

HORIBA
Medical

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

YUMIZEN H550

(Serial no: 308YADH05899)

**Fully Automated Hematology Analyzer
For**

LUPIN DIAGNOSTICS

SOLAPUR

**#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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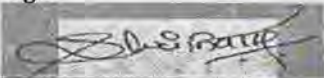
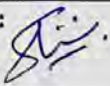
Section4 Performance Qualifications

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

General Instructions:

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H550, Fully 6 Part Automated Hematology Analyzer, at LUPIN DIAGNOSTICS. 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 LUPIN DIAGNOSTICS, 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:	SHRINIVAS DEVKAR		
Title: SR ENGG	Sign: 	Date: 25/09/2023	
Approved by:	LUPIN DIAGNOSTICS, SOLAPUR		
Name:	DR SHIVANI BATTIN		
Title: PATHOLOGIST	Sign: 	Date: 25/09/2023	

YUMIZEN H550

(Serial no: 308YADH05899)

Fully Automated Hematology Analyzer

Installation Qualification

For

LUPIN DIAGNOSTICS

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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: 53(W) x 66.8(D) x 62.1(H)cm with at least 20 cm space at the back of the instrument from the wall.	Yes
3.	Electrical Requirements: Power supply - 100Vac- 240Vac +/- 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. : 308YADH05899	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 : 308YADH05899	Yes
Dimensions : 53(W) x 66.8(D) x 62.1(H)	Yes
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz	yes
Power Consumption: 165 VA	

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 external Printer if required.
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 : 308YADH05899
Customer Details : LUPIN DIAGNOSTICS, SOLAPUR
Installation Date : 25/09/2023
Warranty expires on : 24/09/2028

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.	
Name:	SHRINIVAS DEVKAR	
Title: SR ENGG	Sign: 	Date: 25/09/2023
Approved by:	LUPIN DIAGNOSTICS, SOLAPUR	
Name:	DR SHIVANI BATTIN	
Title: PATHOLOGIST	Sign: 	Date: 25/09/2023

Deviation: NO

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

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YUMIZEN H550

(Serial no: 308YADH05899)

Fully Automated Hematology Analyzer

Operational Qualification

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

Instrument Name : YUMIZENH 550

Serial Number : 308YADH05899

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 AVAIPATHOLOGISTLE 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 ANDALARMS FORSAMPLES	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 : 308YADH05899
Customer Details : LUPIN DIAGNOSTICS, SOLAPUR
Installation Date : 25/09/2023
Warranty expires on : 24/09/2028

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	SHRINIVAS DEVKAR		
Title: SR ENGG	Sign: 	Date: 25/09/2023	
Approved by:	LUPIN DIAGNOSTICS, SOLAPUR		
Name:	DR SHIVANI BATTIN		
Title: PATHOLOGIST	Sign: 	Date: 25/09/2023	

Deviation: NO

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

HORIBA
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HORIBA India Private Limited

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YUMIZEN H550

(Serial no: 308YADH05899)
Fully Automated Hematology Analyzer

Performance Qualification

For

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SOLAPUR**

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4646 5000.

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

Instrument Name : YUMIZEN H550
Serial Number : 308YADH05899

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: 308YADH05899

Parameters	Acceptable Range	Observed Value
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.05
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 $10^3/\text{mm}^3$	$\leq 5 \times 10^3/\text{mm}^3$	0



Conducted By: SHRINIVAS DEVKAR

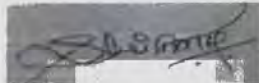


Verified By: DR SHIVANI BATTIN

- **Precision Study:** Precision is checked by running blood sample in 06 replicates & getting CV% in with in acceptance.

Serial No: 308YADH05899

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	0.65	Ok
HGB g/Dl	< 1.5	0.27	Ok
HCT %	< 2.0	0.67	Ok
PLT $10^3/\text{mm}^3$	< 5.0	2.61	Ok
WBC $10^3/\text{mm}^3$	< 2.5	0.83	Ok
MCV μm^3	< 1.5	0.69	Ok



Conducted By: SHRINIVAS DEVKAR

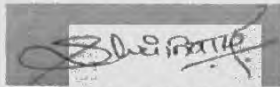


Verified By: DR SHIVANI BATTIN

- **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(ABXMinocal) 10 times, without taking the values of first run, calibrate the instrument using average of the last 10 runs.

Calibration performed successfully by the Quality Assurance(QA) team.



