



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

**YUMIZEN H500**

(Serial no: **910YOXH02934**)

Fully Automated Hematology Analyzer

For

**LUPIN DIAGNOSTIC**

**BHUBANESWAR**

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**General Instructions:**

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H500, Fully 6 part Part Automated Hematology Analyzer, at LUPIN DIAGNOSTIC, BHUBANESWAR. 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 DIAGNOSTIC ,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**

<b>Prepared by:</b>	<b>HORIBA Medical - HORIBA India Pvt. Ltd.</b>		
<b>Name:</b>	<b>Desh Dipak Das</b>		
<b>Title: Engineer</b>	<b>Sign:</b>	<b>Date: 2-11-2023</b>	
<b>Approved by:</b>			
<b>Name:</b>			
<b>Title: LAB in charge</b>	<b>Sign:</b>	<b>Date: 2-11-2023</b>	

**YUMIZEN H500**  
(Serial no: **910YOXH02934**)  
Fully Automated Hematology Analyzer

**Installation Qualification**

For

**LUPIN DIAGNOSTIC**  
**BHUBANESWAR**

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**A. Installation Qualification****1. Installation Requirement :**

<b>Sr. No.</b>	<b>Description</b>	<b>Compliance (Yes/No)</b>
1.	<b>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%.</b>	yes
2.	<b>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.</b>	yes
3.	<b>Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 150VA with earth less than 3 V.</b>	yes
4.	<b>UPS connection available.</b>	yes

**2. The instrument has been checked for the following:**

<b>Sr. No.</b>	<b>Verification</b>	<b>Provided (Yes/No)</b>
1.	<b>Instrument is identified Instrument Serial No. : <b>910YOXH02934</b></b>	yes
2.	<b>Manufacturer's specifications: Technical and Physical Requirement</b>	yes
3.	<b>Accessories / consumables are listed as per checklist ( Provided along)</b>	yes
4.	<b>System checked for any External / physical damage.</b>	yes
5.	<b>Instrument User Manual (Soft Copy)</b>	yes

**3. Equipment Description :**

YUMIZEN H500, Fully Automated Hematology Analyzer

<b>Instrument Identification</b>	<b>Verified Yes/No</b>
Equipment Type : Hematology Analyzer	Yes
Model : YUMIZEN H500	Yes
Manufacturer : HORIBA Medical, France	Yes
Marketed By :HORIBA Medical - HORIBA India Pvt. Ltd.	Yes
Equipment # : One	Yes
Serial Number : <b>910YOXH02934</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 H500.
6. Turn on the inbuilt Printer.
7. All the operating software has been loaded in to Yumizen H500.
8. Now from back side of the instrument turn the power switch ON. Yumizen H500 goes through its power up and self-test sequence.
9. The Yumizen H500 login menu is displayed after the Start up cycle is completed. Enter the credentials.

**C. INSTALLATION CERTIFICATE:**

**Instrument Name** : YUMIZEN H500

**Serial Number** : **910YOXH02934**

**Customer Details with complete address** :LUPIN DIAGNOSTIC,  
BHUBANESWAR

**Installation Date** : 18-8-2023

**Warranty expires on** : 17-8-2028

<b>Prepared by:</b>	<b>HORIBA Medical - HORIBA India Pvt. Ltd.</b>		
<b>Name:</b>	<b>Desh Dipak Das</b>		
<b>Title:Engineer</b>	<b>Sign:</b>	<b>Date:2-11-2023</b>	
<b>Approved by:</b>			
<b>Name:</b>			
<b>Title:LAB Incharge</b>	<b>Sign:</b>	<b>Date:2-11-2023</b>	

**Deviation:**

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



**HORIBA**  
Medical

**YUMIZEN H500**

(Serial no: **910YOXH02934**)

Fully Automated Hematology Analyzer

**Operational Qualification**

For

**LUPIN DIAGNOSTIC**  
**BHUBANESWAR**

**A. Operational Qualification****1. Instrument Identification:**Instrument Name : **YUMIZEN H500**Serial Number : **910YOXH02934****2. Following is the list of actions performed and verified for running the system routinely.**

<b>Sr. No.</b>	<b>Test Name</b>	<b>Test Purpose</b>	<b>Method</b>	<b>Observation</b>
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:

SL	OPARATOR NAME	SIGN	TRAINER	DATE
1			DESH DIPAK DAS	2-11-2023
2				
3				
4				
5				
6				

## **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 H500.  
**Serial Number** : 910YOXH02934  
**Customer Details** : LUPIN DIAGNOSTIC  
**with complete address** BHUBANESWAR  
  
**Installation Date** : 18-8-2023  
**Warranty expires on** : 17-8-2028

<b>Prepared by:</b>	<b>HORIBA Medical - HORIBA India Pvt. Ltd.</b>		
<b>Name:</b>	<b>Desh Dipak Das</b>		
<b>Title:Engineer</b>	<b>Sign:</b>	<b>Date:2-11-2023</b>	
<b>Approved by:</b>			
<b>Name:</b>			
<b>Title:</b>	<b>Sign:</b>	<b>Date:2-11-2023</b>	

**Deviation:**

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



**YUMIZEN H500**

(Serial no: **910YOXH02934**)

Fully Automated Hematology Analyzer

**Performance Qualification**

For

**LUPIN DIAGNOSTIC**  
**BHUBANESWAR**

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

Instrument Name : YUMIZEN H500

Serial Number : 910YOXH02934

**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: 910YOXH02934

Parameters	Acceptable Range	Observed Value
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.01
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:

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: PX443N; Exp: 5-11-2023.**

**Serial No: 910YOXH02934**

PARAMETER	RESULT	RANGE	STATUS
RBC	4.79	4.46-4.86	<b>PASS</b>
HGB	13.0	12.7-13.7	
HCT	42.0	38.5-42.2	
MCV	87.7	83.0-92.0	
MCH	27.2	26.3-30.3	
MCHC	31.0	29.6-35.6	
RDW-CV	12.3	10.0-18.0	
PLT	272	220-280	
MPV	9.7	7.5-11.5	
WBC	8.39	7.40-9.40	
NEU#	4.16	3.03-4.83	
LYM#	3.30	2.74-4.14	
MON#	0.46	0.02-1.02	
EOS#	0.33	0.00-0.50	
BAS#	0.14	0.00-0.50	
NEU%	49.7	36.8-56.8	
LYM%	39.3	33.0-49.0	
MON%	5.4	0.2-12.2	
EOS%	3.9	0.0-6.0	
BAS%	1.7	0.0-6.0	

**Lot: PX443L; Exp: 5-11-2023.**

PARAMETER	RESULT	RANGE	STATUS
RBC	2.23	2.08-2.40	<b>PASS</b>
HGB	5.6	5.3-6.1	
HCT	17.9	16.0-19.0	
MCV	80.1	73.0-83.0	
MCH	25.0	23.4-27.4	
MCHC	31.3	29.6-35.6	
RDW-CV	13.9	13.5-21.5	
PLT	67	45-85	

MPV	9.6	7.7-11.7	<b>PASS</b>
WBC	3.10	2.60-3.40	
NEU#	1.37	0.86-1.52	
LYM#	1.25	0.76-1.42	
MON#	0.19	0.01-0.49	
EOS#	0.22	0.04-0.30	
BAS#	0.07	0.00-0.22	
NEU%	44.1	32.8-52.8	
LYM%	40.4	27.8-51.8	
MON%	6.2	0.5-16.3	
EOS%	7.2	1.2-9.8	
BAS%	2.1	0.0-7.0	

**Lot: PX443H; Exp: 5-11-2023.**

PARAMETER	RESULT	RANGE	STATUS
RBC	5.40	5.03-5.53	<b>PASS</b>
HGB	15.9	15.7-16.9	
HCT	52.0	47.1-52.1	
MCV	96.4	89.0-99.0	
MCH	29.5	28.4-33.4	
MCHC	30.6	29.8-35.8	
RDW-CV	12.1	9.5-17.5	
PLT	520	447-547	
MPV	11.2	8.8 -12.8	
WBC	18.25	16.10-20.50	
NEU#	12.83	10.54-14.44	
LYM#	3.70	2.18-5.18	
MON#	0.62	0.00-1.42	
EOS#	0.76	0.00-1.46	
BAS#	0.34	0.01-1.46	
NEU%	70.2	58.0-78.0	
LYM%	20.3	12.1-28.1	
MON%	3.4	0.0-7.8	
EOS%	4.2	0.0-8.0	
BAS%	1.9	0.0-8.0	

**Conducted By:**

**Verified By:**



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

Serial No: 910YOXH02934

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	1.87	PASS
HGB g/dL	< 1.5	0.94	
HCT %	< 2.0	1.83	
PLT $10^3/\text{mm}^3$	< 5.0	4.11	
WBC $10^3/\text{mm}^3$	< 2.0	1.52	

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) 10 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: CX484 ;Expiry: 05/08/2023**

**Serial No: 910YOXH02934**

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.80	8.04	1.55	<3%	PASSED
RBC	4.57	4.57	1.12	<2%	PASSED
HGB	13.2	13.7	0.89	<1%	PASSED
HCT	38.6	40.0	1.23	<2%	PASSED
PLT	253	257	1.86	<5%	PASSED
MPV	10.4	10.2	1.30	<2%	PASSED

**Conducted By:**

**Verified By:**

- **Carryover Study:** Carry over is checked by running samples (Low & high) in 3 replicates in row(L<sub>1</sub>1,L<sub>1</sub>2,L<sub>1</sub>3) followed by a sample with high values,also 3 consecutive times(H1,H2,H3) and finally by running again the samples with low values 3 times(L<sub>2</sub>1,L<sub>2</sub>2,L<sub>2</sub>3) .
  - Carry Over % =  $(L_{21}-L_{23}) * 100 / (H3-L_{23})$ .

**Serial No: 910YOXH02934**

Parameters	WBC 10 <sup>3</sup> /mm <sup>3</sup>	RBC 10 <sup>6</sup> /mm <sup>3</sup>	HGB g/dL	HCT %	PLT 10 <sup>3</sup> /mm <sup>3</sup>
Carry Over (%)	0.33	0.58	0.0	0.24	0.43
Manufacturer acceptable CV%	<1%	<1%	<1%	<1%	<1%
Status	Passed	Passed	Passed	Passed	Passed

**Conducted By:**

**Verified By:**

**B. PERFORMANCE CERTIFICATE:**

**Instrument Name** : YUMIZEN H500  
**Serial Number** : 910YOXH02934.  
**Customer Details with complete address** : LUPIN DIAGNOSTIC ,  
BHUBANESWAR  
**Installation Date** : 18-08-2023  
**Warranty expires on** : 17-08-2028

<b>Prepared by:</b>	HORIBA Medical - HORIBA India Pvt. Ltd.		
<b>Name:</b>	Desh Dipak Da		
<b>Title:Engineer</b>	<b>Sign:</b>	2-11-2023	
<b>Approved by:</b>			
<b>Name:</b>			
<b>Title:LAB in charge</b>	<b>Sign:</b>	<b>Date:2-11-2023</b>	

**Deviation:**

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

