

**HORIBA**  
Medical

HORIBA India Private Limited

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**HORIBA**  
Medical

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

**YUMIZEN H550**

(Serial no: 909YAXH02656)

Fully Automated Hematology Analyzer

For

**LUPIN DIAGNOSTICS LTD**

JALNA

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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.


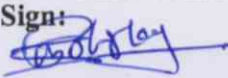
II. Performance Certificate.

#### **Section 5 Attachments**

**General Instructions:**

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H550, fully 6 Part Automated Hematology Analyzer, at KRANAA DIAGNOSTICS LTD. 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
- KRANAA DIAGNOSTICS 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:	Ananta Landge		
Title: Application Specialist	Sign: 	Date: 18/05/2023	
Approved by:	LUPIN DIAGNOSTICS LTD		
Name:	Santosh Bhoskare		
Title: InCharge	Sign: 	Date: 18/05/2023	

# YUMIZEN H550

(Serial no: **909YAXH02656**)

Fully Automated Hematology Analyzer

## Installation Qualification

For

**LUPIN DIAGNOSTICS LTD**

JALNA

---

#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: 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. : 909YAXH02656	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>909YAXH02656</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.

**C. INSTALLATION CERTIFICATE:**

**Instrument Name** : YUMIZEN H550  
**Serial Number** : 909YAXH02656  
**Customer Details with complete address** : LUPIN DIAGNOSTICS LTD ,  
JALNA.  
**Installation Date** : 18/05/2023  
**Warranty expires on** : RR (Reagent Rental).

<b>Prepared by:</b>	HORIBA Medical - HORIBA India Pvt. Ltd.		
<b>Name:</b>	Ananta Landge		
<b>Title: Application Specialist</b>	<b>Sign:</b> 	<b>Date: 18/05/2023</b>	
<b>Approved by:</b>	LUPIN DIAGNOSTICS LTD JALNA		
<b>Name:</b>	DR. Anand Kumar Chordiya		
<b>Title: DR.</b>	<b>Sign:</b> 	<b>Date: 18/05/2023</b>	

**Deviation:**

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



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**YUMIZEN H550**

(Serial no: 909YAXH02656)

Fully Automated Hematology Analyzer

**Operational Qualification**

For

**LUPIN DIAGNOSTICS LTD**

JALNA

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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/>

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

Instrument Name : YUMIZEN H550

Serial Number : 909YAXH02656

**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 BACKGROUND 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 AVAILPATHOLOGISTLE 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**


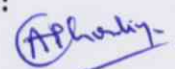
**Operator Training:** The users responsible for the operation of this instrument will be trained on the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented, and the training records will be filled as indicated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

### **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** : 909YAXH02656  
**Customer Details** : LUPIN DIAGNOSTICS LTD  
**with complete address** JALNA  
**Installation Date** : 18/05/2023  
**Warranty expires on** : RR (Reagent Rental).

<b>Prepared by:</b>	HORIBA Medical - HORIBA India Pvt. Ltd.		
<b>Name:</b>	Ananta Landge		
<b>Title: Application Specialist</b>	<b>Sign:</b> 	<b>Date: 18/05/2023</b>	
<b>Approved by:</b>	LUPIN DIAGNOSTICS LTD		
<b>Name:</b>	Dr. ANANDKUMAR CHOURDIYA		
<b>Title: dr.</b>	<b>Sign:</b> 	<b>Date: 18/05/2023</b>	

**Deviation:**

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

**HORIBA**  
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**HORIBA**  
Medical  
YUMIZEN H550

(Serial no: 909YAXH02656)  
Fully Automated Hematology Analyzer

**Performance Qualification**

For

**LUPIN DIAGNOSTICS LTD**  
JALNA

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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

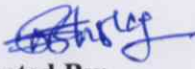

Serial Number : 909YAXH02656

**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: 909YAXH02656

Parameters	Acceptable Range	Observed Value
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.02
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 $10^3/\text{mm}^3$	$\leq 5 \times 10^3/\text{mm}^3$	2



Conducted By: Verified By: 



- **Precision Study:** Precision is checked by running blood sample in 11 replicates & getting CV% in within acceptance.

