



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

YUMIZEN H550
(Serial no: **211YADH05212**)
Fully Automated Hematology Analyzer

For

LUPIN DIAGNOSTICS

Bala nagar

HYDERABAD

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General Instructions:

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H550, 6 Part Fully Automated Hematology Analyzer at LUPIN DIAGNOSTICS, Bala nagar, Hyderabad 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 LUPIN DIAGNOSTICS, Bala nagar, Hyderabad 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:	B.Adibabu		
Title:	Sign:	Date:	
Application Specialist	B. Adibabu	10/02/23	
Reviewed by:			
Name:	A. MEGHANA		
Title:	Sign:	Date:	
Chief of Laboratory	A. Meghana	10/2/23	
Approved by:			
Name:	Dr. MEGHANA. A		
Title:	Sign:	Date:	
Chief of Laboratory	A. Meghana	10/3/23	

HORIBA
Medical

YUMIZEN H550
(Serial no: **211YADH05212**)
Fully Automated Hematology Analyzer

Installation Qualification

For

LUPIN DIAGNOSTICS

BALA NAGAR

HYDERABAD

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 15°C to 30°C and maximum relative humidity of 80%.	YES	<i>B. Adil Babu</i> 10/02/23
2.	Physical Space Requirement: 48 x 40 x 48cm 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 200W 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. : 211YADH05212	YES	<i>B. Adil Babu</i> 10/02/23
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 H 500, 6 PART Fully Automated Hematology Analyzer

Instrument Identification	Verified Yes/No	Verified by / Date
Equipment Type : Hematology Analyzer	YES	B. Adh Bah 10/02/23
Model :YUMIZEN H 550 CT/OT	YES	
Manufacturer : HORIBA Medical, France	YES	
Marketed By :HORIBA Medical - HORIBA India Pvt. Ltd.	YES	
Equipment # : One	YES	
Serial Number : 211YADH05212	YES	
Dimensions : h48 x w40 x 48 cm	YES	
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.

Qualified Trained employee name	Verified By	Date
B. Raju		10/02/23
G. Bhaskar		10/02/23
P. Saji Kumar		10/02/23

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.

A. 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. Connect the instrument to the Printer.
7. All the operating software has been loaded in to YUMIZEN H550
8. Switch ON the Printer. 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 software launch is completed.

B. INSTALLATION CERTIFICATE:

Instrument Name : YUMIZEN H550
Serial Number : 211YADH05212.
Customer Details : LUPIN DIAGNOSTICS, Bala nagar,
With complete address Hyderabad
Installation Date : 10/02/2023
Warranty expires on :

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	B.adibabu		
Title: Application Specialist	Sign: <i>B. Adibabu</i>	Date: 10/02/23	
Reviewed by:			
Name:	A. MEGHANA		
Title: <i>chief of labo</i>	Sign: <i>A. Meghana</i>	Date: 10/2/23.	
Approved by:			
Name:	Dr. MEGHANA . A		
Title: <i>chief of Lab</i>	Sign: <i>A. Meghana</i>	Date: 10/3/23	

Deviation:

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

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Medical

YUMIZEN H550

(Serial no: **211YADH05212**)

Fully Automated Hematology Analyzer

Operational Qualification

For

LUPIN DIAGNOSTICS

BALA NAGAR

HYDERABAD

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

Instrument Name : YUMIZEN H550

Serial Number : 211YADH05212.

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 software. MAIN MENU is displayed after login. Check for any errors on the screen.	OK	<i>J. Adibabu</i> 10/02/23
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 stat icon 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 Reports Icon and view the current results. To view archived reports, Select Archives from File menu 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. and press on Print Icon to print LJ graph. To view the raw data click on Zoom icon and view the data.	OK	<i>B. Adisabhu</i> <i>10/02/23</i>
8..	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.	OK	

A. 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.	<i>D. Bhaskar</i>	<i>Sr. Technician</i>	<i>[Signature]</i>	<i>10/02/23</i>
2.	<i>B. Raju</i>	<i>Lab Supervisor</i>	<i>[Signature]</i>	<i>10/02/23</i>
3.	<i>P. Sajin Kumar</i>	<i>Sr. Technician</i>	<i>[Signature]</i>	<i>10/02/23</i>
4.				
5.				
6.				
7.				
8.				
9.				
10.				

B. Operator Maintenance Protocol

Maintenance and Troubleshooting: Run Cytometer rinsing during shutdown and cleaning whenever required. Run Concentrated Cleaning Procedure once in a week or whenever required.

