

HORIBA

Medical

Installation Qualification, Performance, Qualification and Operational Qualification

YUMIZEN H550
(Serial no: **211YADH04088**)
Five Part Hematology Analyzer

For

LUPIN DIAGNOSTICS

**6/2, Anekal Main Road, Suryanagar Phase I,
Suryanagar, Bengaluru, Chandrapura -Chatrakane,
Karnataka 562106.**

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General Instructions:

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H550, Five Part Hematology Analyzer, at LUPIN DIAGNOSTICS, BENGALURU 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, BENGALURU 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:	Mr. MITHUN KRISHNA C U		
Title:	Sign:	Date:	
ENGINEER-CUSTOMER SUPPORT	<i>Mithun</i>	13/7/2023	
Reviewed by:	LUPIN DIAGNOSTICS, BENGALURU		
Name:	<i>Vigneshwalan . S</i>		
Title:	Sign:	Date:	
<i>Lab Incharge</i>	<i>Vigneshwalan . S</i>	13/7/2023	
Approved by:	LUPIN DIAGNOSTICS, BENGALURU		
Name:	<i>Vigneshwalan . S</i>		

HORIBA

Medical

YUMIZEN H550

(Serial no:**211YADH04088**)

Five Part Hematology Analyzer

Installation Qualification

For

LUPIN DIAGNOSTICS

**6/2, Anekal Main Road, Suryanagar Phase I,
Suryanagar, Bengaluru, Chandrapura -Chatrakane,
Karnataka 562106.**

A. 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 16°C to 34°C and maximum relative humidity of 80%.	Yes	8/7/2023
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 165 VA 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.:211YADH04088	Yes	8/7/2023
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	

2. Equipment Description:

YUMIZEN H550, Five Part Hematology Analyzer

Instrument Identification	Verified Yes/No	Verified by / Date
Equipment Type: Hematology Analyzer	YES	8/7/2023
Model: YUMIZEN H550	YES	
Manufacturer: HORIBA Medical, France	YES	
Marketed By: HORIBA Medical - HORIBA India Pvt. Ltd.	YES	
Equipment #: One	YES	
Serial Number :211YADH04088	YES	
Dimensions :53(W) x 66.8(D) x 62.1(H)	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
Rajesh.A	<i>Rajesh.A</i>	08/07/23
Yeshwanth Padashetty	<i>Yeshwanth</i>	08/07/23
Sreesagar Deepak. B. N		
Mithun Krishna C U	<i>Mithun</i>	8/7/23.

3. 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.

4. 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 backside 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 : 211YADH04088
Customer Details : LUPIN DIAGNOSTICS,
With complete address : 6/2, Anekal Main Road, Suryanagar Phase I, Suryanagar,
Bangalore, Chandrapura -Chatrakane,
Karnataka 562106
Installation Date : 8/7/2023
Warranty expires on : RR

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. MITHUN KRISHNA C U		
Title:	Sign:	Date:	
Customer Support Engineer	Mithun	8/7/2023	
Reviewed by:	LUPIN DIAGNOSTICS, BENGALURU		
Name:	Vigneshwaram. S		
Title:	Sign:	Date:	
Lab Incharge	[Signature]	8/7/2023	
Approved by:	LUPIN DIAGNOSTICS, BENGALURU		
Name:	Dr. JYOTI JADI YAPPAGAUDAR		
Title:	Sign:	Date:	
CONSULTANT PATHOLOGIST	[Signature]	8/7/23	

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

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YUMIZEN H550
(Serial no: **211YADH04088**)
Five Part Hematology Analyzer

Operational Qualification

For

LUPIN DIAGNOSTICS

**6/2, Anekal Main Road, Suryanagar Phase I,
Suryanagar, Bengaluru, Chandrapura -Chatrakane,
Karnataka 562106.**

#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 : 211YADH04088

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 yumizen Application software. Start up cycle is performed .Login in as User and check for the Screen Errors.	Done	8/7/2023
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.	Done	
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	Done	
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.	Done	
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.	Done	
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.	Done	

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 on QC Runs ,Click on Datas .	Done	8/7/2023
8..	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.	Done	

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:

Sr. No.	Operators	Designation	Name & Sign of the Trainer.	Date
1.	Vigneshwaleen. S	Lab. Incharge	Mithun	14/7/23
2.	Mahesh Boopathi	Lab Technician	Mithun	14/7/23
3.	Sandhya	Lab Technician	Mithun	14/7/23
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
16.				

