

**HORIBA**  
Medical

HORIBA India Private Limited

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**HORIBA**  
Medical

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

**YUMIZEN H550**  
(Serial no: **109YAXH03477**)  
Fully Automated Hematology Analyzer

For

**LUPIN DIAGNOSTICS,  
AHMEDNAGAR**

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#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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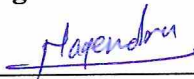

- I. Performance Qualification.
- II. Performance Certificate.

### **Section 5 Attachments**

**General Instructions:**

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H550, Fully 6 Part Automated Hematology Analyzer, at LUPIN DIAGNOSTICS, 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 DIAGNOSTICS, 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>Nagendra Bansode</b>		
<b>Title: Application Specialist</b>	<b>Sign:</b> 	<b>Date: 06/10/2021</b>	
<b>Approved by:</b>	<b>LUPIN DIAGNOSTICS,</b>		
<b>Name:</b>	<b>Dr. Sagar Kulat</b>		
<b>Title: Head of Department</b>	<b>Sign:</b> 	<b>Date: 06/10/2021</b>	

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savadi, Ahmednagar-414001

**YUMIZEN H550**  
(Serial no: **109YAXH03477**)  
Fully Automated Hematology Analyzer

**Installation Qualification**

For

**LUPIN DIAGNOSTICS,**  
AHMEDNAGAR

**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: 53(W) x 66.8(D) x 62.1(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. : <b>109YAXH03477</b>	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 H550, Fully Automated Hematology Analyzer

<b>Instrument Identification</b>	<b>Verified Yes/No</b>
Equipment Type : Hematology Analyzer	Yes
Model : YUMIZEN H550	Yes
Manufacturer : HORIBA Medical, France	Yes
Marketed By : HORIBA Medical - HORIBA India Pvt. Ltd.	Yes
Equipment # : One	Yes
Serial Number : <b>109YAXH03477</b>	Yes
Dimensions : 53(W) x 66.8(D) x 62.1(H)	Yes
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz	yes
Power Consumption: 165 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.


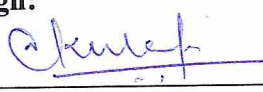
**B. Installation Procedure:**

1. Putting the system at the predefined and 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 external 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.

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**C. INSTALLATION CERTIFICATE:**

**Instrument Name** : YUMIZEN H550  
**Serial Number** : **109YAXH03477**  
**Customer Details with complete address** : LUPIN DIAGNOSTICS,  
AHMEDNAGAR.  
**Installation Date** : 05/10/2021  
**Warranty expires on** : RR (Reagent Rental).

<b>Prepared by:</b>	HORIBA Medical - HORIBA India Pvt. Ltd.		
<b>Name:</b>	Nagendra Bansode		
<b>Title: Application Specialist</b>	<b>Sign:</b> 	<b>Date:06/10/2021</b>	
<b>Approved by:</b>	LUPIN DIAGNOSTICS, , WANOWRIE, AHMEDNAGAR		
<b>Name:</b>	Dr. Sagar Kulat		
<b>Title: Head of Department</b>	<b>Sign:</b> 	<b>Date:06/10/2021</b>	

**Deviation:** NO

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savadi, Ahmednagar-414001

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



**YUMIZEN H550**

(Serial no: **109YAXH03477**)

**Fully Automated Hematology Analyzer**

**Operational Qualification**

For

**LUPIN DIAGNOSTICS,  
AHMEDNAGAR**

**A. Operational Qualification****1. Instrument Identification:**

Instrument Name : YUMIZEN H550

Serial Number : 109YAXH03477

**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**

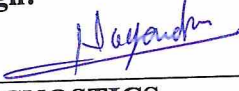
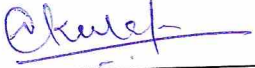
**Operator Training:** The users responsible for the operation of this instrument will be trained on the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filled as indicated on training sheet:

### **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** : 109YAXH03477  
**Customer Details with complete address** : LUPIN DIAGNOSTICS,  
AHMEDNAGAR.  
**Installation Date** : 05/10/2021  
**Warranty expires on** : RR (Reagent Rental).

