

HORIBA Medical

Installation Qualification, Performance, Qualification and Operational Qualification

YUMIZEN H500

(Serial no: **308YODH05905**)

Five Part Hematology Analyzer

For

BGS MCH HOSPITAL

**BGS VIJNATHAM SOUTH CAMPUS, NAGARUR,
DASANAPURA, BANGALORE NORTH 562123**

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General Instructions:

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H500, Five Part Hematology Analyzer, at BGS MCH HOSPITAL, 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 BGS MCH HOSPITAL, 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. A. AJAY SHET		
Title: ENGINEER-CUSTOMER SUPPORT	Sign: 	Date: 30/03/2024	
Reviewed by:	BGS MCH HOSPITAL, BENGALURU		
Name:			
Title:	Sign:	Date:	
Approved by:	BGS MCH HOSPITAL, BENGALURU		
Name:			

HORIBA

Medical

YUMIZEN H500

(Serial no: **308YODH05905**)

Five Part Hematology Analyzer

Installation Qualification

For

BGS MCH HOSPITAL

**BGS VIJNATHAM SOUTH CAMPUS, NAGARUR,
DASANAPURA, BANGALORE NORTH 562123**

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	30/03/2024
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.:308YODH05905	Yes	30/03/2024
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 H500, Five Part Hematology Analyzer

Instrument Identification	Verified Yes/No	Verified by / Date
Equipment Type: Hematology Analyzer	YES	30/03/2024
Model: YUMIZEN H500	YES	
Manufacturer: HORIBA Medical, France	YES	
Marketed By: HORIBA Medical - HORIBA India Pvt. Ltd.	YES	
Equipment #: One	YES	
Serial Number : 308YODH05905	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		
Yeshwanth Padashetty		
Sreesagar Deepak. B. N		
Mithun Krishna C U		
A.AJAY SHET		30/03/24

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 H500.
6. Turn on the inbuilt Printer.
7. All the operating software has been loaded in to YUMIZEN H500.
8. Now from backside 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 : 308YODH05905
Customer Details : BGS MCH HOSPITAL,
With complete address : BGS VIJNATHAM SOUTH CAMPUS, NAGARUR,
DASANAPURA, BANGALORE NORTH 562123
Installation Date : 16/03/2024
Warranty expires on :1 YEAR

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. A. AJAY SHET		
Title:	Sign:	Date:	
Customer Support Engineer		30/03/2024	
Reviewed by:	BGS MCH HOSPITAL, BENGALURU		
Name:			
Title:	Sign:	Date:	
Approved by:	BGS MCH HOSPITAL, BENGALURU		
Name:			
Title:	Sign:	Date:	

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

HORIBA

Medical

YUMIZEN H500

(Serial no: **308YODH05905**)

Five Part Hematology Analyzer

Operational Qualification

For

BGS MCH HOSPITAL

**BGS VIJNATHAM SOUTH CAMPUS, NAGARUR,
DASANAPURA, BANGALORE NORTH 562123**

A. Operational Qualification

1. Instrument Identification:

Instrument Name : YUMIZEN H500

Serial Number : 308YODH05905

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	30/03/2024
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	30/03/2024
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.				
2.				
3.				
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 H500.
Serial Number : 308YODH05905
Customer Details : BGS MCH HOSPITAL,
With complete address : BGS VIJNATHAM SOUTH CAMPUS, NAGARUR,
DASANAPURA, BANGALORE NORTH 562123
Installation Date : 16/03/2024
Warranty expires on : 1 YEAR

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr.A. AJAY SHET		
Title:	Sign:	Date:	
Customer Support Engineer		30/03/2024	
Reviewed by:	BGS MCH HOSPITAL, BENGALURU		
Name:			
Title:	Sign:	Date:	
Approved by:	BGS MCH HOSPITAL, BENGALURU		
Name:			
Title:	Sign:	Date:	

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

HORIBA

Medical

YUMIZEN H500
(Serial no: **308YODH05905**)
Five Part Hematology Analyzer

Design Qualification

For

BGS MCH HOSPITAL

**BGS VIJNATHAM SOUTH CAMPUS, NAGARUR,
DASANAPURA, BANGALORE NORTH 562123**


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 H500
Serial Number : 308YODH05905
Customer Details : BGS MCH HOSPITAL,
With complete address : BGS VIJNATHAM SOUTH CAMPUS, NAGARUR,
DASANAPURA, BANGALORE NORTH 562123
Installation Date : 16/03/2024
Warranty expires on :1 YEAR