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 : 211YADH04088
Customer Details : LUPIN DIAGNOSTICS,
With complete address : 6/2, Anekal Main Road, Suryanagar Phase I,
Suryanagar, Bengaluru, Chandrapura -Chatrakane,
Karnataka 562106
Installation Date : 8/7/2023
Warranty expires on :RR

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. MITHUN KRISHNA C U		
Title:	Sign:	Date:	
Customer Support Engineer	<i>Mithun</i>	13/7/23 .	
Reviewed by:	LUPIN DIAGNOSTICS, BENGALURU		
Name:	<i>Vigneshwaran. S.</i>		
Title:	Sign:	Date:	
Leib Incharge	<i>V. S.</i>	13/7/2023	
Approved by:	LUPIN DIAGNOSTICS, BENGALURU		
Name:	<i>Dr Jyoti JADYAPPIYAGUDAR</i>		
Title:	Sign:	Date:	
CONSULTANT PATHOLOGIST	<i>Jyoti</i>	13/7/23	

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

HORIBA

Medical

YUMIZEN H550
(Serial no: **211YADH04088**)
Five Part Hematology Analyzer

Design Qualification

For

LUPIN DIAGNOSTICS
6/2, Anekal Main Road, Suryanagar Phase I,
Suryanagar, Bengaluru, Chandrapura -Chatrakane,
Karnataka 562106.

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. RDW-CV = Red Cell Distribution Width (Coefficient of Variation)
10. RDW-SD = Red Cell Distribution Width (Standard Deviation)
11. PDW = Platelet Distribution Width
12. MPV = Mean Platelet Volume
13. PCT = Plateletcrit
14. P-LCC # = Platelet Large Cell Concentration
15. P-LCR % = Platelet Large Cell Ratio
16. NEUT# = Neutrophil Count
17. LYMPH# = Lymphocyte Count
18. MONO# = Monocyte Count
19. EOSI# = Eosinophil Count
20. BASO# = Basophil Count
21. NEUT% = Neutrophil Percent
22. LYMPH% = Lymphocyte Percent
23. MONO% = Monocyte Percent
24. EOSI% = Eosinophil Percent
25. BASO% = Basophil Percent
26. LIC# = Large Immature Cells Count
27. LIC% = Large Immature Cells Percent

B. DESIGN CERTIFICATE:

Instrument Name : YUMIZEN H550
Serial Number : 211YADH04088
Customer Details : LUPIN DIAGNOSTICS,
With complete address : 6/2, Anekal Main Road, Suryanagar Phase I,
Suryanagar, Bengaluru, Chandrapura -Chatrakane,
Karnataka 562106
Installation Date : 8/7/2023
Warranty expires on : RR

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. MITHUN KRISHNA C U		
Title:	Sign:	Date:	
Customer Support Engineer	Mithun	13/7/23	
Reviewed by:	LUPIN DIAGNOSTICS, BENGALURU		
Name:	Vigneshwaran. S		
Title:	Sign:	Date:	
Lab Incharge	S. Vigneshwaran	13/7/2023	
Approved by:	LUPIN DIAGNOSTICS, BENGALURU		
Name:	DR. JYOTI JABJIYAPPA GOUTAR		
Title:	Sign:	Date:	
CONSULTANT PATHOLOGIST	Jyoti	13/7/23	

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

HORIBA

Medical

YUMIZEN H550

(Serial no:**211YADH04088**)

Five Part Hematology Analyzer

Performance Qualification

For

LUPIN DIAGNOSTICS

**6/2, Anekal Main Road, Suryanagar Phase I,
Suryanagar, Bengaluru, Chandrapura -Chatrakane,
Karnataka 562106.**

A. Performance Qualification


A. Instrument Identification:

Instrument Name : YUMIZEN H550.
Serial Number : 211YADH04088

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: 211YADH04088

Parameters	Acceptable Range	Observed Value	Verified by Sign/Date
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.00	
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 $10^3/\text{mm}^3$	$\leq 5 \times 10^3/\text{mm}^3$	2	


Conducted By:


Verified By:

- **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 (ABX Minocal) 6 times without taking the values of first run, calibrate the instrument using average of the last 5 runs.

Lot: CX 484; **Expiry:** 05/08/2023.

Serial No: 211YADH04088

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.80	9.21	1.44	<3%	PASSED
RBC	4.54	4.56	0.63	<2%	PASSED
HGB	13.3	13.5	0.73	<1%	PASSED
HCT	36.4	35.9	0.35	<2%	PASSED
PLT	277	273	2.23	<5%	PASSED

Mithun
Conducted By:

[Signature]
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 PX443; Exp: 05/11/23

Serial No: 211YADH04088

Level I: Low Control

Parameters	Target	Tolerance	Observed Value Dated 10/10/2023	Comments
RBC 10 ⁶ /mm ³	2.24	0.16	2.21	Passed
HGB g/dL	5.7	0.40	5.6	Passed
HCT %	16.3	1.50	17.1	Passed
MCV μm ³	72.8	5.00	77.1	Passed
MCH pg	25.4	2.00	25.2	Passed
MCHC g/dL	35	3.00	32.6	Passed
RDW %	18.3	4.00	15	Passed
PLT 10 ³ /mm ³	82	20.0	88	Passed
MPV μm ³	10.7	2.00	12.4	Passed
WBC 10 ³ /mm ³	3	0.40	3.07	Passed
NEU %	44	10.0	40.8	Passed
NEU#	1.32	0.35	1.25	Passed
LYM%	40.3	12.0	36.7	Passed
LYM #	1.21	0.33	1.13	Passed
MON %	7.9	5.8	8.9	Passed
MON #	0.24	0.19	0.27	Passed
EOS%	4.3	6.7	8.1	Passed
EOS#	0.13	0.21	0.25	Passed
BAS%	3.5	2.6	5.5	Passed
BAS#	0.11	0.06	0.17	Passed

