes
4.	<b>UPS connection available.</b>	yes

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

<b>Sr. No.</b>	<b>Verification</b>	<b>Provided (Yes/No)</b>
1.	<b>Instrument is identified Instrument Serial No. : 902YAXH02141</b>	yes
2.	<b>Manufacturer's specifications: Technical and Physical Requirement</b>	yes
3.	<b>Accessories / consumables are listed as per checklist ( Provided along)</b>	yes
4.	<b>System checked for any External / physical damage.</b>	yes
5.	<b>Instrument User Manual (Soft Copy)</b>	yes

### **3. Equipment Description :**

YUMIZEN H550, Fully Automated Hematology Analyzer

<b>Instrument Identification</b>	<b>Verified Yes/No</b>
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 <b>YAXH02141</b>	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.
9. 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 with complete address** : PATHKIND DUIAGNOSTIC PVT LTD,  
RASMI NAGAR LANKA  
VARANASI221005

**Installation Date** : 24/04/2019

**Warranty expires on** : RR (Reagent Rental).

<b>Prepared by:</b>	<b>HORIBA Medical - HORIBA India Pvt. Ltd.</b>		
<b>Name:</b>	<b>ARUN PRAKASH</b>		
<b>Title:Executive support</b>	<b>Customer</b>	<b>Sign:</b>	<b>Date:24/04/2019</b>
<b>Approved by:</b>	<b>PATHKIND LANKA VARANASI</b>		
<b>Name:</b>	<b>PRADESH KUMAR SINGH</b>		
<b>Title:LAB Incharge</b>		<b>Sign:</b>	<b>Date:24/04/2019</b>

**Deviation:**

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

**HORIBA**  
Medical

**YUMIZEN H550**

(Serial no: **902YAXH02141**)

Fully Automated Hematology Analyzer

**Operational Qualification**

For

**PATHKIND DIAGNOSTIC PVT LTD**  
VARANASI

**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.**

<b>Sr. No.</b>	<b>Test Name</b>	<b>Test Purpose</b>	<b>Method</b>	<b>Observation</b>
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.	Ok
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 OF SAMPLE ANALYSIS	1. To run Stat/ Manual sample, press on sample identification and enter the sample ID and press on validate.	ok

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).

<b>Prepared by:</b>	HORIBA Medical - HORIBA India Pvt. Ltd.		
<b>Name:</b>	ARUN PRAKASH		
<b>Title:Customer support</b>	<b>Sign:</b>	<b>Date:24/04/19</b>	
<b>Approved by:</b>	PATHKIND DIAGNOSTIC Pvt Ltd		
<b>Name:</b>	PRADESH KUMAR SINGH		
<b>Title:</b>	<b>Sign:</b>	<b>Date:24/04/2019</b>	

**Deviation:**

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



**YUMIZEN H550**

**(Serial no:902YAXH02141)**

Fully Automated Hematology Analyzer

## **Performance Qualification**

For

**PATHKIND DIAGNOSTIC PVT LTD**  
**VARANASI**

**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 $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.0
RBC $10^6/\text{mm}^3$	$\leq 0.02 \times 10^6/\text{mm}^3$	0.00
HGB g/dL	$\leq 0.3 \text{ g/dl}$	0.0
PLT $10^3/\text{mm}^3$	$\leq 10 \times 10^3/\text{mm}^3$	0

Conducted By:

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**

<b>LEVEL</b>	<b>STATUS</b>
<b>LOW ( PX 426L)</b>	<b>OK</b>
<b>NORMAL (PX426N)</b>	<b>OK</b>
<b>HIGH (PX426H)</b>	<b>OK</b>

**Conducted By:**

**Verified 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 $10^6/\text{mm}^3$	< 2.0	0.6	
HGB g/dL	< 1.5	0.5	
HCT %	< 2.0	0.7	
PLT $10^3/\text{mm}^3$	< 5.0	3.9	
WBC $10^3/\text{mm}^3$	< 2.5	1.2	
GRA %	<4	2.0	
LYM%	<10	1.3	
MON%	<20	6.4	

Conducted By:

Verified By:

- **Carryover Study:** 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 <sup>3</sup> /mm <sup>3</sup>	RBC 10 <sup>6</sup> /mm <sup>3</sup>	HGB g/dL	HCT %	PLT 10 <sup>3</sup> /mm <sup>3</sup>
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:

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).