B. OPERATIONAL CERTIFICATE:

Instrument Name : YUMIZEN H 500
Serial Number : 211YADH05212.
Customer Details : LUPIN DIAGNOSTICS, Bala nagar,
With complete address Hyderabad
Installation Date : 10/02/2023
Warranty expires on :

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	B.Adibabu		
Title: Application Specialist	Sign: B. Adibabu	Date: 10/02/23	
Reviewed by:			
Name:	A. Meghem		
Title: chief of Lab	Sign: A. Meghem	Date: 10/2/23	
Approved by:			
Name:	A. Meghem		
Title: chief of Lab	Sign: A. Meghem	Date: 10/2/23	

Deviation:

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

HORIBA
Medical

YUMIZEN H550

(Serial no: **211YADH05212**)

Fully Automated Hematology Analyzer

Performance Qualification

For

LUPIN DIAGNOSTICS

BALA NAGAR

HYDERABAD

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

Instrument Name : YUMIZEN H550
Serial Number : 211YADH05212.

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: 211YADH05212

Parameters	Acceptable Range	Observed Value	Verified by Sign/Date
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^9/\text{L}$	0.01	PASSED
RBC $10^6/\text{mm}^3$	$\leq 0.03 \times 10^{12}/\text{L}$	0.00	PASSED
HGB g/dL	$\leq 0.3 \text{ g/dl}$	0.0	PASSED
PLT $10^3/\text{mm}^3$	$\leq 5 \times 10^9/\text{L}$	1	PASSED

Conducted By: *Z. Adil Baber*Verified By: *[Signature]*

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

Serial No: 211YADH05212

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	0.83	PASSED
HGB g/dL	< 1.5	0.55	PASSED
HCT %	< 2.0	1.08	PASSED
PLT $10^3/\text{mm}^3$	< 5.0	3.06	PASSED
WBC $10^3/\text{mm}^3$	< 3.0	1.37	PASSED

Conducted By: B. Adibabu

Verified By: J

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

Access: Main Screen > Quality Assurance > Calibration

Procedure: Go to Quality Assurance icon on main screen and then Calibration icon. Run Calibrator (ABX Minocal) 11 times, without taking the values of first run, calibrate the instrument using average of the last 5 runs. Run Calibrator as a sample to verify the calibration.

Lot: CX480; **Expiry:** 04/05/2023.

Serial No: 211YADH05212

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.60	8.71	1.20	<2%	PASSED
RBC	4.53	4.28	1.22	<2%	PASSED
HGB	13.2	13.5	0.54	<1.5%	PASSED
HCT	38.2	38.6	1.21	<2%	PASSED
PLT	250	249	1.48	<5%	PASSED

Conducted By: *B. Adibakur*

Verified By: *J*

- **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 Diffrol PX440L; **Exp:** 05/05/2023.

Serial No: 211YADH05212

Level I: Low Control

Parameters	Range (As per Kit Insert)	Observed Value Dated 2/15/2023	Comments
RBC 10 ⁶ /mm ³	2.29 - 0.16	2.22	Passed
HGB g/dL	6.0 - 0.40	6.2	Passed
HCT %	17.8 - 1.5	16.9	Passed
MCV μm ³	77.7 - 5.0	76.3	Passed
MCH pg	26.2 - 2.0	28.1	Passed
MCHC g/dL	33.7 - 3.0	36.8	Passed
RDW %	12.1 - 4.0	13.7	Passed
PLT 10 ³ /mm ³	91 - 20	94	Passed
MPV μm ³	9.7 - 2.0	10.1	Passed
WBC 10 ³ /mm ³	2.95 - 0.40	2.89	Passed
NEU %	40.4-10.0	44.3	Passed
NEU #	1.19-0.35	1.28	Passed
LYM %	41.9-12.0	39.0	Passed
LYM #	1.24-0.33	1.13	Passed
MON %	7.5-7.3	7.6	Passed
MON #	0.22-0.22	0.22	Passed
EOS %	6.4-6.4	6.9	Passed
EOS #	0.19-0.19	0.20	Passed
BAS %	3.8-3.8	2.2	Passed
BAS #	0.11-0.11	0.06	Passed

Level II: Normal Control

Parameters	Range (As per Kit Insert)	Observed Value Dated 2/15/2023	Comments
RBC 10 ⁶ /mm ³	4.47-0.20	4.42	Passed
HGB g/dL	13.0-0.5	13.3	Passed
HCT %	38.6-2.0	37.2	Passed
MCV μm ³	86.4-5.0	84.1	Passed
MCH pg	29.1-2.0	30.1	Passed
MCHC g/dL	34.7-3.0	35.8	Passed
RDW %	11.2-4.0	12.7	Passed
PLT 10 ³ /mm ³	288-30	285	Passed
MPV μm ³	8.9-2.0	9.2	Passed
WBC 10 ³ /mm ³	8.43-1.0	8.15	Passed
NEU %	43.8-10.0	48.0	Passed
NEU #	3.63-0.90	3.92	Passed
LYM %	43.0-8.0	41.0	Passed

