



HORIBA India Private Limited

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Http : //www.horiba.com
CIN : U73100DL2006PTC158232

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **Yumizen H500** bearing serial no: **001YOXH03179** installed at **MKAS HEALTH CARE SERVICE PVT LTD**. Baleswar was calibrated on 01/07/2024.

Calibrator : ABX MINOCAL

Lot No. : CX497

Expiry Date. : 05/09/2024

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

Next calibration cycle is due on 25/06/2025.

Abhishek Dhiman

(Product Manager - QC)

For **Horiba India Pvt. Ltd.**

HORIBA
Medical

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

YUMIZEN H500

(Serial no:**001YOXH03179**)

Fully Automated Hematology Analyzer

For

MKAS HEALTH CARE SERVICES PVT. LTD.

201,2ND FLOOR, SANJAY HEIGHTS, BALASORE, PIN-756003

#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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General Instructions:

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H500, Fully 6 Part Automated Hematology Analyzer, at MKAS HEALTH CARE SERVICES PVT. LTD., BALASORE. 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
- MKAS HEALTH CARE SERVICES PVT. LTD., 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:	Desh Dipak Das		
Title: Executive Customer support	Sign: <i>Desh Dipak Das</i>	Date: 21-1-2022	
Approved by:	MKAS HEALTH CARE SERVICES PVT. LTD.		
Name:	Dr. Mahesh Biswal		
Title: Lab Director	Sign: <i>M. Biswal</i>	Date: 21-1-2022	

YUMIZEN H500
(Serial no: **001YOXH03179**)
Fully Automated Hematology Analyzer

Installation Qualification

For

MKAS HEALTH CARE SERVICES PVT. LTD.
201,2ND FLOOR, SANJAY HEIGHTS, BALASORE, PIN-756003

#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)
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: 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 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. :001YOXH03179	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 H500, Fully Automated Hematology Analyzer

Instrument Identification	Verified Yes/No
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 : 001YOXH03179	Yes
Dimensions : 36(W) x 36(D) x 53(H)	Yes
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz	yes
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.

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 preinspected location (Having suitable Working Conditions).
2. Removal of the internal packing material of the system.
3. Place the Instrument on the benchtop (Vibration free).
4. Connect the Power cord to the YumizenH500.
6. Turn on the inbuilt Printer.
7. All the operating software has been loaded in to YumizenH500.
8. Now fromback side of the instrument turn the power switch ON. YumizenH500goes through its power up and self-test sequence.
- 9.The YumizenH500 login menuis displayed after the Start up cycle is completed. Enter the credentials.

C. INSTALLATION CERTIFICATE:

Instrument Name : YUMIZEN H500
Serial Number : 001YOXH03179
Customer Details with complete address : MKAS HEALTH CARE SERVICES PVT. LTD.,
BALASORE
Installation Date : 21-8-2021
Warranty expires on : 21-8-2026

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Desh Dipak Das		
Title: Executive Customer support	Sign:	<i>Desh Dipak Das</i>	Date: 21-1-2022
Approved by:	MKAS HEALTH CARE SERVICES PVT. LTD.		
Name:	Dr. Mahesh Biswal		
Title: Lab Director	Sign:	<i>Mahesh Biswal</i>	Date: 21-1-2022

Deviation: No Deviation

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

HORIBA

Medical

YUMIZEN H500

(Serial no:001YOXH03179)

Fully Automated Hematology Analyzer

Operational Qualification

For

MKAS HEALTH CARE SERVICES PVT. LTD.

201,2ND FLOOR, SANJAY HEIGHTS, BALASORE, PIN-756003

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

1. Instrument Identification:

Instrument Name

: YUMIZEN H500

Serial Number

: 001YOXH03179


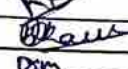
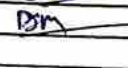
2. Following is the list of actions performed and verified for running the system routinely.