<b>Prepared by:</b>	HORIBA Medical - HORIBA India Pvt. Ltd.		
<b>Name:</b>	Nagendra Bansode		
<b>Title: Application Specialist</b>	<b>Sign:</b> 	<b>Date:06/10/2021</b>	
<b>Approved by:</b>	LUPIN DIAGNOSTICS,		
<b>Name:</b>	Dr. Sagar Kulat		
<b>Title: Head of Department</b>	<b>Sign:</b> 	<b>Date:06/10/2021</b>	

**Deviation:** NO

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savedi, Ahmednagar-414001

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

**HORIBA**  
Medical

HORIBA India Private Limited

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**HORIBA**  
Medical

**YUMIZEN H550**  
(Serial no: **109YAXH03477**)  
Fully Automated Hematology Analyzer

**Performance Qualification**

For

**LUPIN DIAGNOSTICS,**  
AHMEDNAGAR

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

Instrument Name : YUMIZEN H550  
Serial Number : 109YAXH03477

**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: 109YAXH03477

Parameters	Acceptable Range	Observed Value
WBC 10 <sup>3</sup> /mm <sup>3</sup>	$\leq 0.3 \times 10^3 / \text{mm}^3$	0.04
RBC 10 <sup>6</sup> /mm <sup>3</sup>	$\leq 0.02 \times 10^6 / \text{mm}^3$	0.00
HGB g/dl	$\leq 0.3 \text{ g/dl}$	0.0
PLT 10 <sup>3</sup> /mm <sup>3</sup>	$\leq 10 \times 10^3 / \text{mm}^3$	0

Conducted by:

  
Mr. Nagendra Bansode

Verified by:

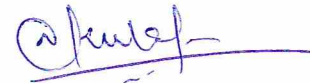
  
Dr. Sagar Kulat

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savadi, Ahmednagar-414001

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

**Serial No: 109YAXH03477**

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	0.75	Ok
HGB g/dL	< 1.5	0.83	Ok
HCT %	< 2.0	1.04	Ok
PLT $10^3/\text{mm}^3$	< 5.0	2.10	Ok
WBC $10^3/\text{mm}^3$	< 2.5	1.52	Ok

**Conducted by:****Mr. Nagendra Bansode****Verified by:****Dr. Sagar Kulat**

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savedi, Ahmed Nagar-414001

- **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) 11 times, without taking the values of first run, calibrate the instrument using average of the last 10 runs. Run Calibrator as a sample to verify the calibration.

**Lot:** CX463; **Expiry:** 5/11/2021.

**Serial No:** 109YAXH03477

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.80	8.52	1.37	<3%	PASSED
RBC	4.40	3.85	1.30	<2%	PASSED
HGB	12.8	12.5	0.60	<1.5%	PASSED
HCT	37.0	31.8	1.57	<2%	PASSED
PLT	250	215	1.95	<5%	PASSED
MPV	9.4	9.4	1.75	<3%	PASSED

Conducted by:

*Nagendra*

**Mr. Nagendra Bansode**

Verified by:

*Sagar Kulat*

**Dr. Sagar Kulat**

**LUPIN DIAGNOSTIC**

Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savedi, Ahmednagar-414001



- **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 PX431; **Exp:** 05/11/2021.

**Serial No:** 109YAXH03477

LEVEL	STATUS
LOW (PX431L)	PASSED
NORMAL (PX431N)	PASSED
HIGH (PX431H)	PASSED

**Conducted by:**

*Nagendra*

**Mr. Nagendra Bansode**

**Verified by:**

*Sagar Kulat*

**Dr. Sagar Kulat**

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savadi, Ahmednagar-414001

- **Carryover Study:** Carry over is checked by running quality controls /samples (high & low) in 3 replicates & getting CV% in within acceptance.
  - Carry Over % =  $(L1-L3) * 100 / (H3-L3)$ .

