

HORIBA
Medical

HORIBA India Private Limited

HORIBA
Medical

ABX YUMIZEN H550

(Serial no: 207YAXH03883)

Fully Automated Hematology Analyzer

Installation Qualification

For

LUPIN DIAGNOSTICS DL LAB BHOPAL

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.

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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	Mr. Ravindra Singh Chouhan
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.		
3.	Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 150VA with earth less than 3 V.		
4.	UPS connection available.		

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. : 207YAXH03883	YES	Mr. Ravindra Singh Chouhan
2.	Manufacturer's specifications: Technical and Physical Requirement		
3.	Accessories / consumables are listed as per checklist (Provided along)		
4.	System checked for any External / physical damage.		
5.	Instrument User Manual Soft Copy)		

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3. Equipment Description :

YUMIZEN H550, Fully Automated Hematology Analyzer

Instrument Identification	Verified Yes/No	Verified by / Date
Equipment Type : Hematology Analyzer	YES	Mr. RAVINDRA SINGH CHOUHAN
Model : YUMIZEN H550		
Manufacturer : HORIBA Medical, France		
Marketed By :HORIBA Medical - HORIBA India Pvt. Ltd.		
Equipment # : One		
Serial Number : 207YAXH03883		
Dimensions : 36(W) x 36(D) x 53(H)		
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz		
Power Consumption: 150 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.

Qualified Trained employee name	Verified By	Date
1. Connecting Tubes	Mr. RAVINDRA SINGH CHOUHAN	24.11.2022
2. Straw		

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.

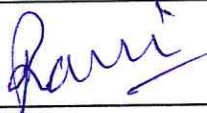
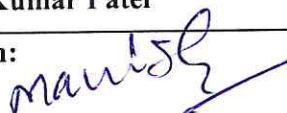
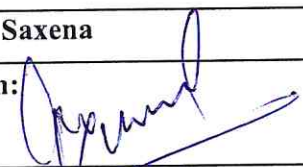
Nandhi

C. INSTALLATION CERTIFICATE:

Instrument Name : YUMIZEN H550.
Serial Number : 207YAXH03883
Customer Address : LUPIN DIAGNOSTICS LAB BHOPAL

Intallation Date : 24.11.2022

Report Sign Off

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Ravindra Singh Chouhan		
Title: Engineer Customer Support	Sign:		Date: 24.11.2022
Reviewed by:	LUPIN DIAGNOSTICS LAB BHOPAL		
Name:	Mr. Manish Kumar Patel		
Title: Lab Admin	Sign:		Date: 24.11.2022
Approved by:	LUPIN Diagnostics Lab Bhopal		
Name:	Dr. Priyanka Saxena		
Title: Pathologist	Sign:		Date: 24.11.2022

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



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LUPIN DIAGNOSTICS LAB BHOPAL

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646
5000.

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Mandya

A. Operational Qualification**1. Instrument Identification:**Instrument Name : **YUMIZEN H550**

Serial Number : 207YAXH03883

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 H550 Application software. Start up cycle is performed .Login in as Lab Tech and check for the Screen Errors.	PASS	RAVINDRA SINGH CHOUHAN
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.		
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.		
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.		
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.		
6.	ARCHIVE AND CURRENT REPORTS	TO RECOVER THE SAMPLE RESULT FROM ARCHIVE AND	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.		

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		CURRENT REPORTS			
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 .	PASS	Mr. Ravindra Singh Chouhan
8..	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.		

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.	Dr. Priyanka Saxena	Pathologist	Mr. Ravindra Singh Chouhan	24.11.2022
2.	Mr. Manish Kumar Patel	Lab manager		
3.	Mr. Laxmi Narayan Umre	Technician		
4.	Mr. Salman Sheikh	Technician		
5.	Miss. Pooja Sursuje	Technician		

C. Operator Maintenance Protocol


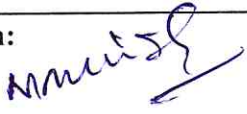
Maintenance and Troubleshooting: Perform Concentration Cleaning as advised by the HORIBA Medical Representative .Run a Shutdown cycle before switching off the analyzer .

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D. OPERATIONAL CERTIFICATE:

Instrument Name : YUMIZEN H550.
Serial Number : 207YAXH03883
Customer Address : LUPIN DIAGNOSTICS LAB BHOPAL
Installation Date : 24.11.2022

Report Sign Off

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Ravindra Singh Chouhan		
Title: Engineer Customer Support	Sign:		Date: 24.11.2022
Reviewed by:	LUPIN Diagnostics Lab Bhopal		
Name:	Mr. Manish Kumar Patel		
Title: Lab Manager	Sign:		Date: 24.11.2022

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



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(Serial no: 207YAXH03883)

Fully Automated Hematology Analyzer

Performance Qualification

For

LUPIN Diagnostics Lab Bhopal

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.

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A. Performance Qualification

Mansh

A. Instrument Identification:

Instrument Name : YUMIZEN H550.
Serial Number : 207YAXH03883

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: 207YAXH03883

Parameters	Acceptable Range	Observed Value	Verified by Sign/Date
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.05	Mr. Ravindra Singh Chouhan
RBC $10^6/\text{mm}^3$	$\leq 0.03 \times 10^6/\text{mm}^3$	0	
HGB g/Dl	$\leq 3 \text{ g/dl}$	0.0	
PLT $10^3/\text{mm}^3$	$\leq 05 \times 10^3/\text{mm}^3$	0	

Conducted & Verified By: Mr. Ravindra Singh Chouhan

- 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, calibrated the instrument using average of the last 5 runs. Run Calibrator as a sample to verify the calibration.

