

# HORIBA

Explore the future

## HORIBA India Private Ltd.

246, Okhla Industrial

Estate, Phase - III 110

020 New Delhi, India

Tel: +91 (11) 4646 5000 / 4669 5001

Fax: +91 (11) 4669 5010 / 4646 5020

HIN/MED/2022-2023/100647

24<sup>th</sup> March 2022

## CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **ABX YUMIZEN H550** bearing serial number: **012YAXH03173** installed at **Redcliff lifetech Pvt.Ltd., Jaipur** as calibrated on 24<sup>th</sup> March 2022

Calibrator : ABX MINOCAL

Lot No. : CX468

Expiry Date : 05<sup>th</sup> April 2022

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

Next calibration cycle is due on 23<sup>rd</sup> **March 2023**.



**Shrish Dixit**

(Head- Products & Marketing)

For **Horiba India Pvt. Ltd.**

# **HORIBA**

Medical

YUMIZEN H550

(Serial no: **012YAXH03173**)

Fully Automated Hematology Analyzer

## **Performance Qualification**

For

**REDCLIFFE LIFETECH PVT LTD**

**1 st FLOOR BLOCK 2/9 , CHITRAKOOT**

**GANDHI PATH , VAISHALI NAGAR**

**JAIPUR**

---

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

Visit us: <http://www.horiba.com/in/>

---

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

Instrument Name : YUMIZEN H550.  
Serial Number : 012YAXH03173

**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: 012YAXH03173

Parameters	Acceptable Range	Observed Value	Verified by Sign/Date
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.05	
RBC $10^6/\text{mm}^3$	$\leq 0.02 \times 10^6/\text{mm}^3$	0	
HGB g/dL	$\leq 0.3 \text{ g/dl}$	0	
PLT $10^3/\text{mm}^3$	$\leq 5 \times 10^3/\text{mm}^3$	0	

  
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) 06 times, without taking the values of first run, calibrate the instrument using average of the last 05 runs. Run Calibrator as a sample to verify the calibration.

**Lot: CX468; Expiry: 05/04/2022.**

**Serial No: 012YAXH03173**

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.90	8.74	0.93	<3%	PASSED
RBC	4.60	4.04	1.04	<2%	PASSED
HGB	13.0	13.1	0.42	<1.5%	PASSED
HCT	38.6	34.0	1.27	<2%	PASSED
PLT	263	224	1.93	<5%	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 PX434; Exp: 05/05/2020.**

Serial No: 012YAXH03173

Level I: Low Control

Parameters	Range	Observed Value Dated 24/03/2022	Comments
RBC 10 <sup>6</sup> /mm <sup>3</sup>	2.14-2.46	2.31	Passed
HGB g/dl	6.0-6.8	6.3	Passed
HCT %	17.4-20.4	18.6	Passed
MCV μm <sup>3</sup>	77.0-87.0	80.0	Passed
MCH pg	25.8-29.8	27.3	Passed
MCHC g/dL	30.9-36.9	33.8	Passed
RDW %	10.5-18.5	11.6	Passed
PLT 10 <sup>3</sup> /mm <sup>3</sup>	52.92	68	Passed
MPV μm <sup>3</sup>	8.2-12.2	10.6	Passed
WBC 10 <sup>3</sup> /mm <sup>3</sup>	1.95-2.75	2.59	Passed
NEU %	39.8-59.8	47.5	Passed
NEU#	0.82-1.52	1.23	Passed
LYM%	19.1-43.1	39.0	Passed
LYM #	0.40-1.06	1.01	Passed
MON %	0.0-17.8	4.4	Passed
MON #	0.00-0.42	0.11	Passed
EOS%	0.0-14.4	7.2	Passed
EOS#	0.00-0.34	0.19	Passed
BAS%	0.0-6.0	1.9	Passed
BAS#	0.00-0.14	0.05	Passed

**Level II: Normal Control**

Parameters	Range	Observed Value Dated 24/03/2022	Comments
RBC 10 <sup>6</sup> /mm <sup>3</sup>	4.46-4.86	4.64	Passed
HGB g/dL	13.1-14.1	13.4	Passed
HCT %	38.1-42.1	38.9	Passed
MCV $\mu\text{m}^3$	81.0-91.0	84.0	Passed
MCH pg	27.2-31.2	28.9	Passed
MCHC g/dL	30.9-36.9	34.5	Passed
RDW %	10.0-18.0	10.7	Passed
PLT 10 <sup>3</sup> /mm <sup>3</sup>	235-295	253	Passed
MPV $\mu\text{m}^3$	8.2-12.2	10.1	Passed
WBC 10 <sup>3</sup> /mm <sup>3</sup>	6.20-8.20	7.92	Passed
NEU %	44.6-64.6	53.0	Passed
NEU #	3.03-4.83	4.20	Passed
LYM %	25.9-41.9	37.8	Passed
LYM #	1.74-3.14	2.99	Passed
MON %	0.00-11.0	4.5	Passed
MON #	0.00-0.80	0.36	Passed
EOS%	0.0-8.8	3.4	Passed
EOS#	0.00-0.64	0.27	Passed
BAS%	0.0-3.2	1.3	Passed
BAS#	0.00-0.24	0.10	Passed