Serial No: 109YAXH03477

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 (%)	-0.9	0.9	0.9	0.9	0.9
Manufacturer acceptable CV%	<1%	<1%	<1%	<1%	<1%
Status	Passed	Passed	Passed	Passed	Passed

Conducted by:

Nagendra

Mr. Nagendra Bansode

Verified by:


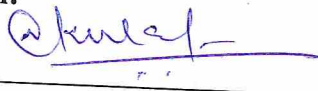
Sagar Kulat

Dr. Sagar Kulat

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savadi, Ahmednagar-414001

**B. PERFORMANCE CERTIFICATE:**

Instrument Name : YUMIZEN H550  
Serial Number : 109YAXH03477.  
Customer Details with complete address : LUPIN DIAGNOSTICS,  
Mohammadwadi, AHMEDNAGAR-411028.  
Installation Date : 06/10/2021  
Warranty expires on : RR (Reagent Rental) - 5yrs

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Nagendra Bansode		
Title: Application Specialist	Sign: 	06/10/2021	
Approved by:	LUPIN DIAGNOSTICS,		
Name:	Dr. Sagar Kulat		
Title: Head of Department	Sign: 	Date:06/10/2021	

**Deviation:** No

**LUPIN DIAGNOSTIC**  
Behind Zopadi Cantin,  
Opp. Monica D.Ed. College  
Savadi, Ahmednagar-414001

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



**HORIBA**

Explore the future

**HORIBA India Private Ltd.**

246, Okhla Industrial

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020 New Delhi, India

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HIN/MED/2023-2024/0084

06<sup>th</sup> July 2023.

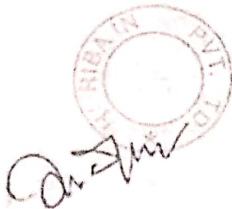
### CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer ABX Yumizen H550 bearing serial number: 109YAXH03477 installed at Lupin diagnostics Ahmednagar was Calibrated on 06<sup>th</sup> July 2023.

Calibrator : ABX MINOCAL  
Lot No. : CX484  
Expiry Date : 05<sup>th</sup> August 2023.

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

Next calibration cycle is due on 05<sup>th</sup> July 2024.



**Shrish Dixit**  
(Head- Products & Marketing)  
For Horiba India Pvt. Ltd.

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Automotive Test Systems | Process & Environment | Medical | Semiconductor | Scientific

**HORIBA**  
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Scanned with OKEN Scanner

### Blank Cycle Logs

Running Date	Operator	WBC 10 <sup>3</sup> /μL	RBC 10 <sup>6</sup> /μL	HGB g/dL	PLT 10 <sup>3</sup> /μL	Status	Technical alarms
06/07/2023 06:10:46 AM	ABX	0.00	0.00	0.0	4	Passed	
06/07/2023 01:07:26 PM	ABX	0.00	0.00	0.0	3	Passed	

Registered and Corporate Office:  
 Lupin Diagnostics Limited (formerly known as Lupin Healthcare Limited), 3<sup>rd</sup> Floor, Kalpataru Inspire, Off W. E. Highway, Santacruz (East),  
 Mumbai - 400 055, India. | CIN : U24100MH2011PLC214885

06/07/2023 01:07:51 PM

Printed by : ABX

S/N 109YAXH03477



# Repeatability Report (part 1)

Number of repeatability run report selected for statistic calculation 10/11

Coefficient	WBC (10 <sup>3</sup> /μL)	RBC (10 <sup>6</sup> /μL)	HGB (g/dL)	HCT (%)	PLT (10 <sup>3</sup> /μL)	MCV (μm <sup>3</sup> )	RDW-CV (%)	RDW-SD (μm <sup>3</sup> )	P-LCR (%)
Minimum	6.31	5.12	14.6	42.4	214	82.4	15.9	44.5	18.5
Maximum	6.66	5.33	14.8	44.1	236	83.2	16.8	46.2	20.9
Mean	6.54	5.22	14.7	43.2	224	82.7	16.3	45.1	19.7
Difference	0.35	0.22	0.2	1.8	22	0.8	0.9	1.7	2.4
2 SD	0.21	0.14	0.1	1.2	15	0.5	0.6	1.4	1.3
CV(%)	1.57	1.33	0.47	1.36	3.30	0.28	1.93	1.53	3.38