<b>Prepared by:</b>	HORIBA Medical - HORIBA India Pvt. Ltd.		
<b>Name:</b>	ARUN PRAKASH		
<b>Title:Executive support</b>	<b>Customer</b>	<b>Sign:</b>	24/04/2019
<b>Approved by:</b>	PATHKIND DIAGNOSTIC Pvt Ltd		
<b>Name:</b>	PRADESH KUMAR SINGH		
<b>Title:LAB in charge</b>	<b>Sign:</b>	<b>Date:24/04/2019</b>	







**Logs - Blank**

Date/Time	Operator	Status	WBC (10 <sup>9</sup> /μL)	RBC (10 <sup>6</sup> /μL)	HGB (g/dL)	PLT (10 <sup>9</sup> /μL)
03/04/2022 11:42:34 PM	PATHKIND	●	0.01	0.01	0.0	0
03/05/2022 12:27:54 AM	PATHKIND	●	0.01	0.01	0.0	1
03/05/2022 12:35:25 AM	PATHKIND	●	0.01	0.00	0.0	4
03/05/2022 01:08:05 AM	PATHKIND	●	0.04	0.00	0.0	0
03/05/2022 05:37:26 AM	PATHKIND	●	0.02	0.00	0.0	1
03/05/2022 06:25:01 AM	PATHKIND	●	0.03	0.01	0.0	1
03/05/2022 02:42:55 PM	PATHKIND	●	0.02	0.00	0.0	2
03/06/2022 12:31:01 AM	PATHKIND	●	0.00	0.01	0.0	2
03/06/2022 02:11:44 AM	PATHKIND	●	0.02	0.00	0.0	1
03/06/2022 03:14:33 AM	PATHKIND	●	0.01	0.00	0.0	0
03/07/2022 12:33:21 AM	PATHKIND	●	0.01	0.00	0.0	1

Parameters: 0.03, 0.01, 0.0, 2  
Status: PASSED  
Comment:  Add Comments

QUAL COMM REAG SYST Print Help

QC - Control Run Report

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

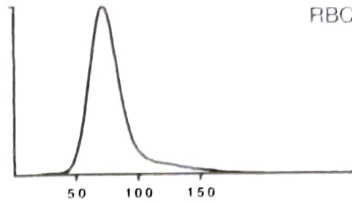
Operator PATHKIND

Name PX434N  
Level Normal  
Lot number PX434N

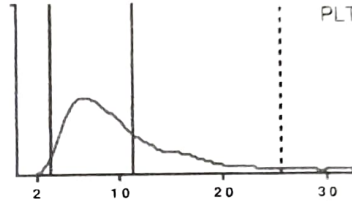
Sample ID PX434N  
Exp. date 05/05/2022

Alarms

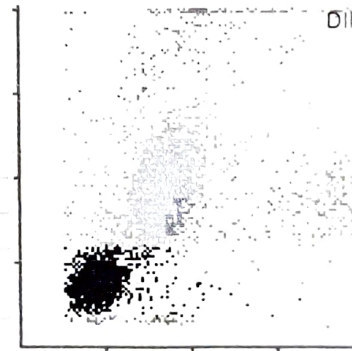
			Range
RBC	4.63	10 <sup>6</sup> /μL	4.46 - 4.86
HGB	13.2	g/dL	13.1 - 14.1
HCT	39.4	%	38.1 - 42.1
MCV	85.1	μm <sup>3</sup>	81.0 - 91.0
MCH	28.6	pg	27.2 - 31.2
MCHC	33.6	g/dL	30.9 - 36.9
RDW-CV	13.5	%	10.0 - 18.0



			Range
PLT	248	10 <sup>3</sup> /μL	235 - 295
MPV	9.8	μm <sup>3</sup>	8.2 - 12.2



			Range		Range
WBC	7.39	10 <sup>3</sup> /μL	6.20 - 8.20		
	#			%	
NEU	3.57	3.03 - 4.83	48.2	44.6 - 64.6	
LYM	2.81	1.74 - 3.14	38.1	25.9 - 41.9	
MON	0.41	0.00 - 0.80	5.6	0.0 - 11.0	
EOS	0.38	0.00 - 0.64	5.1	0.0 - 8.8	
AS	0.22	0.00 - 0.24	3.0	0.0 - 3.2	



*Handwritten signature and initials.*

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 :