**Checked By: SHRINIVAS DEVKAR
BATTIN**



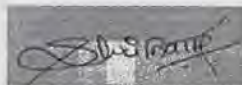
Verified By: DR SHIVANI

- **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 PX443; **Exp:** 05/11/2023.

Serial No: 308YADH05899

LEVEL	STATUS
LOW (PX443L)	PASSED
NORMAL (PX443N)	PASSED
HIGH (PX443H)	PASSED



Conducted By: SHRINIVAS DEVKAR
BATTIN



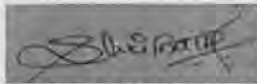
Verified By: DR SHIVANI

▪ 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

Serial No: 308YADH05899

QUALIFIED TRAINED EMPLOYEE NAME	VERIFIED BY	DATE
DR SHIVANI BATTIN	SHRINIVAS	25-09-2023
KHEMSING RATHOD	SHRINIVAS	25-09-2023
GULJAR MUCHALE	SHRINIVAS	25-09-2023
APURVA GURRAM	SHRINIVAS	25-09-2023
RATAN PAWAR	SHRINIVAS	25-09-2023
LAKUL BHALEKAR	SHRINIVAS	25-09-2023
SWATI PUJARI	SHRINIVAS	25-09-2023





Conducted By: SHRINIVAS DEVKAR
BATTIN



Verified By: DR SHIVANI

B. PERFORMANCE CERTIFICATE:

Instrument Name : YUMIZEN H550
Serial Number : 308YADH05899
Customer Details : LUPIN DIAGNOSTICS, SOLAPUR
Installation Date : 25/09/2023
Warranty expires on : 24/09/2028

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	SHRINIVAS DEVKAR		
Title: SR ENGINEER	Sign: 	Date: 25/09/2023	
Approved by:	LUPIN DIAGNOSTICS, SOLAPUR		
Name:	DR SHIVANI BATTIN		
Title: PATHOLOGIST	Sign: 	Date: 25/09/2023	

Deviation: NO

Conclusion: Instrument has been qualified for Performance. Hence it has been taken for Sample Process.



HORIBA India Private Ltd.

246, Okhla Industrial

Estate, Phase - III 110

020 New Delhi, India

Tel: +91 (11) 4646 5000 / 4669 5001

Fax: +91 (11) 4669 5010 / 4646 5020

HIN/MED/2023-2024/0187

25th September 2023.

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **ABX Yumizen H550** bearing serial number: **308YADH05899** installed **Lupin Diagnostic, Solapur, was** Calibrated on **25th September 2023.**

Calibrator : ABX MINOCAL
Lot No. : CX486
Expiry Date : 05th October 2023.

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

Next calibration cycle is due on 24th September 2024.



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

Emergency Stop

QUAL

COMM

REAG

SYST

LUPIN

Home > Quality Assurance > Calibration

CALIBRATION



Calibrator Information

Sample ID 1

Exp. date 10/05/2023

Lot number CX 486

Modified on

Name MINOCAL



Home

Coefficients

	WBC	RBC	HGB	HCT	PLT
New	1.005	0.983	0.960	0.914	1.075
Current	1.080	0.998	0.960	0.870	1.060
Target	8.00	4.50	12.9	35.7	265
Mean	8.94	4.47	12.7	35.5	270
CV(%)	1.31	0.79	0.94	0.78	1.53

Selected runs 5/6
(5 minimum)

Run Date & Time	WBC (10 ³ /mm ³)	RBC (10 ⁶ /mm ³)	HGB (g/dL)	HCT (%)	PLT (10 ³ /mm ³)
✓ 09/22/2023 02:36:51 PM	8.96 h	4.44	12.7	35.3	269
✓ 09/22/2023 02:38:14 PM	8.97 h	4.52	12.7	35.9	269
✓ 09/22/2023 02:40:02 PM	8.86 h	4.46	12.7	35.4	275
✓ 09/22/2023 02:41:23 PM	9.12 h	4.47	12.7 ℓ	35.6	272
✓ 09/22/2023 02:42:46 PM	8.81 h	4.43 ℓ	12.5 ℓ	35.1	264
09/22/2023 02:45:15 PM	9.02 h	4.54	12.7	36.0	269

Start Rack



Stat Mode

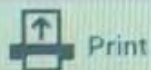
5



Results



Back



Print



Targets



Start Calibration



Cancel



Validate Calibration