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. A. AJAY SHET		
Title:	Sign:	Date:	
Customer Support Engineer		30/03/2024	
Reviewed by:	BGS MCH HOSPITAL, BENGALURU		
Name:			
Title:	Sign:	Date:	
Approved by:	BGS MCH HOSPITAL, BENGALURU		
Name:			
Title:	Sign:	Date:	

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

HORIBA

Medical

YUMIZEN H500

(Serial no: **308YODH05905**)

Five Part Hematology Analyzer

Performance Qualification
For

BGS MCH HOSPITAL

**BGS VIJNATHAM SOUTH CAMPUS, NAGARUR,
DASANAPURA, BANGALORE NORTH 562123**

A. Performance Qualification

A. Instrument Identification:

Instrument Name : YUMIZEN H500.

Serial Number : 308YODH05905

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: 308YODH05905



Conducted By: *JAYMEZ*

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 493; Expiry: 05/05/2024.

Serial No:308YODH05905

The screenshot displays the 'CALIBRATION' screen for a Minocal calibrator. At the top, there are status indicators for Emergency Stop, QUAL, COMM, REAG, and SYST. The navigation path is 'Home > Quality Assurance > Calibration'. The screen shows the following information:

- Calibrator Information:**
 - Sample ID: CX493
 - Lot number: CX493
 - Name: MINOCAL
 - Exp. date: 05/05/2024
 - Modified on: [blank]
- Coefficients Table:**

	WBC	RBC	HGB	HCT	PLT
New	1.168	1.027	0.997	0.925	1.095
Current	1.168	1.027	0.997	0.925	1.095
Target	8.75	4.51	13.2	36.6	260
Mean	8.91	4.24	13.3	34.9	243
CV(%)	1.66	0.46	0.34	0.69	1.13
- Selected runs (5/6 minimum):**

Run Date & Time	WBC (10 ⁹ /mm ³)	RBC (10 ¹² /mm ³)	HGB (g/dL)	HCT (%)	PLT (10 ⁹ /mm ³)
<input type="checkbox"/> 23/03/2024 01:05:36 PM	8.84	4.36 ℓ	13.4 h	35.9	259
<input checked="" type="checkbox"/> 23/03/2024 01:06:47 PM	8.73	4.27 ℓ	13.2	35.2 ℓ	244 ℓ
<input checked="" type="checkbox"/> 23/03/2024 01:07:52 PM	8.84	4.25 ℓ	13.3	35.0 ℓ	243 ℓ
<input checked="" type="checkbox"/> 23/03/2024 01:09:03 PM	8.90	4.23 ℓ	13.3	34.6 ℓ	244 ℓ
<input checked="" type="checkbox"/> 23/03/2024 01:10:09 PM	8.94	4.23 ℓ	13.2	34.7 ℓ	238 ℓ
<input checked="" type="checkbox"/> 23/03/2024 01:11:15 PM	9.13 h	4.25 ℓ	13.3	34.9 ℓ	244 ℓ

At the bottom, there are buttons for 'Print', 'Targets', 'Start Calibration', 'Cancel', and 'Validate Calibration'. The status is 'READY' and the timestamp is '01:25 PM 28/03/2024'.

Conducted By: JAYSHETI

Verified By:

CALIBRATION CERTIFICATE

This is to state that the hematology cell counter model **HORIBA Medical: YUMIZEN H500**, bearing **Serial no: 308YODH05905** installed at **BGS MCH HOSPITAL, Bangalore, Karnataka** was calibrated with Calibrator on **23RD MARCH 2024**.

Subsequently controls were processed and found them in respective range.

Calibrator Used: **ABX MINOCAL**

Lot No.: **CX 493**

Expiry Date: **05/05/2024**

SI No.	WBC	RBC	HGB	HCT	PLT
1	8.73	4.27	13.2	35.2	244
2	8.84	4.25	13.3	35	243
3	8.9	4.23	13.3	34.6	244
4	8.94	4.23	13.2	34.7	238
5	9.13	4.25	13.3	34.9	244
MEAN	8.9	4.24	13.3	34.9	243
TARGET	8.75	4.51	13.2	36.6	260
CV	1.6	0.46	0.34	0.69	1.13
REMARK		Passed	Passed	Passed	Passed
Acceptable CV%	<2%	<2%	<1%	<2%	<5%

Sr. No	Tested Parameter	Remarks
1	Repeatability/ Precision	Passed
2	Start up/Blank Cycle	Passed
3	Carry Over	Passed
4	Calibration	Passed
5	Quality Control	Passed

Next calibration cycle is due on **22ND MARCH 2025**.