Level II: Normal Control

Parameters	Target	Tolerance	Observed Value Dated 10/10/2023	Comments
RBC 10 ⁶ /mm ³	4.66	0.20	4.72	Passed
HGB g/dL	13.1	0.50	13.2	Passed
HCT %	37.9	2.00	39.7	Passed
MCV μm ³	81.4	5.00	84.2	Passed
MCH pg	28.1	2.00	28.0	Passed
MCHC g/dL	34.5	3.00	33.3	Passed
RDW %	15.9	4.00	14	Passed
PLT 10 ³ /mm ³	274	30.0	274	Passed
MPV μm ³	9.6	2.00	11.5	Passed
WBC 10 ³ /mm ³	8.4	1.00	9.07	Passed
NEU %	45.3	10.0	46	Passed
NEU #	3.81	0.90	4.16	Passed
LYM %	42.2	8.00	38.6	Passed
LYM #	3.54	0.70	3.50	Passed
MON %	6	3.9	7.0	Passed
MON #	0.5	0.32	0.64	Passed
EOS%	3.5	4.1	5.2	Passed
EOS#	0.29	0.34	0.48	Passed
BAS%	3	1.2	3.2	Passed
BAS#	0.25	0.10	0.29	Passed

Level III: High Control

Parameters	Target	Tolerance	Observed Value Dated 10/10/2023	Comments
RBC 10 ⁶ /mm ³	5.28	0.25	5.28	Passed
HGB g/dL	16.2	0.60	16.2	Passed
HCT %	47.2	2.50	49	Passed
MCV μm ³	89.4	5.00	92.8	Passed
MCH pg	30.7	2.50	30.7	Passed
MCHC g/dL	34.3	3.00	33.1	Passed
RDW %	13.9	4.00	12.9	Passed
PLT 10 ³ /mm ³	528	50.0	530	Passed
MPV μm ³	10.3	2.00	12.3	Passed
WBC 10 ³ /mm ³	18.3	2.20	17.69	Passed
NEU %	66.8	10.0	63.8	Passed
NEU #	12.22	1.90	11.28	Passed
LYM %	20.8	8.00	20.5	Passed
LYM #	3.81	1.50	3.63	Passed
MON %	4.3	3.1	5.4	Passed
MON #	0.79	0.56	0.96	Passed
EOS%	4.1	4.70	4.4	Passed
EOS#	0.75	0.86	0.77	Passed
BAS%	4	4	5.9	Passed
BAS#	0.92	0.92	1.05	Passed

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Conducted By:

[Signature]
Verified By:

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

Serial No: 211YADH04088

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	1.09	PASS
HGB g/dL	< 1.5	0.34	PASS
HCT %	< 2.0	1.06	PASS
PLT $10^3/\text{mm}^3$	< 5.0	2.74	PASS
WBC $10^3/\text{mm}^3$	< 2.5	1.10	PASS

Mithun
Conducted By:

Verified By: *[Signature]*

- Carryover Study: Carryover 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: 211YADH04088

Parameters	WBC $10^3/mm^3$	RBC $10^6/mm^3$	HGB g/dL	PLT $10^3/mm^3$
Carry Over (%)	0.8	0.3	0	0.2
Manufacturer acceptable CV%	<2%	<2%	<2%	<2%
Status	Passed	Passed	Passed	Passed

Nithin
Conducted By:

[Signature]
Verified By:

B. PERFORMANCE CERTIFICATE:

Instrument Name : YUMIZEN H550.
Serial Number : 211YADH04088
Customer Details : LUPIN DIAGNOSTICS,
With complete address : 6/2, Anekal Main Road, Suryanagar Phase I, Suryanagar,
Bengaluru, Chandrapura -Chatrakane, Karnataka 562106
Installation Date : 8/7/2023
Warranty expires on :RR

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. MITHUN KRISHNA C U		
Title: Deputy Service Manager	Sign: <i>Mithun</i>	14/7/23	
Reviewed by:	LUPIN DIAGNOSTICS, BENGALURU		
Name:	<i>Vigneshwaran. S</i>		
Title: <i>Lab Incharge</i>	Sign: <i>Vignesh</i>	Date: 14/7/2023	
Approved by:	LUPIN DIAGNOSTICS, BENGALURU		
Name:	<i>R. JYOTI JADSY APPAGOUDAR</i>		
Title: <i>CONSULTANT PATHOLOGIST</i>	Sign: <i>Jyoti</i>	Date: 14/7/23	

Conclusion: Instrument has been qualified for Performance.