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 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	Mrs. Kanaka Lata Swain		DESH DAS	21-8-2021
2	Mr. Rameswar Raul			
3	Mr. Dibyajyoti Dasmohapatra			
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 : 001YOXH03179
Customer Details : MKAS HEALTH CARE SERVICES PVT. LTD.
with complete address : BALASORE
Installation Date : 21-8-2021
Warranty expires on : 21-8-2026

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Desh Dipak Das		
Title: Executive Customer support	Sign: <i>Desh Dipak Das</i>	Date: 21-1-2022	
Approved by:	MKAS HEALTH CARE SERVICES PVT. LTD.		
Name:	Dr. Mahesh Biswal		
Title: Lab Director	Sign: <i>M. Biswal</i>	Date: 21-1-2022	

Deviation: No Deviation

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

HORIBA

Medical

YUMIZEN H500

(Serial no: **001YOXH03179**)

Fully Automated Hematology Analyzer

Performance Qualification

		0.3
		0.20
	For J1	0.3
		0

MKAS HEALTH CARE SERVICES PVT. LTD.

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#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.
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A. Performance Qualification**A. Instrument Identification:**

Instrument Name : YUMIZEN H500
Serial Number: 001YOXH03179

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: 001YOXH03179

Parameters	Acceptable Range	Observed Value
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.0
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: *Desh Dipak Das*

Verified By:

Atul Kumar

- **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: PX433N; Exp: 3-7-2022.**

Serial No: 001YOXH03179

PARAMETER	RESULT	RANGE	STATUS
RBC	4.58	4.40-4.80	PASS
HGB	13.5	13.1-14.1	
HCT	39.6	37.6-41.6	
MCV	86.4	81.0-91.0	
MCH	29.5	27.6-31.6	
MCHC	34.1	31.4-37.4	
RDW-CV	12.7	10.0-18.0	
PLT	286	243-303	
MPV	10.8	8.9-12.9	
WBC	7.17	6.1-8.1	
NEU#	4.05	2.92-4.72	
LYM#	2.52	1.75-3.15	
MON#	0.22	0.00-0.64	
EOS#	0.30	0.00-0.46	
BAS#	0.08	0.00-0.24	
NEU%	56.4	46.0-66.0	
LYM%	35.2	26.5-42.5	
MON%	3.1	0.0-9.0	
EOS%	4.2	0.0-6.6	
BAS%	1.1	0.0-3.4	

Lot: PX433L; Exp: 5-3-2022.

PARAMETER	RESULT	RANGE	STATUS
RBC	2.40	2.20-2.52	PASS
HGB	6.6	6.2-7.1	
HCT	19.1	18.2-21.2	
MCV	80.5	78.5-88.5	
MCH	28.0	26.4-30.4	
MCHC	35.1	31.0-37.0	
RDW-CV	14.0	12.0-20.0	
PLT	75	59-99	
MPV	10.1	9.0-13.0	
WBC	2.60	2.05-2.85	
NEU#	1.33	0.91-1.61	
LYM#	1.07	0.49-1.15	
MON#	0.08	0.00-2.7	
EOS#	0.25	0.00-0.50	
BAS#	0.07	0.00-0.22	

NEU%			PASS
LYM%	47.4		
MON%	38.4	38.5-58.5	
EOS%	2.7	19.7-43.7	
BAS%	8.9	0.0-12.2	
	2.6	0.0-19.2	
		0.0-8.2	

Lot: PX433H; Exp: 5-3-2022.

PARAMETER	RESULT	RANGE	STATUS
RBC			PASS
HGB	5.11	4.95-5.45	
HCT	16.2	15.8-17.0	
MCV	46.4	44.8-49.8	
MCH	90.8	86-96	
MCHC	31.8	29.0-34.0	
RDW-CV	35.0	31.7-37.7	
PLT	12.8	10-18	
MPV	541	486-586	
WBC	10.5	8.4-12.4	
NEU#	16.46	14.20-18.60	
LYM#	12.07	9.89-13.69	
MON#	2.86	1.34-4.34	
EOS#	0.70	0.00-1.48	
BAS#	0.57	0.00-1.32	
NEU%	0.26	0.00-0.76	
LYM%	73.2	61.9-81.9	
MON%	17.4	9.3-25.3	
EOS%	4.3	0.00-9.0	
BAS%	3.5	0.0-8.0	
	1.6	0.0-4.6	