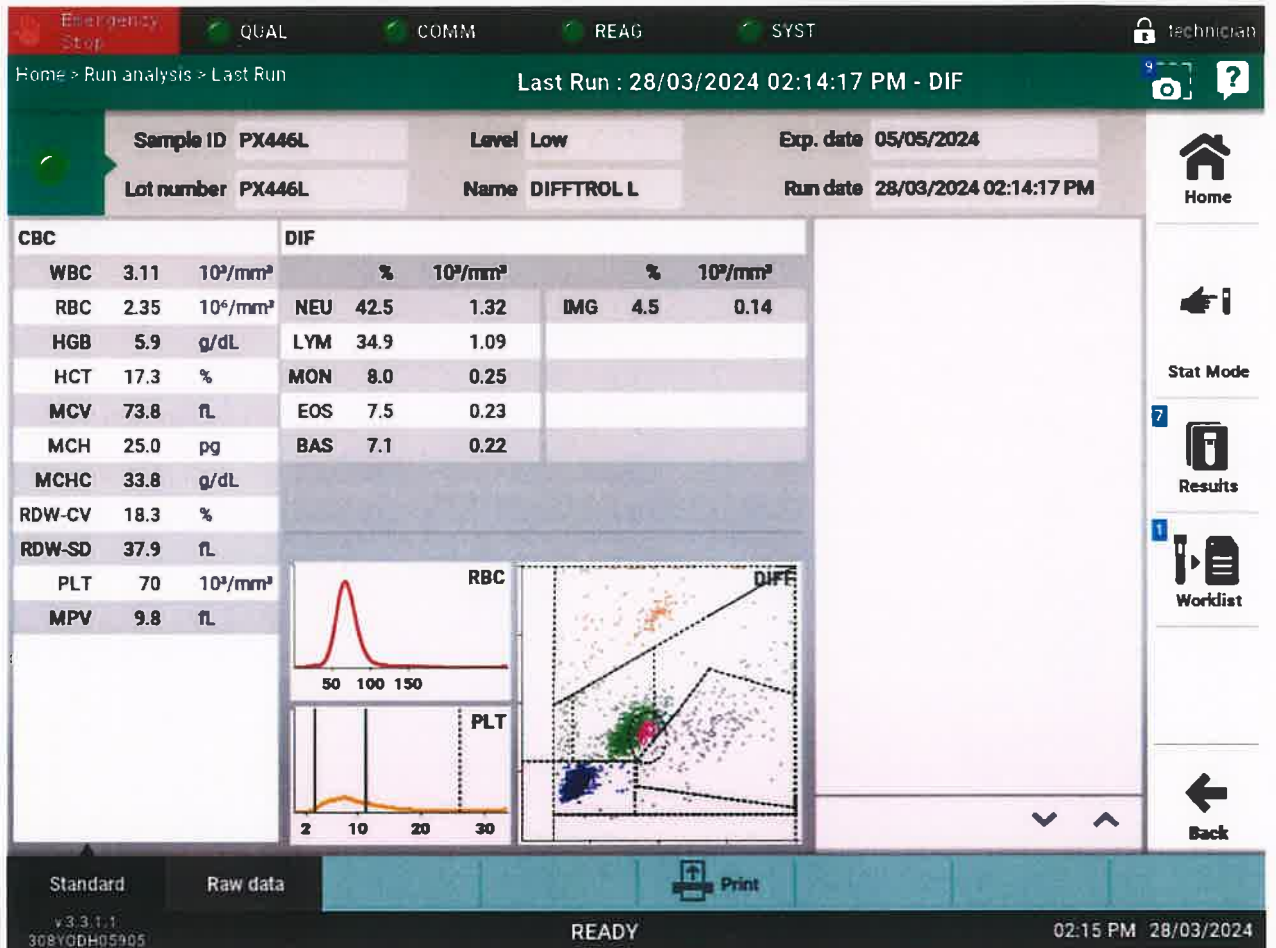
A. AJAY SHET
Engineer- Customer Support
Horiba Medical.