Serial No: : 909YAXH02656

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	1.03	Ok
HGB g/dL	< 1.5	0.43	Ok
HCT %	< 2.0	1.02	Ok
PLT $10^3/\text{mm}^3$	< 5.0	2.98	Ok
WBC $10^3/\text{mm}^3$	< 2.5	1.98	Ok


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 10 runs. Run Calibrator as a sample to verify the calibration. **Lot:** CX483; **Expiry:** 07/05/2023.

Serial No: 909YAXH02656

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.90	8.59	1.57	<2%	PASSED
RBC	4.52	4.45	1.26	<2%	PASSED
HGB	12.8	12.7	0.54	<1.5%	PASSED
HCT	37.1	36.5	1.60	<2%	PASSED
PLT	258	271	2.60	<5%	PASSED
MPV	10.3	11.0	1.72	<3%	PASSED

  
Conducted By:

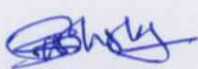
  
Verified By:

- **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:** ABX Difftrol PX442; **Exp:** 09/05/2023.

Serial No: 909YAXH02656

LEVEL	STATUS
LOW ( PX440L)	PASSED
NORMAL (PX440N)	PASSED
HIGH (PX440H)	PASSED

  
Conducted By:

  
Verified By:

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

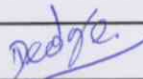
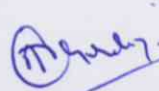
Serial No: 909YAXH02656

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 (%)	0.73	0.67	0.8	0.56	0.87
Manufacturer acceptable CV%	<1%	<1%	<1%	<1%	<1%
Status	Passed	Passed	Passed	Passed	Passed

  
Conducted By:  
Verified By:

**B. PERFORMANCE CERTIFICATE:**

**Instrument Name** : YUMIZEN H550  
**Serial Number** : 909YAXH02656.  
**Customer Details with complete address** : LUPIN DIAGNOSTICS LTD ,  
JALNA  
**Installation Date** : 18/05/2023  
**Warranty expires on** : RR (Reagent Rental).

<b>Prepared by:</b>	HORIBA Medical - HORIBA India Pvt. Ltd.		
<b>Name:</b>	Ananta Landge		
<b>Title: Application Specialist</b>	<b>Sign:</b> 	18/05/2023	
<b>Approved by:</b>	LUPIN DIAGNOSTICS LTD		
<b>Name:</b>	DR.Anandkumar Chourdiya		
<b>Title: Pathologist</b>	<b>Sign:</b> 	Date:18/05/2023	

**Deviation: no**

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

**HORIBA**  
Medical

**HORIBA India Private Limited**

246, Okhla Industrial Estate Phase-III,  
New Delhi 110020, India  
Tel : +91 (11) 4646 5000 / 4669 5001  
Fax : +91 (11) 4646 5020  
http : //www.horiba.com  
CIN : U73100DL2006PTC153232

HIN/MED/2022-2023/1005101  
18 may 2023

**CALIBRATION CERTIFICATE**

This is to certify that the Hematology Analyzer **YUMIZEN H550** bearing serial number:  
**909YAXH02656** installed at **Lupin diagnostic Jalna** as calibrated on 18 may 2023

Calibrator : ABXMINOCAL  
L lotNo. : CX483  
ExpiryDate : 05<sup>th</sup> july 2023

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

Next calibration cycle is due on 17 may **2024**

A circular stamp with the text "HORIBA INDIA PVT. LTD." around the perimeter. A handwritten signature is written across the center of the stamp.