Run Date & Time	WBC (10 <sup>3</sup> /μL)	RBC (10 <sup>6</sup> /μL)	HGB (g/dL)	HCT (%)	PLT (10 <sup>3</sup> /μL)	MCV (μm <sup>3</sup> )	RDW-CV (%)	RDW-SD (μm <sup>3</sup> )	P-LCR (%)	Operator
06/07/2023 01:11:46 PM	6.60	5.31	14.9	44.0	231	82.7	16.4	45.4	19.0	ABX
✓ 06/07/2023 01:13:18 PM	6.48	5.24	14.8	43.4	224	82.8	16.0	44.5	19.9	ABX
✓ 06/07/2023 01:14:56 PM	6.56	5.31	14.7	43.8	219	82.5	16.1	44.5	19.7	ABX
✓ 06/07/2023 01:16:31 PM	6.54	5.24	14.7	43.4	220	82.8	16.5	45.4	18.8	ABX
✓ 06/07/2023 01:18:04 PM	6.66	5.20	14.7	43.0	233	82.8	16.4	45.4	20.0	ABX
✓ 06/07/2023 01:19:44 PM	6.64	5.33	14.7	44.1	228	82.7	16.7	46.2	20.9	ABX
✓ 06/07/2023 01:21:22 PM	6.64	5.16	14.7	42.7	214	82.8	15.9	44.5	18.5	ABX
✓ 06/07/2023 01:22:59 PM	6.49	5.12	14.6	42.4	214	82.9	16.5	45.4	19.3	ABX
✓ 06/07/2023 01:24:34 PM	6.51	5.22	14.6	43.5	223	83.2	16.8	46.2	19.9	ABX
06/07/2023 01:26:12 PM	6.59	5.14	14.6	42.4	236	82.4	16.1	44.5	19.9	ABX
✓ 06/07/2023 01:27:53 PM	6.31	5.20	14.6	42.8	227	82.5	16.1	44.5	19.7	ABX



## Repeatability Report (part 2)

Number of repeatability run report selected for statistic calculation 10/11

Coefficient	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	LIC% (%)
Minimum	62.6	22.7	9.1	0.5	0.6	0.7
Maximum	65.3	24.7	11.0	1.0	1.1	1.2
Mean	64.2	23.9	10.2	0.8	0.8	1.0
Difference	2.6	2.0	1.9	0.5	0.5	0.5
2 SD	1.5	1.3	1.2	0.3	0.3	0.3
CV(%)	1.19	2.67	5.90	17.92	18.01	16.47

Run Date & Time	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	LIC% (%)	Operator
06/07/2023 01:11:46 PM	63.9	24.4	10.4	0.8	0.5	0.8	ABX
✓ 06/07/2023 01:13:18 PM	63.8	24.2	10.2	0.9	0.9	1.2	ABX
✓ 06/07/2023 01:14:56 PM	65.0	23.5	9.5	0.9	1.1	1.0	ABX
✓ 06/07/2023 01:16:31 PM	63.9	24.7	9.7	1.0	0.7	1.2	ABX
✓ 06/07/2023 01:18:04 PM	55.3	22.7	10.6	0.5	0.9	1.0	ABX
✓ 06/07/2023 01:19:44 PM	63.9	24.1	10.3	0.8	0.9	1.1	ABX
✓ 06/07/2023 01:21:22 PM	62.6	24.7	10.9	0.9	0.9	0.8	ABX
✓ 06/07/2023 01:22:59 PM	64.6	23.3	10.2	1.0	0.9	1.1	ABX
✓ 06/07/2023 01:24:34 PM	63.9	23.7	11.0	0.7	0.7	1.1	ABX
06/07/2023 01:26:12 PM	64.4	24.0	10.2	0.8	0.6	0.9	ABX
✓ 06/07/2023 01:27:53 PM	64.9	24.4	9.1	0.9	0.7	0.7	ABX



