

**HORIBA**  
Medical

HORIBA India Private Limited

**HORIBA**  
Medical

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

**YUMIZEN H550**

(Serial no: 103YAXH03289)

**Fully Automated Hematology Analyzer**

For

**JEEVAN SURAKSHA  
BANKURA**

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#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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#### General Instructions:

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H550, Fully 6 part Part Automated Hematology Analyzer, at JEEVAN SURAKSHA BANKURA 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
- JEEVAN SURAKSHA BANKURA ,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:	GOURAB BHATTACHARYA		
Title: Executive support	Customer	Sign: 	Date: 9/11/2021
Approved by:	JEEVAN SURAKSHA BANKURA		
Name:	Swarnit saini		
Title:	Sign: LUPIN DIAGNOSTICS Katjuriwanga, Chhatna Road Bankura, Pin- 722102	Date: 9/11/2021	

**HORIBA**  
Medical

**YUMIZEN H550**

(Serial no:103YAXH03289)

Fully Automated Hematology Analyzer

**Installation Qualification**

For

**JEEVAN SURAKSHA BANKURA**  
BURDWAN

**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. : <b>103YAXH03289</b>	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

<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 : <b>103YAXH03289</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 : **103YAXH03289**  
Customer Name : JEEVAN SURAKSHA BANKURA  
Installation Date : 9/11/2021  
Warranty expires on : RR (Reagent Rental).

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	GOURAB BHATTACHARYA		
Title:Executive support	Customer	Sign: 	Date:9/11/2021
Approved by:	JEEVAN SURAKSHA BANKURA		
Name:	Sourav Sen		
Title:	Sign:  LUPIN DIAGNOSTICS Katjuridanga, Chhatna Road Bankura, Pin- 722102	Date:9/11/2021	

**Deviation:**

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



**HORIBA**  
Medical

**YUMIZEN H550**

(Serial no: **103YAXH03289**)

**Fully Automated Hematology Analyzer**

**Operational Qualification**

For

**LUPIN HEALTHCARE LTD**

**BURDWAN**

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

Instrument Name : YUMIZEN H550

Serial Number : 103YAXH03289

**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.	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**


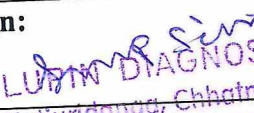
**Operator Training:** The users responsible for the operation of this instrument will be trained on the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filled as indicated 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 : 103YAXH03289  
Customer Name : LUPIN HEALTHCARE LTD  
Installation Date : 9/11/2021  
Warranty expires on : RR (Reagent Rental).

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	GOURAB BHATTACHARYA		
Title: Customer support	Sign: 	Date: 9/11/2021	
Approved by:	JEEVAN SURAKSHA BANKURA		
Name:	Swarup Saini		
Title:	Sign:  LUPIN DIAGNOSTICS Kafjurdanga, Chhatna Road Bankura, Pin- 722102	Date: 9/11/2021	

### Deviation:

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

**HORIBA**  
Medical

**YUMIZEN H550**  
(Serial no: **103YAXH03289**)  
Fully Automated Hematology Analyzer

**Performance Qualification**

For

**LUPIN HEALTHCARE LTD**  
BURDWAN

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

Instrument Name : YUMIZEN H550  
Serial Number : 103YAXH03289

**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: 906YAXH02453

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 DIFFTROL- PX 432; Exp: 01/05/2022.**

Serial No: 103YAXH03289

LEVEL	STATUS
LOW (PX432L)	OK
NORMAL (PX432N)	OK
HIGH (PX432H)	OK

Conducted By: *CebE*

Verified By: *RZ*

**CALIBRATION:** To calibrate the instrument using calibrator (Minocal) and verify the same.  
**Procedure:** go to Quality Assurance icon on main screen and SEVEN calibration icon. Run calibrator (Minocal) 07 times, calibrates the instrument using average of the last 07 runs. Run calibrator as asample to verify the calibration.

. Lot: CX464, Expiry: 05/12/2021

Parameter	Target Value (As per kit insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.70	7.62	1.26	<2%	PASSED
RBC	4.51	4.49	1.12	<2%	PASSED
HGB	13.0	12.9	0.28	<2%	PASSED
HCT	37.4	42.7	1.09	<2%	PASSED
PLT	258	233	3.58	<5%	PASSED

Conducted By:



Verified By:





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

Serial No: 103YAXH03289

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	0.80	PASSED
HGB g/dL	< 1.5	0.62	PASSED
HCT %	< 2.0	0.81	PASSED
PLT $10^3/\text{mm}^3$	< 5.0	4.00	PASSED
WBC $10^3/\text{mm}^3$	< 2.5	1.01	PASSED

Conducted By:





Verified By:



**B. PERFORMANCE CERTIFICATE:**

Instrument Name : YUMIZEN H550  
Serial Number : 103YAXH03289  
Customer Name : JEEVAN SURAKSHA BANKURA  
Installation Date : 9/11/2021  
Warranty expires on : RR (Reagent Rental).

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	GOURAB BHATTACHARYA		
Title:Executive support	Customer	Sign: 	9/11/2021
Approved by:	JEEVAN SURAKSHA BANKURA		
Name:	Swatrup Saini		
Title:	Sign: 	Date:9/11/2021	

LUPIN DIAGNOSTICS  
Katturidanga, Chhatna Road  
Bankura, Pin- 722102

**Deviation:**

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

# HORIBA

Explore the future

**HORIBA India Private Limited**

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HIN/MED/2021/153877

9<sup>TH</sup> NOVEMBER 2021


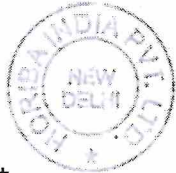
## CALIBRATION CERTIFICATE

This is to certify that the hematology analyzer **YUMIZENH550** bearing serial no: **103YAXH03289** installed at **Jeevan Suraksha Hospital** was calibrated on 9<sup>TH</sup> NOVEMBER 2021.

Calibrator : ABX MINOCAL  
Lot No. : CX464  
Expiry Date : 9<sup>TH</sup> NOVEMBER 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> NOVEMBER 2022

Shrish Dixit

(Marketing Manager)

For Horiba India Pvt Ltd

## HORIBA India Private Limited

246, Okhla Industrial Estate Phase-III,  
New Delhi 110020, India  
Tel : +91 (11) 4646 5000 / 4669 5001  
Fax : +91 (11) 4646 5020  
http : //www.horiba.com  
CIN : U73100DL2006PTC153232

HIN/MED/2022/139983

4th November 2022

## CALIBRATION CERTIFICATE

This is to certify that the hematology analyzer Yumizen H550 bearing serial no: 103YAXH03289 Installed at Lupin Diagnostic Ltd, Bankura was calibrated on 4th November 2022.

Calibrator : ABX MINOCAL  
Lot No. : CX476  
Expiry Date : 05th December 2022

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

Next calibration cycle is due on 4th November 2023



A handwritten signature in blue ink, appearing to be 'Shrish Dixit'.

Shrish Dixit

(Marketing Manager)

For Horiba India Pvt Ltd