ShrishDixit

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



# HORIBA

Medical

## **HORIBAIndiaPrivateLimited**

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<http://www.horiba.com>

CIN:U73100DL2006FTC153232

## Blank Cycle Logs

Running Date	Operator	WBC 10 <sup>9</sup> /μL	RBC 10 <sup>9</sup> /μL	HGB g/dL	PLT 10 <sup>3</sup> /μL	Status	Technical alarms
05/18/2023 01:18:11 PM	technician	0.08	0.00	0.0	0	Passed	
05/18/2023 01:54:18 PM	ABX	0.05	0.00	0.0	1	Passed	
05/18/2023 05:34:20 PM	technician	0.05	0.00	0.0	0	Passed	

## Calibration Report

Sample ID CX483  
Lot number CX483

Name ABXMINOCAL

Exp. date 07/05/2023  
Modified on

Coefficient	WBC	RBC	HGB	HCT	PLT	MPV
New	1.143	1.030	1.000	1.046	1.140	1.004
Current	1.143	1.030	1.000	1.030	1.140	1.004
Target	8.90	4.52	12.8	37.1	258	10.3
Mean	8.59	4.45	12.7	36.5	271	11.0
CV(%)	1.57	1.26	0.54	1.60	2.60	1.45

Number of calibration run selected for coefficient calculation (minimum 5) 6/6

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> )
✓	05/18/2023 05:40:40 PM	8.71	4.56	12.8	37.5	280 h	11.0 h
✓	05/18/2023 05:42:12 PM	8.54 l	4.42 l	12.7	36.2	269 h	11.0 h
✓	05/18/2023 05:43:42 PM	8.71	4.45 l	12.8	36.5	265	11.0 h
✓	05/18/2023 05:45:12 PM	8.35 l	4.42 l	12.7	36.1 l	277 h	10.9 h
✓	05/18/2023 05:46:42 PM	8.63 l	4.41 l	12.7	36.0 l	276 h	11.3 h
✓	05/18/2023 05:48:12 PM	8.59 l	4.45 l	12.8	36.9	262	11.0 h

**QC - Control Run Report**

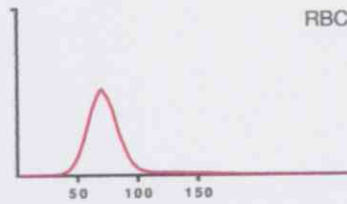
**Run Date** 05/18/2023 06:10:35 PM

**Operator** technician

**Name** ABXdiffrol L  
**Level** Low  
**Lot number** PX441L

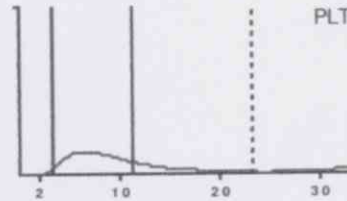
**Sample ID** PX441L  
**Exp. date** 07/05/2023

			<b>Range</b>
<b>RBC</b>	2.32	10 <sup>6</sup> /μL	2.16 - 2.48
<b>HGB</b>	5.8	g/dL	5.4 - 6.2
<b>HCT</b>	18.1	%	16.2 - 19.2
<b>MCV</b>	78.0	μm <sup>3</sup>	71.5 - 81.5
<b>MCH</b>	25.1	pg	23.0 - 27.0
<b>MCHC</b>	32.2	g/dL	29.7 - 35.7
<b>RDW-CV</b>	14.4	%	12.0 - 20.0

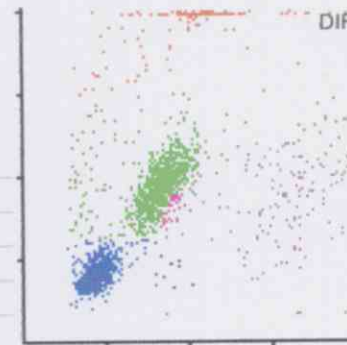


**Alarms**

			<b>Range</b>
<b>PLT</b>	67	10 <sup>3</sup> /μL	48 - 88
<b>MPV</b>	8.8	μm <sup>3</sup>	7.1 - 11.1



<b>WBC</b>	3.08	10 <sup>3</sup> /μL	<b>Range</b>	2.50 - 3.30
	<b>#</b>		<b>Range</b>	<b>%</b>
<b>NEU</b>	1.42	0.84 - 1.54	46.1	31.2 - 51.2
<b>LYM</b>	1.19	0.88 - 1.54	38.6	29.7 - 53.7
<b>MON</b>	0.18	0.00 - 0.42	6.0	0.0 - 14.4
<b>EOS</b>	0.24	0.00 - 0.36	7.6	0.0 - 12.2
<b>BAS</b>	0.05	0.00 - 0.22	1.7	0.0 - 7.6