## Calibration Report

Sample ID CX484  
Lot number CX484

Name ABX MINOCAL

Exp. date 05/08/2023  
Modified on

Coefficient	WBC	RBC	HGB	HCT	PLT	MPV
New	1.147	1.028	0.979	1.077	1.060	1.019
Current	1.125	1.021	0.986	1.042	1.060	0.990
Target	8.80	4.57	13.2	38.6	253	10.4
Mean	8.63	4.54	13.3	37.1	253	10.1
CV(%)	1.29	0.76	0.40	0.80	2.97	1.03

Number of calibration run selected for coefficient calculation (minimum 5) 10/11

Sel.	Run Time	WBC (10 <sup>3</sup> /μL)	RBC (10 <sup>6</sup> /μL)	HGB (g/dL)	HCT (%)	PLT (10 <sup>3</sup> /μL)	MPV (μm <sup>3</sup> )
	06/07/2023 01:33:28 PM	8.56	4.53	13.2	37.0	259	10.2
✓	06/07/2023 01:35:42 PM	8.64	4.55	13.2	37.4	256	10.2
✓	06/07/2023 01:37:20 PM	8.41	4.51	13.2	37.0	248	10.2
✓	06/07/2023 01:38:52 PM	8.63	4.52	13.2	37.0	261	10.1
✓	06/07/2023 01:40:30 PM	8.72	4.51	13.2	36.8	259	10.1
✓	06/07/2023 01:42:11 PM	8.56	4.58	13.3	37.4	256	10.1
✓	06/07/2023 01:43:55 PM	8.48	4.51	13.3	36.8	241	10.0
✓	06/07/2023 01:45:31 PM	8.68	4.56	13.3	37.2	243	10.0
✓	06/07/2023 01:47:02 PM	8.75	4.52	13.3	36.8	250	10.0
✓	06/07/2023 01:48:44 PM	8.67	4.58	13.3	37.4	254	9.9
✓	06/07/2023 01:50:22 PM	8.72	4.60	13.3	37.6	264 h	10.1



## Calibration Report

Sample ID CX484  
Lot number CX484

Name ABX MINOCAL

Exp. date 05/08/2023  
Modified on

Coefficient	WBC	RBC	HGB	HCT	PLT	MPV
New	1.147	1.028	0.979	1.077	1.060	1.019
Current	1.147	1.028	0.979	1.077	1.060	1.019
Target	8.80	4.57	13.2	38.6	253	10.4
Mean	8.63	4.54	13.3	37.1	253	10.1
CV(%)	1.29	0.76	0.40	0.80	2.97	1.03

Number of calibration run selected for coefficient calculation (minimum 5) 10/11

Sel.	Run Time	WBC (10 <sup>3</sup> /μL)	RBC (10 <sup>6</sup> /μL)	HGB (g/dL)	HCT (%)	PLT (10 <sup>3</sup> /μL)	MPV (μm <sup>3</sup> )
	06/07/2023 01:33:28 PM	8.56	4.53	13.2	37.0	259	10.2
✓	06/07/2023 01:35:42 PM	8.64	4.55	13.2	37.4	256	10.2
✓	06/07/2023 01:37:20 PM	8.41	4.51	13.2	37.0	248	10.2
✓	06/07/2023 01:38:52 PM	8.63	4.52	13.2	37.0	261	10.1
✓	06/07/2023 01:40:30 PM	8.72	4.51	13.2	36.8	259	10.1
✓	06/07/2023 01:42:11 PM	8.56	4.58	13.3	37.4	256	10.1
✓	06/07/2023 01:43:55 PM	8.48	4.51	13.3	36.8	241	10.0
✓	06/07/2023 01:45:31 PM	8.68	4.56	13.3	37.2	243	10.0
✓	06/07/2023 01:47:02 PM	8.75	4.52	13.3	36.8	250	10.0
✓	06/07/2023 01:48:44 PM	8.67	4.58	13.3	37.4	254	9.9
✓	06/07/2023 01:50:22 PM	8.72	4.60	13.3	37.6	264 h	10.1