LYM #	3.63-0.70	3.34	Passed
MON %	5.1-4.4	4.8	Passed
MON #	0.43-0.37	0.39	Passed
EOS %	3.8-3.7	3.7	Passed
EOS #	0.32-0.31	0.30	Passed
BAS %	4.2-4.2	2.5	Passed
BAS #	0.35-0.35	0.20	Passed

Level III: High Control

Parameters	Range (As per Kit Insert)	Observed Value Dated 2/15/2023	Comments
RBC 10 ⁶ /mm ³	5.11-0.25	5.10	Passed
HGB g/dL	15.9-0.6	16.5	Passed
HCT %	45.4-2.5	46.0	Passed
MCV μm ³	88.8-5.0	90.2	Passed
MCH pg	31.1-2.5	32.4	Passed
MCHC g/dL	35.0-3.0	35.9	Passed
RDW %	10.6-4.0	12.2	Passed
PLT 10 ³ /mm ³	549-50	546	Passed
MPV μm ³	9.52.0	9.7	Passed
WBC 10 ³ /mm ³	18.70-2.20	17.79	Passed
NEU %	64.0-10.0	67.8	Passed
NEU #	11.97-1.90	12.07	Passed
LYM %	22.7-8.0	21.4	Passed
LYM #	4.25-1.50	3.80	Passed
MON %	4.1-3.6	3.8	Passed
MON #	0.76-0.66	0.68	Passed
EOS %	4.7-4.7	4.2	Passed
EOS #	0.88-0.73	0.74	Passed
BAS %	4.5-4.5	2.8	Passed
BAS #	0.84-0.84	0.50	Passed

Conducted By: *B. Adibabau*

Verified By: *A*

- **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: 211YADH05212

Parameters	WBC 10 ³ /mm ³	RBC 10 ⁶ /mm ³	HGB g/Dl	PLT 10 ³ /mm ³	
Carry Over (%)	-0.56	-1.08	-0.98	-0.84	
Manufacturer acceptable CV%	<1%	<1%	<1%	<2%	
Status	Passed	Passed	Passed	Passed	

Conducted By: *TS. Adil Babbar*

Verified By:

J

B. PERFORMANCE CERTIFICATE:

Instrument Name : YUMIZEN H550
Serial Number : 211YADH05212.

Customer Details : LUPIN DIAGNOSTICS, Bala nagar,
With complete address Hyderabad

Installation Date : 10/02/2023

Warranty expires on :

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	B.Adibabu		
Title: Application Specialist	Sign: B. Adibabu	Date: 10/02/23	
Reviewed by:			
Name:	A. MEGHANA		
Title: chief of Lab	Sign: A. Meghana	Date: 10/2/23	
Approved by:			
Name:	A. MEGHANA		
Title: chief of Lab	Sign: A. Meghana	Date: 10/2/23	

Deviation:

Conclusion: Instrument has been qualified for Performance.



YUMIZEN H550

(Serial no: **211YADH05212**)

Fully Automated Hematology Analyzer

Design Qualification

For

LUPIN DIAGNOSTICS

BALA NAGAR

HYDERABAD

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. PDW = Platelet Distribution Width
10. MPV = Mean Platelet Volume
11. PCT = Plateletcrit
12. PLCR = Platelet Large Cell Ratio
13. PLCC = Platelet Large Cell Content
14. NEUT# = Neutrophil Count
15. LYMPH# = Lymphocyte Count
16. MONO# = Monocyte Count
17. EO# = Eosinophil Count
18. BASO# = Basophil Count
19. LIC# = Large Immature Cell Count
20. NEUT% = Neutrophil Percent
21. LYMPH% = Lymphocyte Percent
22. MONO% = Monocyte Percent
23. EO% = Eosinophil Percent
24. BASO% = Basophil Percent
25. LIC% = Large Immature Cell Percent
26. RDW-CV=Red Cell Distribution (CV)
27. RDW -SD-Red Cell Distribution (SD)

B. DESIGN CERTIFICATE:

Instrument Name : YUMIZEN H550
Serial Number : 211YADH05212.
Customer Details : LUPIN DIAGNOSTICS, Bala nagar,
With complete address Hyderabad
Installation Date : 10/02/2023
Warranty expires on :

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	B.adibabu		
Title: Application Specialist	Sign: B. Adibabu	Date: 10/02/23	
Reviewed by:			
Name:	A. MEGHANA		
Title: chief of lab	Sign: d. Meghem	Date: 10/2/23	
Approved by:			
Name:	A. MEGHANA		
Title: chief of lab	Sign: d. Meghem	Date: 10/2/23	

Deviation:

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