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

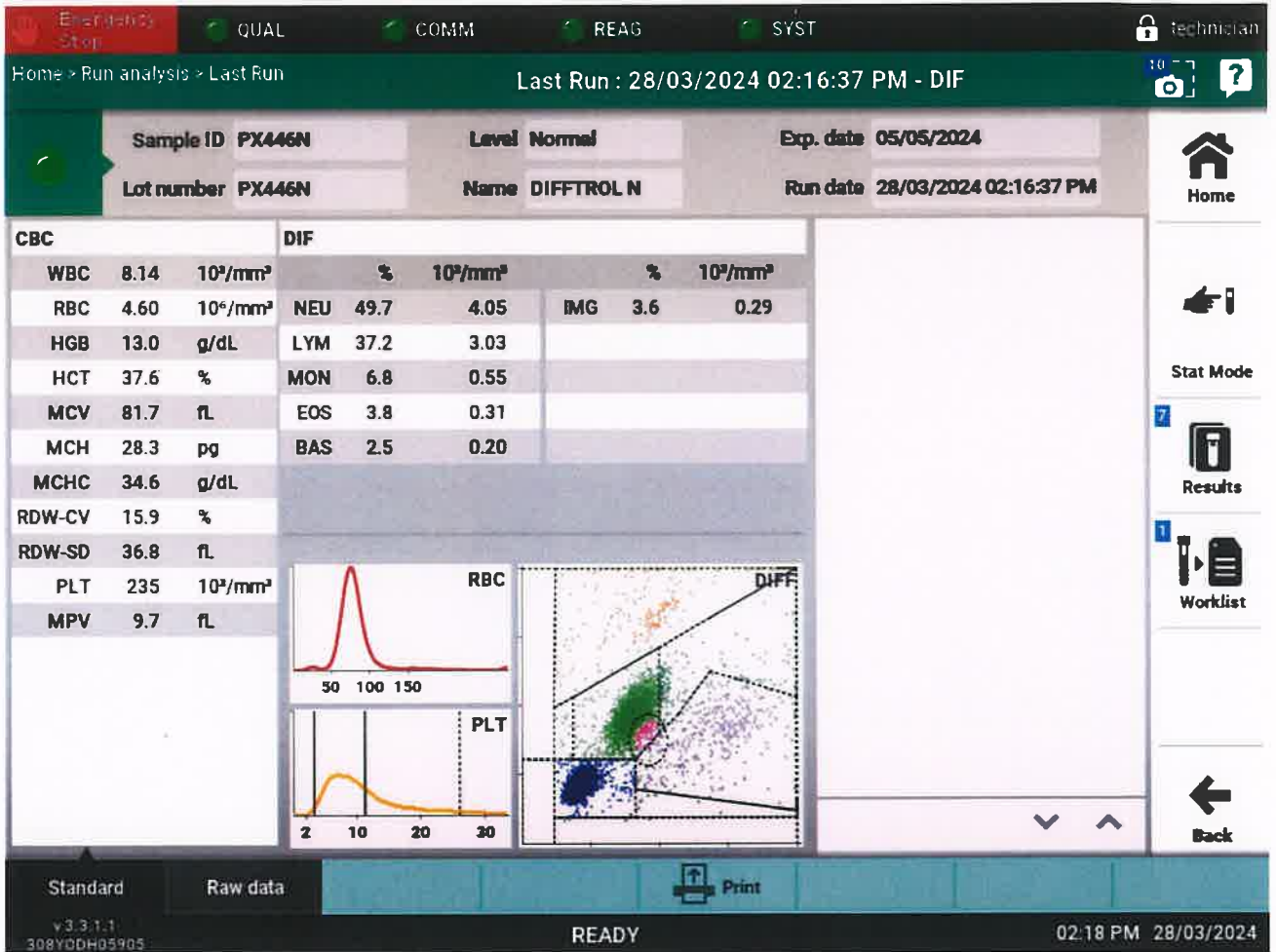
Lot: ABX DIFFTROL PX446; **Exp:** 05/05/24