**Results**

**Run Date** 06/07/2023 01:54:14 PM

**Operator** ABX

**Last Name**

**Sample ID** CAL AS SAMPLE

**First Name** CX484

**Rack/Pos**

**Gender** Unknown

**Department**

**Patient ID** AUTO\_PID00062

**Age**

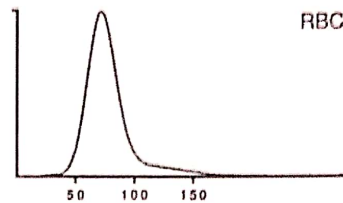
**Physician**

**Birth Date**

**Type** Standard

**Sample comments**

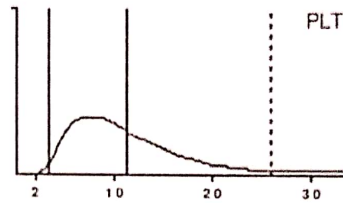
			Range
RBC	4.52	10 <sup>6</sup> /μL	3.80 - 6.00
HGB	13.0	g/dL	11.5 - 17.0
HCT	37.9	%	35.0 - 52.0
MCV	84.0	μm <sup>3</sup>	76.0 - 100.0
MCH	28.8	pg	27.0 - 34.0
MCHC	34.3	g/dL	32.0 - 35.0
DW-CV	16.1	%	11.0 - 17.0
RDW-SD	42.8	μm <sup>3</sup>	37.0 - 49.0



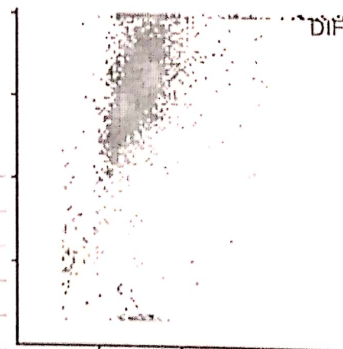
**Recommended actions**

- Slide review
- Alerts**
- Control failed
- WBC**
- Background Noise
- Abnormal Differentiation
- Susp. Pathologies**
- PLT aggregate ?
- Lymphopenia
- Neutropenia
- Eosinophilia
- Malaria P. falciparum ?
- Malaria P. vivax ?

			Range
PLT	248	* 10 <sup>3</sup> /μL	150 - 400
PCT	0.25	%	0.15 - 0.40
MPV	10.2	* μm <sup>3</sup>	8.0 - 11.0
PDW	19.0	* μm <sup>3</sup>	11.0 - 22.0
P-LCC	93	10 <sup>3</sup> /μL	44 - 140
P-LCR	37.7	%	18.0 - 50.0



			Range
WBC	8.88	* 10 <sup>3</sup> /μL	3.50 - 10.00
	#		
NEU	0.99	L*	1.60 - 7.00
			11.4  *
			40.0 - 73.0
LYM	0.13	L*	1.00 - 3.00
			1.5  *
			15.0 - 45.0
MON	0.01	l*	0.20 - 0.80
			0.1  *
			4.0 - 12.0
EOS	7.52	H*	0.00 - 0.50
			86.6 h*
			0.5 - 7.0
BAS	0.03	*	0.00 - 0.15
			0.4 *
			0.0 - 2.0
LIC	0.20	h*	0.00 - 0.10
			2.3 h*
			0.0 - 1.0



**Slide Review**

Neutrophil	Myeloblast	Anisocytosis
Lymphocyte	Promyelocyte	Hypochromia
Monocyte	Myelocyte	Polychromasia
Eosinophil	Metamyelocyte	Poikilocytosis
Basophil	Blast	Microcytosis
Atypical Lymphocyte	Target Cell	Macrocytosis
Other	Sickle Cell	Platelet Clumps

Reviewed on \_\_\_\_\_ by \_\_\_\_\_ Signature :