Conducted By: *Desh Dipak Das*

Verified By: *All Natural*

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

Serial No: 001YOXH03179

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	0.81	PASS
HGB g/dL	< 1.5	0.41	
HCT %	< 2.0	0.73	
PLT $10^3/\text{mm}^3$	< 5.0	2.48	
WBC $10^3/\text{mm}^3$	< 2.5	1.59	

Conducted By: *Desh Dipak Das*Verified By: *Atul Kishor*

- **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) 7 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: CX466 ;**Expiry:** 02/05/2022

Serial No:001YOXH03179

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.80	8.62	1.51	<3%	PASSED
RBC	4.51	4.67	0.97	<2%	PASSED
HGB	13.5	13.6	0.29	<1%	PASSED
HCT	39.2	39.1	1.0	<2%	PASSED
PLT	251	248	3.86	<5%	PASSED

Conducted By: *Desh Dipak Das*

Verified By:

Atul Kishore

- **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: 001YOXH03179

Parameters	WBC $10^3/\text{mm}^3$	RBC $10^6/\text{mm}^3$	HGB g/dL	HCT %	PLT $10^3/\text{mm}^3$
Carry Over (%)	0.83	0.64	0.96	0.7	0.22
Manufacturer acceptable CV%	<1%	<1%	<1%	<1%	<1%
Status	Passed	Passed	Passed	Passed	Passed

Conducted By: *Desh Dipak Das*Verified By: *Alu. Jitendra*

B. PERFORMANCE CERTIFICATE:

Instrument Name : YUMIZEN H500
Serial Number :001YOXH03179.
Customer Details with complete address : MKAS HEALTH CARE SERVICES PVT. LTD.,
BALASORE
Installation Date :21-8-2021
Warranty expires on :21-8-2026

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Desh Dipak Das		
Title: Executive support	Customer	Sign: <i>Desh Dipak Das</i>	Date:21-1-2022
Approved by:	MKAS HEALTH CARE SERVICES PVT. LTD.		
Name:	Dr. Mahesh Biswal		
Title: Lab Director	Sign: <i>Mahesh Biswal</i>	Date:21-1-2022	

Deviation: No Deviation

Conclusion: Instrument has been qualified for Performance.

HORIBA 6 PART
JAPAN

Blank Cycle Logs

Running Date Comments	Operator	WBC 10 ⁹ /µL	RBC 10 ¹² /µL	HGB g/dL	PLT 10 ⁹ /µL	Status	Technical alarms
01/21/2022 09:53:18 AM	MKAS	0.00	0.00	0.0	0	Passed	
01/21/2022 09:28:55 AM	MKAS	0.00	0.00	0.0	0	Passed	
01/21/2022 10:21:14 AM	technician	0.00	0.01	0.0	0	Passed	
01/21/2022 10:22:42 AM	technician	0.00	0.00	0.0	0	Passed	

Repeatability Report (part 1)

HORIBA 6 PART
JAPAN

Number of repeatability run report selected for statistic calculation 6/6

Coefficient	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	HCT (%)	PLT (10 ³ /μL)	MCV (μm ³)	RDW-CV (%)	RDW-SD (μm ³)	P-LCR (%)
Minimum	7.27	5.32	15.3	45.7	375	85.5	11.8	44.9	26.2
Maximum	7.56	5.44	15.5	46.6	402	85.9	12.0	45.8	28.5
Mean	7.43	5.39	15.4	46.2	386	85.7	11.9	45.2	27.8
Difference	0.28	0.11	0.2	0.9	27	0.4	0.2	0.9	2.2
2 SD	0.24	0.09	0.1	0.7	19	0.3	0.1	0.9	1.6
CV(%)	1.59	0.81	0.41	0.73	2.48	0.16	0.62	1.03	2.90