Serial No: 308YODH05905

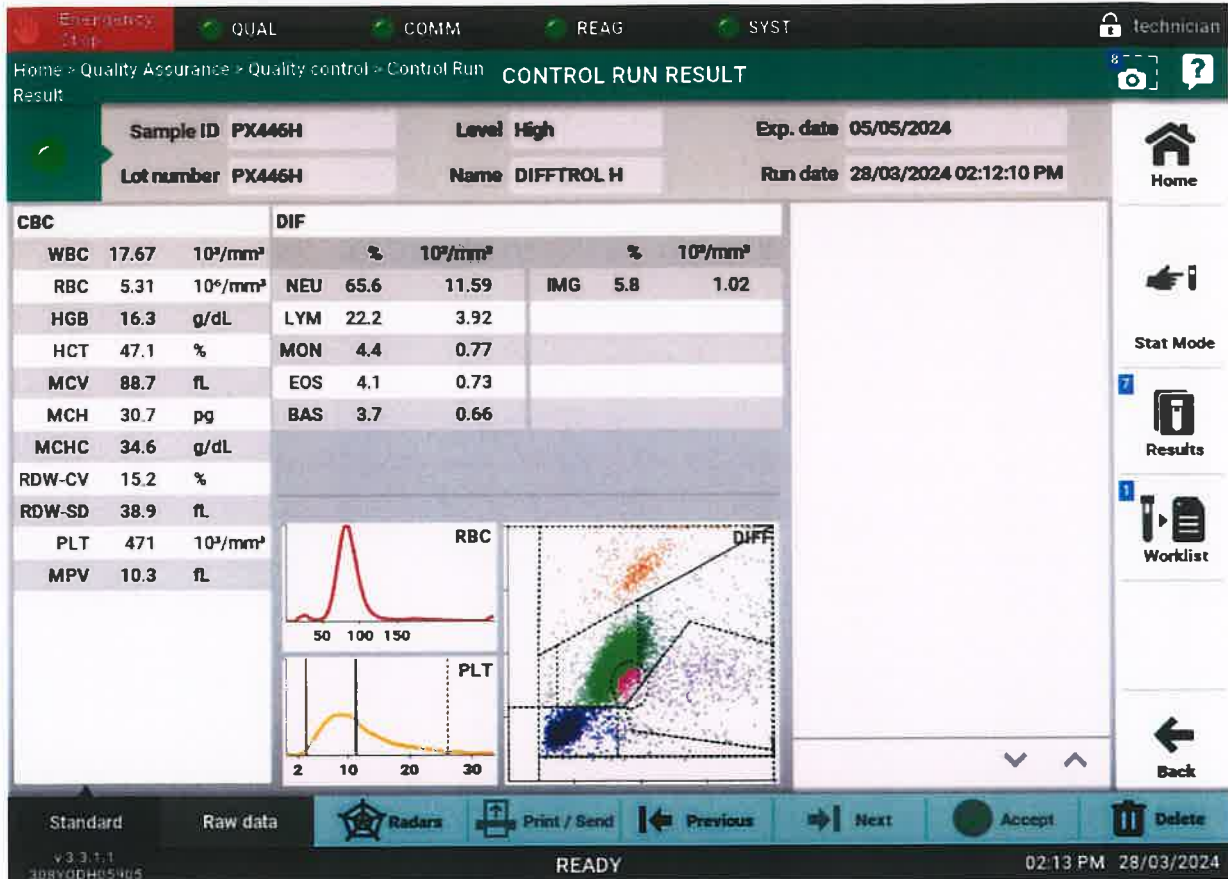
Level I: Low Control



Level II: Normal Control



Level III: High Control



Conducted By: *J. P. S. NET*

Verified By:

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

Serial No: 308YODH05905

Emergency stop QUAL COMM REAG SYST BGSHospital

Home > Quality Assurance > Repeatability **REPEATABILITY**

SID: surash	WBC	RBC	HGB	PLT	HCT	MCV
Min	6.54	4.93	14.1	247	40.6	82.1
Max	6.79	5.04	14.2	273	41.8	83.0
Mean	6.68	4.97	14.2	263	41.1	82.7
Difference	0.25	0.11	0.2	26	1.2	1.0
2 SD	0.17	0.06	0.1	18	0.6	0.6
CV(%)	1.25	0.61	0.38	3.44	0.77	0.33