Run Date 06/07/2023 02:05:38 PM

Operator ABX

Name PX442L

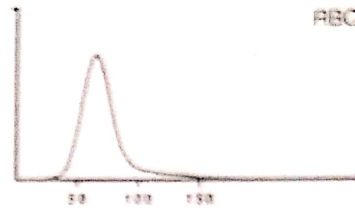
Sample ID PX442L

Level Low

Exp. date 05/09/2023

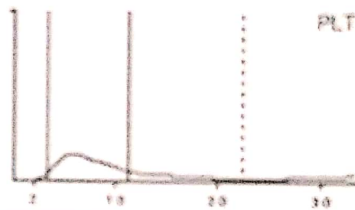
Lot number PX442L

			Range
RBC	2.44	10 <sup>9</sup> /μL	2.19 - 2.51
HGB	5.9	g/dL	5.6 - 6.4
HCT	18.8	%	16.8 - 19.8
MCV	77.2	μm <sup>3</sup>	73.0 - 83.0
MCH	24.2	pg	23.5 - 27.5
MCHC	31.4	g/dL	29.7 - 35.7
RDW-CV	17.4	%	12.0 - 20.0

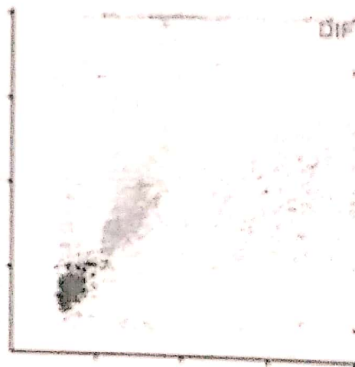


Alarms

			Range
PLT	69	10 <sup>9</sup> /μL	43 - 83
MPV	8.8	μm <sup>3</sup>	6.8 - 10.8



WBC	3.08	10 <sup>9</sup> /μL	Range 2.55 - 3.35	
	#	Range	%	Range
NEU	1.54	1.01 - 1.71	50.3	36.0 - 56.0
LYM	1.06	0.76 - 1.42	34.3	25.1 - 49.1
MON	0.17	0.00 - 0.38	5.4	0.0 - 12.8
EOS	0.30	0.00 - 0.36	9.6	0.0 - 12.4
BAS	0.01	0.00 - 0.26	0.4	0.0 - 8.6



Slide Review

- Neutrophil
- Lymphocyte
- Monocyte
- Eosinophil
- Basophil
- Atypical Lymphocyte
- Other

- Myeloblast
- Promyelocyte
- Myelocyte
- Metamyelocyte
- Blast
- Target Cell
- Sickle Cell

- Anisocytosis
- Hypochromia
- Polychromasia
- Poikilocytosis
- Microcytosis
- Macrocytosis
- Platelet Clumps

Reviewed on \_\_\_\_\_ by \_\_\_\_\_ Signature :

QC - Control Run Report

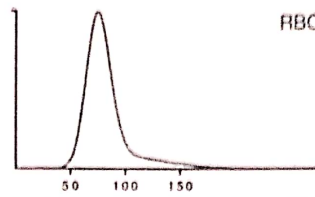
Run Date 06/07/2023 02:02:08 PM

Operator | ABX

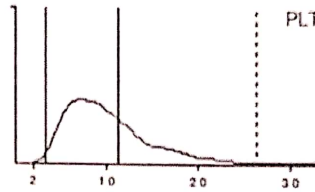
Name PX442N  
Level Normal  
Lot number PX442N

Sample ID | PX442N  
Exp. date | 05/09/2023

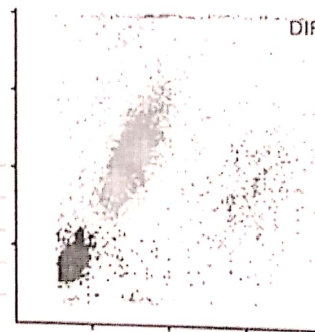
			Range
RBC	4.75	10 <sup>6</sup> /μL	4.48 - 4.88
HGB	13.3	g/dL	13.0 - 14.0
HCT	41.8	%	39.2 - 43.2
MCV	88.0	μm <sup>3</sup>	83.0 - 93.0
MCH	28.0	pg	26.8 - 30.8
MCHC	31.8	g/dL	29.8 - 35.8
RDW-CV	13.5	%	9.5 - 17.5