Lot: CX476

Expiry: 05.12.2022

Serial No: 207YAXH03883

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.93	8.94	1.05	<3%	PASSED
RBC	4.54	4.47	1.08	<2%	PASSED
HGB	12.9	13.1	0.36	<1.5%	PASSED
HCT	37.7	36.9	1.22	<2%	PASSED
PLT	249	237	3.92	<5%	PASSED

Conducted & Verified By: Mr. Ravindra Singh Chouhan (Engineer Customer Support)

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



Serial No: 207YAXH03883

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	<2%	1.00	PASS
HGB g/dL	<1.5%	0.22	PASS
HCT %	<2%	1.23	PASS
PLT $10^3/\text{mm}^3$	<5%	1.87	PASS
WBC $10^3/\text{mm}^3$	<3%	1.07	PASS

Conducted & Verified By:
Mr. Ravindra Singh Chouhan

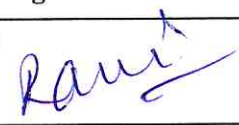
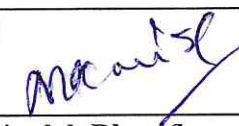

(Engineer Customer Support)

B. PERFORMANCE CERTIFICATE:

Instrument Name : YUMIZEN H550.
Serial Number : 207YAXH03883
Customer Address : LUPIN DIAGNOSTICS LAB BHOPAL
Installation Date : 24.11.2022

Report Sign Off

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.
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Name:	Mr. Ravindra Singh Chouhan		
Title: Engineer Customer Support:	Sign: 	Date: 24.11.2022	
Reviewed by:	LUPIN DIAGNOSTICS LAB BHOPAL		
Name:	Mr. Manish Kumar Patel		
Title: Lab Admin	Sign: 	Date: 24.11.2022	
Approved by:	Lupin Diagnostics lab Bhopal		
Name:	Dr. Priyanka Saxena		
Title: Pathologist	Sign: 	Date: 24.11.2022	

Conclusion: Instrument has been qualified for sample performance.



HORIBA

Explore the future

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/2024-2025/0457

29th February 2024.

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **ABX Yumizen H550** bearing **serial number: 207YAXH03883** installed **Lupin Diagnostic Bhopal, Bhopal** was Calibrated on **29th February 2024.**

Calibrator : ABX MINOCAL
Lot No. : CX492
Expiry Date : 05th April 2024.

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

Next calibration cycle is due on 28th February 2025.



Shrish Dixit

(Head- Products & Marketing)

For **Horiba India Pvt. Ltd.**

Calibration

Calibrator Information

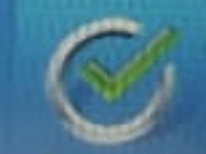
Sample ID Exp. date
 Lot number Name Modified on

Coefficients		WBC	RBC	HGB	HCT	PLT	MPV
New		1.162	1.034	1.008	1.046	1.469 H	0.991
Current		1.120	1.000	1.000	1.070	1.150 H	1.000
Target		8.90	4.54	13.0	37.9	336	10.9
Mean		8.58	4.39	12.9	37.5	263 L	11.0
CV(%)		1.40	0.89	0.51	0.88	1.52	1.58

Selected runs (5 minimum) 5/7 ◀ ▶

	Run Date & Time	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	HCT (%)	PLT (10 ³ /μL)	MPV (μm ³)
<input checked="" type="checkbox"/>	02/29/2024 06:42:37 PM	8.52	4.43	13.0	37.9	258	11.4
<input checked="" type="checkbox"/>	02/29/2024 06:44:56 PM	8.45	4.33	12.8	37.3	264	11.0
<input type="checkbox"/>	02/29/2024 06:46:41 PM	8.70	4.44	13.0	37.8	256	10.9
<input checked="" type="checkbox"/>	02/29/2024 06:48:35 PM	8.72	4.41	13.0	37.5	267	10.9
<input checked="" type="checkbox"/>	02/29/2024 06:50:23 PM	8.70	4.42	13.0	37.7	266	10.9
<input type="checkbox"/>	02/29/2024 06:52:17 PM	8.50	4.49	12.9	38.0	275	10.9
<input checked="" type="checkbox"/>	02/29/2024 06:54:11 PM	8.51	4.38	12.9	37.1	259	11.0

QUAL COMM REAG SYST



Calibrator Information

Sample ID **CX492**

Exp. date **03/01/2024**

Lot number **CX492**

Name **CX492**

Modified on

Coefficients		WBC	RBC	HGB	HCT	PLT	MPV
New		1.159	1.027	1.008	1.047	1.464 H	0.991
Current		1.120	1.000	1.000	1.070	1.150 H	1.000
Target		8.90	4.54	13.0	37.9	336	10.9
Mean		8.60	4.42	12.9	37.7	264 L	11.0
CV(%)		1.39	1.15	0.46	0.71	2.58	1.53

Selected runs (5 minimum) **6/6** < ||| >

	Run Date & Time	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	HCT (%)	PLT (10 ³ /μL)	MPV (μm ³)
<input checked="" type="checkbox"/>	02/29/2024 06:42:37 PM	8.52	4.43	13.0	37.9	258	11.4
<input checked="" type="checkbox"/>	02/29/2024 06:44:56 PM	8.45	4.33	12.8	37.3	264	11.0
<input checked="" type="checkbox"/>	02/29/2024 06:46:40 PM	8.70	4.44	13.0	37.8	256	10.9
<input checked="" type="checkbox"/>	02/29/2024 06:48:35 PM	8.72	4.41	13.0	37.5	267	10.9
<input checked="" type="checkbox"/>	02/29/2024 06:50:23 PM	8.70	4.42	13.0	37.7	266	10.9
<input checked="" type="checkbox"/>	02/29/2024 06:52:17 PM	8.50	4.49	12.9	38.0	275	10.9

QUAL
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