**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 :

**QC - Control Run Report**

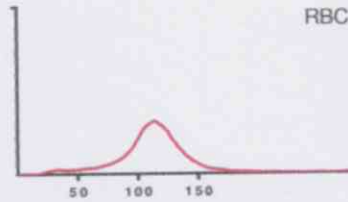
**Run Date** 05/18/2023 05:58:13 PM

**Operator** technician

**Name** ABXdifftrol H  
**Level** High  
**Lot number** PX441H

**Sample ID** PX441H  
**Exp. date** 07/05/2023

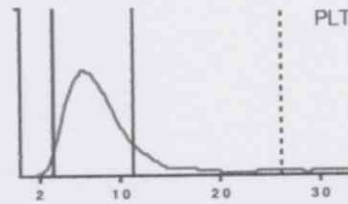
			<b>Range</b>
<b>RBC</b>	4.16	10 <sup>6</sup> /μL	4.86 - 5.36
<b>HGB</b>	15.1	g/dL	15.1 - 16.3
<b>HCT</b>	46.9	%	44.5 - 49.5
<b>MCV</b>	112.8	μm <sup>3</sup>	87.0 - 97.0
<b>MCH</b>	36.2	pg	28.2 - 33.2
<b>MCHC</b>	32.1	g/dL	30.4 - 36.4
<b>RDW-CV</b>	16.4	%	10.0 - 18.0



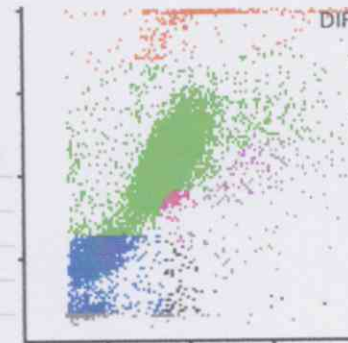
**Alarms**

**Control failed**  
 RBC below tolerance  
 HGB below tolerance  
 PLT above tolerance  
 WBC above tolerance  
 MCV above tolerance  
 MCH above tolerance  
 NEU# above tolerance

			<b>Range</b>
<b>PLT</b>	903	10 <sup>3</sup> /μL	439 - 539
<b>MPV</b>	7.8	μm <sup>3</sup>	7.3 - 11.3



			<b>Range</b>
<b>WBC</b>	20.73	10 <sup>3</sup> /μL	16.20 - 20.60
	<b>#</b>	<b>Range</b>	<b>%</b>
<b>NEU</b>	14.96	10.67 -	72.2
<b>LYM</b>	4.27	2.12 - 5.12	20.6
<b>MON</b>	0.37	0.00 - 1.48	1.8
<b>EOS</b>	0.93	0.00 - 1.44	4.5
<b>BAS</b>	0.20	0.00 - 1.50	0.9



**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 :

**QC - Control Run Report**

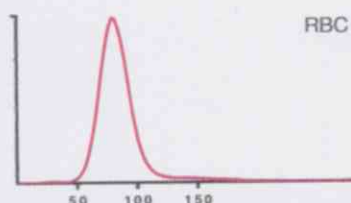
**Run Date** 05/18/2023 06:06:32 PM

**Operator** technician

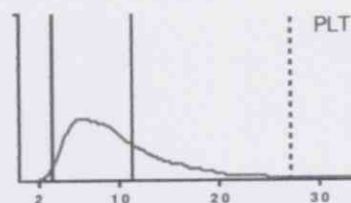
**Name** ABXdifftrol N  
**Level** Normal  
**Lot number** PX441N

**Sample ID** PX441N  
**Exp. date** 07/05/2023

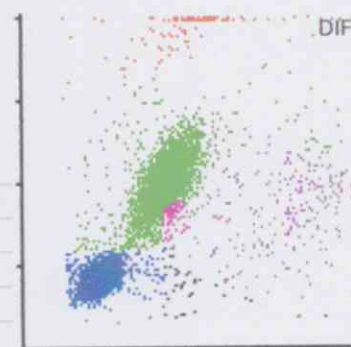
			<b>Range</b>
<b>RBC</b>	4.69	10 <sup>6</sup> /μL	4.39 - 4.79
<b>HGB</b>	13.3	g/dL	12.7 - 13.7
<b>HCT</b>	40.9	%	37.9 - 41.9
<b>MCV</b>	87.3	μm <sup>3</sup>	82.0 - 92.0
<b>MCH</b>	28.3	pg	26.8 - 30.8
<b>MCHC</b>	32.4	g/dL	30.1 - 36.1
<b>RDW-CV</b>	11.4	%	11.0 - 19.0