			Range
PLT	258	10 <sup>3</sup> /μL	221 - 281
MPV	9.5	μm <sup>3</sup>	7.4 - 11.4



			Range		Range
WBC	8.37	10 <sup>3</sup> /μL	7.30 - 9.30		
	#		Range	%	Range
NEU	4.52		3.18 - 4.98	54.1	39.2 - 59.2
LYM	3.21		2.57 - 3.97	38.3	31.4 - 47.4
MON	0.40		0.00 - 0.90	4.8	0.0 - 10.8
EOS	0.23		0.00 - 0.46	2.7	0.0 - 5.6
BAS	0.01		0.00 - 0.54	0.1	0.0 - 6.4



Slide Review

Neutrophil	Myeloblast	Anisocytosis
Lymphocyte	Promyelocyte	Hypochromia
Monocyte	Myelocyte	Polychromasia
Eosinophil	Metamyelocyte	Poikilocytosis
Basophil	Blast	Microcytosis
Atypical Lymphocyte	Target Cell	Macrocytosis
Other	Sickle Cell	Platelet Clumps

Reviewed on \_\_\_\_\_ by \_\_\_\_\_ Signature :

06/07/2023 02:03:48 PM

Printed by : ABX

S/N 109YAXH03477

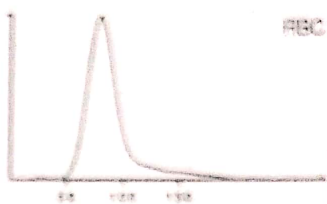
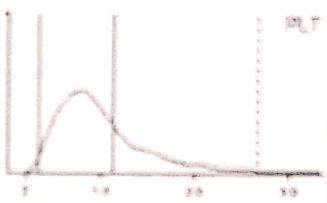
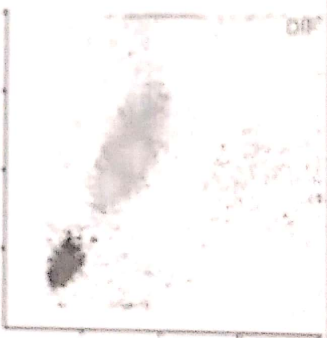
QC - Control Risk Report

Run Date 06/07/2023 02:04:09 PM

Operator ABX

Name PX662H  
Level High  
Lot number PX662H

Sample ID PX662H  
Exp. date 05/09/2023

			Range		Alarms	
RBC	5.33	10 <sup>6</sup> /μL	5.08 - 5.58	 <p>RBC</p>		
HGB	16.4	g/dL	16.0 - 17.2			
HCT	50.0	%	48.1 - 53.1			
MCV	93.8	μm <sup>3</sup>	90.0 - 100.0			
MCH	30.7	pg	28.6 - 33.6			
MCHC	32.8	g/dL	29.8 - 35.8			
RDW-CV	13.2	%	10.0 - 18.0			
PLT	478	10 <sup>3</sup> /μL	426 - 526	 <p>PLT</p>		
MPV	9.4	μm <sup>3</sup>	7.4 - 11.4			
WBC	17.15	10 <sup>3</sup> /μL	15.40 - 19.80	 <p>DIFF</p>		
	#	Range	%			Range
NEU	13.04	10.68 -	76.0			61.5 - 81.5
LYM	2.91	1.56 - 4.56	17.0			9.4 - 25.4
MON	0.40	0.00 - 1.06	2.4			0.0 - 6.0
EOS	0.78	0.00 - 1.58	4.5			0.0 - 9.0
BAS	0.02	0.00 - 1.26	0.1			0.0 - 7.2

Slide Review

Neutrophil	Myeloblast	Anisocytosis
Lymphocyte	Promyelocyte	Hypochromia
Monocyte	Myelocyte	Polychromasia
Eosinophil	Metamyelocyte	Poikilocytosis
Basophil	Blast	Microcytosis
Atypical Lymphocyte	Target Cell	Macrocytosis
Other	Sickle Cell	Platelet Clumps

Reviewed on \_\_\_\_\_ by \_\_\_\_\_ Signature :