Selected runs 10/11

Run Date & Time	WBC (10 ⁹ /mm ³)	RBC (10 ⁹ /mm ³)	HGB (g/dL)	PLT (10 ⁹ /mm ³)	HCT (%)	MCV (fL)
<input checked="" type="checkbox"/> 28/03/2024 01:12:38 PM	6.59	4.98	14.1	269	41.1	82.6
<input checked="" type="checkbox"/> 28/03/2024 01:13:43 PM	6.62	4.98	14.1	266	41.2	82.7
<input type="checkbox"/> 28/03/2024 01:14:50 PM	6.54	5.02	14.1	251	41.6	82.9
<input checked="" type="checkbox"/> 28/03/2024 01:15:54 PM	6.61	4.94	14.1	265	40.9	82.7
<input checked="" type="checkbox"/> 28/03/2024 01:17:06 PM	6.75	4.98	14.2	273	41.1	82.6
<input checked="" type="checkbox"/> 28/03/2024 01:18:18 PM	6.78	4.95	14.1	269	41.0	82.9
<input checked="" type="checkbox"/> 28/03/2024 01:19:33 PM	6.69	4.98	14.2	265	41.1	82.6
<input checked="" type="checkbox"/> 28/03/2024 01:20:47 PM	6.54	4.98	14.1	266	41.3	83.0

Print Start Repeatability Cancel

v 3.3.1.1 308YODH05905 **READY** 01:25 PM 28/03/2024

Emergency
QUAL COMM REAG SYST BGSHospital

Home > Quality Assurance > Repeatability **REPEATABILITY**

SID: suresh	WBC	RBC	HGB	PLT	HCT	MCV
Min	6.54	4.93	14.1	247	40.6	82.1
Max	6.79	5.04	14.2	273	41.8	83.0
Mean	6.68	4.97	14.2	263	41.1	82.7
Difference	0.25	0.11	0.2	26	1.2	1.0
2 SD	0.17	0.06	0.1	18	0.6	0.6
CV(%)	1.25	0.61	0.38	3.44	0.77	0.33

Selected runs 10/11

Run Date & Time	WBC (10 ³ /mm ³)	RBC (10 ⁶ /mm ³)	HGB (g/dL)	PLT (10 ³ /mm ³)	HCT (%)	MCV (fL)
<input type="checkbox"/> 28/03/2024 01:14:30 PM	6.54	4.92	14.1	251	41.0	82.5
<input checked="" type="checkbox"/> 28/03/2024 01:15:54 PM	6.61	4.94	14.1	265	40.9	82.7
<input checked="" type="checkbox"/> 28/03/2024 01:17:06 PM	6.75	4.98	14.2	273	41.1	82.6
<input checked="" type="checkbox"/> 28/03/2024 01:18:18 PM	6.78	4.95	14.1	269	41.0	82.9
<input checked="" type="checkbox"/> 28/03/2024 01:19:33 PM	6.69	4.98	14.2	265	41.1	82.6
<input checked="" type="checkbox"/> 28/03/2024 01:20:47 PM	6.54	4.98	14.1	266	41.3	83.0
<input checked="" type="checkbox"/> 28/03/2024 01:21:52 PM	6.68	5.04	14.2	247	41.8	83.0
<input checked="" type="checkbox"/> 28/03/2024 01:23:06 PM	6.79	4.95	14.2	247	40.6	82.1
<input checked="" type="checkbox"/> 28/03/2024 01:24:13 PM	6.71	4.93	14.2	260	40.8	82.8

Print Start Repeatability Cancel

v.3.3.1.1 30BYGDH05905 READY 01:25 PM 28/03/2024

Conducted By: JIM SNEJ

Verified BY :

- **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: 308YODH05905


Parameters	WBC 10 ³ /mm ³	RBC 10 ⁶ /mm ³	HGB g/dL	PLT 10 ³ /mm ³
Carry Over (%)	-0.1	-1.7	-1.8	-0.9
Manufacturer acceptable CV%	<2%	<2%	<2%	<2%
Status	Passed	Passed	Passed	Passed

Conducted By: JIM SHEI

Verified By:

B. PERFORMANCE CERTIFICATE:

Instrument Name : YUMIZEN H500.
Serial Number : 308YODH05905
Customer Details : BGS MCH HOSPITAL,
With complete address : BGS VIJNATHAM SOUTH CAMPUS, NAGARUR,
DASANAPURA, BANGALORE NORTH 562123
Installation Date : 16/03/2024
Warranty expires on : 1 YEAR

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. A. AJAY SHET		
Title:	Sign:		
Deputy Service Manager		30/03/2024	
Reviewed by:	BGS MCH HOSPITAL, BENGALURU		
Name:			
Title:	Sign:	Date:	
Approved by:	BGS MCH HOSPITAL, BENGALURU		
Name:			
Title:	Sign:	Date:	

Conclusion: Instrument has been qualified for Performance.