			<b>Range</b>
<b>PLT</b>	245	10 <sup>3</sup> /μL	210 - 270
<b>MPV</b>	9.2	μm <sup>3</sup>	7.3 - 11.3



			<b>Range</b>
<b>WBC</b>	8.34	10 <sup>3</sup> /μL	7.20 - 9.20
	<b>#</b>	<b>Range</b>	<b>%</b>
<b>NEU</b>	4.17	2.97 - 4.77	49.8
<b>LYM</b>	3.38	2.74 - 4.14	40.6
<b>MON</b>	0.39	0.00 - 0.80	4.7
<b>EOS</b>	0.25	0.00 - 0.48	3.0
<b>BAS</b>	0.15	0.00 - 0.50	1.9
		<b>Range</b>	<b>%</b>
		37.2 - 57.2	
		34.0 - 50.0	
		0.0 - 9.8	
		0.0 - 5.8	
		0.0 - 6.0	



**Alarms**

**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 :



## Repeatability Report (part 2)

Number of repeatability run report selected for statistic calculation 5/5

Coefficient	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	LIC% (%)
Minimum	57.5	23.8	7.3	6.8	1.0	0.3
Maximum	59.8	26.0	8.5	7.9	1.3	0.5
Mean	59.0	24.7	7.9	7.3	1.1	0.4
Difference	2.3	2.2	1.2	1.1	0.3	0.2
2 SD	1.7	1.9	1.0	0.9	0.3	0.2
CV(%)	1.48	3.89	6.64	6.20	12.07	25.00

Sel	Run Date &Time	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	LIC% (%)	Operator
✓	10/03/2023 01:43:42 PM	59.8	23.8	8.5	6.9	1.0	0.5	ABX
✓	10/03/2023 01:45:44 PM	57.5	26.0	7.3	7.9	1.3	0.5	ABX
✓	10/03/2023 01:47:22 PM	59.2	25.5	7.4	6.8	1.1	0.4	ABX
✓	10/03/2023 01:48:58 PM	59.0	24.4	8.2	7.4	1.0	0.3	ABX
✓	10/03/2023 01:50:33 PM	59.4	24.0	8.1	7.5	1.0	0.3	ABX

## Repeatability Report (part 1)

Number of repeatability run report selected for statistic calculation 5/5

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	5.22	4.47	12.8	36.9	210	82.2	9.7	34.4	32.5
Maximum	5.48	4.55	12.9	37.5	221	83.0	10.4	36.1	34.8
Mean	5.35	4.50	12.8	37.1	214	82.6	10.0	34.9	34.0
Difference	0.26	0.08	0.1	0.6	12	0.9	0.7	1.7	2.2
2 SD	0.25	0.06	0.1	0.5	9	0.6	0.5	1.5	1.8
CV(%)	2.32	0.65	0.41	0.67	2.05	0.37	2.42	2.15	2.66

Sel	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
✓	10/03/2023 01:43:42 PM	5.22	4.55	12.9	37.5	221	82.5	10.4	36.1	34.0	ABX
✓	10/03/2023 01:45:44 PM	5.25	4.50	12.9	37.2	215	82.5	10.1	34.4	34.7	ABX
✓	10/03/2023 01:47:22 PM	5.48	4.48	12.9	37.2	212	83.0	10.1	35.3	34.1	ABX
✓	10/03/2023 01:48:58 PM	5.48	4.47	12.9	36.9	210	82.6	9.9	34.4	34.8	ABX
✓	10/03/2023 01:50:33 PM	5.32	4.49	12.8	36.9	214	82.2	9.7	34.4	32.5	ABX