Sel	Run Date & Time	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	HCT (%)	PLT (10 ³ /μL)	MCV (μm ³)	RDW-CV (%)	RDW-SD (μm ³)	P-LCR (%)	Operator
✓	01/21/2022 09:57:15 AM	7.36	5.36	15.3	45.9	388	85.6	11.8	44.9	26.2	technician
✓	01/21/2022 09:58:54 AM	7.35	5.32	15.4	45.7	377	85.9	12.0	45.8	28.1	technician
✓	01/21/2022 10:00:15 AM	7.49	5.44	15.4	46.6	402	85.7	11.8	44.9	28.5	technician
✓	01/21/2022 10:01:34 AM	7.56	5.37	15.4	46.0	375	85.7	12.0	45.8	27.8	technician
✓	01/21/2022 10:02:50 AM	7.55	5.42	15.4	46.4	384	85.6	11.8	44.9	28.1	technician
✓	01/21/2022 10:04:07 AM	7.27	5.42	15.5	46.3	388	85.5	11.9	44.9	28.2	technician

QC - Control Run Report

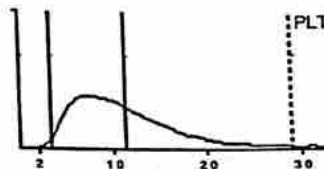
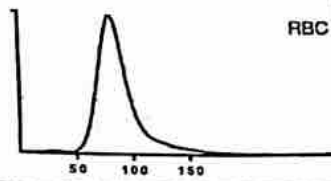
Run Date: 01/21/2022 11:06:42 AM

Name: ABXdifftrol H
Level: High
Lot number: PX433H

Operator: technician

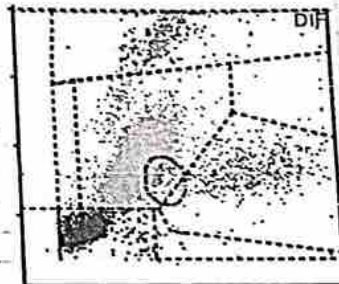
Sample ID: PX433H
Exp. date: 03/05/2022

			Range
RBC	5.11	10 ⁶ /μL	4.95 - 5.45
HGB	16.2	g/dL	15.8 - 17.0
HCT	46.4	%	44.8 - 49.8
MCV	90.8	μm ³	86.0 - 96.0
MCH	31.8	pg	29.0 - 34.0
MCHC	35.0	g/dL	31.7 - 37.7
RDW-CV	12.8	%	10.0 - 18.0
RDW-SD	48.5	μm ³	37.0 - 53.0
Range			
PLT	541	10 ³ /μL	486 - 586
MPV	10.5	μm ³	8.4 - 12.4



Alarms

WBC	16.46	10 ³ /μL	14.20 - 18.60	
Range				
	#	Range	%	Range
NEU	12.07	9.89 - 13.69	73.2	61.9 - 81.9
LYM	2.86	1.34 - 4.34	17.4	9.3 - 25.3
MON	0.70	0.00 - 1.48	4.3	0.0 - 9.0
EOS	0.57	0.00 - 1.32	3.5	0.0 - 8.0
BAS	0.26	0.00 - 0.76	1.6	0.0 - 4.6



Raw Data

PLT counts (by sections)

S1	S2	S3	S4	S5	S6
433	426	409	446	397	418
S7	S8	S9	S10	S11	S12
406	433	439	424	424	431

RBC counts (by sections)

S1	S2	S3	S4	S5	S6
4701	4659	4643	4686	4752	4710
S7	S8	S9	S10	S11	S12
4547	4729	4527	4684	4641	4680

WBC counts (by sections) and others

S1	S2	S3	S4	S5	S6
1123	1080	1025	1021	1050	1090
S7	S8	S9	S10	S11	S12
1083	1085	1125	1102	1008	

HBG measures (Optical Intensity)

L1	L2	L3	L4	L5	L6
3732	3732	3733	614	614	614
L7	L8	L9	L10	L11	L12
614	614	614	614	615	614
L13					
614					

RMeasured : 9360
Correlated : 9344
Optical Intensity : 188

HORIBA

Explore the future

QUALITY ASSURANCE CERTIFICATE

*This is to certify that the Horiba hematology analyzer model
Yumzen H50... bearing s.no... 00140XH03179... has
been tested in terms of Reproducibility & Calibration.
The test reports of background Check, Repeatability and Quality
Control values were all found within the prescribed limits.
The instrument is working satisfactorily.*

Checked by



Date: 28/04/2020

Verified by