**Level III: High Control**

Parameters	Range	Observed Value Dated 24/03/2022	Comments
RBC 10 <sup>6</sup> /mm <sup>3</sup>	4.99-5.49	5.22	Passed
HGB g/dL	15.8-17.0	16.1	Passed
HCT %	44.7-49.7	46.4	Passed
MCV $\mu\text{m}^3$	85.0-95.0	88.9	Passed
MCH pg	28.8-33.8	30.8	Passed
MCHC g/dL	31.8-37.8	34.8	Passed
RDW %	10.0-18.0	34.6	Passed
PLT 10 <sup>3</sup> /mm <sup>3</sup>	472-572	507	Passed
MPV $\mu\text{m}^3$	8.2-12.2	10.1	Passed
WBC 10 <sup>3</sup> /mm <sup>3</sup>	14.10-18.50	16.7	Passed
NEU %	59.3-79.3	68.4	Passed
NEU #	9.40-13.20	11.43	Passed
LYM %	9.8-25.8	19.9	Passed
LYM #	1.40-4.40	3.32	Passed
MON %	0.0-11.2	4.8	Passed
MON #	0.00-1.82	0.81	Passed
EOS%	0.0-11.0	5.3	Passed
EOS#	0.00-1.80	0.89	Passed
BAS%	0.0-3.6	1.6	Passed
BAS#	0.00-0.58	0.27	Passed

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

Serial No: 012YAXH03173

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	0.67	PASSED
HGB g/Dl	< 1.5	0.66	PASSED
HCT %	< 2.0	0.78	PASSED
PLT $10^3/\text{mm}^3$	< 5.0	2.40	PASSED
WBC $10^3/\text{mm}^3$	< 3.0	1.85	PASSED

  
Conducted By :


  
Verified By:



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

Serial No: 012YAXH03173

Parameters	WBC $10^3/\text{mm}^3$	RBC $10^6/\text{mm}^3$	HGB g/dL	PLT $10^3/\text{mm}^3$
Carry Over (%)	0.3	0.4	0.3	0.46
Manufacturer acceptable CV%	<2%	<2%	<2%	<2%
Status	Passed	Passed	Passed	Passed

  
Conducted by:

  
Verified by:

**B. PERFORMANCE CERTIFICATE:**

**Instrument Name** : YUMIZEN H550.  
**Serial Number** : 012YAXH03173  
**Customer Details** : REDCLIFFE LIFETECH PVT LTD.  
**With complete address** # 1ST FLOOR BLOCK 2/9 , CHITRAKOOT , GANDHI  
PATH , VAISHALI NAGAR , JAIPUR  
**Installation Date** : 22/03/2022  
**Warranty expires on** : RR

<b>Prepared by:</b>	HORIBA Medical - HORIBA India Pvt. Ltd.		
<b>Name:</b>	Mr.RAMCHANDRA REWAR		
<b>Title:</b>	<b>Sign:</b> <i>[Signature]</i>		
<b>Engineer Customer Support</b>	<i>for - Rakesh</i>		
<b>Reviewed by:</b>	REDCLIFFE LIFETECH PVT LTD.		
<b>Name:</b>	Dr. Meenakshyee Joshi		
<b>Title:</b>	<b>Sign:</b> <i>For - Rakesh</i>	<b>Date:</b>	<i>22/03/2022</i>
<b>Approved by:</b>	REDCLIFFE LIFETECH PVT LTD.		
<b>Name:</b>	Dr. Meenakshyee Joshi		
<b>Title:</b>	<b>Sign:</b> <i>for - Rakesh</i>	<b>Date:</b>	<i>22/03/2022</i>

**Deviation:**

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

**QC - Control Run Report**

**Run Date** 08/14/2022 10:06:25 AM

**Operator** REDCLIFFE

**Name** ABXdifftrol L

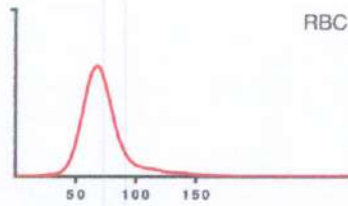
**Sample ID** PX436L

**Level** Low

**Exp. date** 09/05/2022

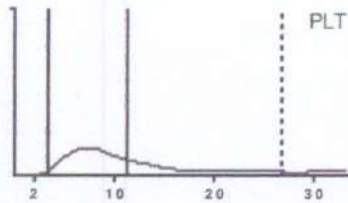
**Lot number** PX436L

			<b>Range</b>
<b>RBC</b>	2.32	10 <sup>6</sup> /μL	2.22 - 2.54
<b>HGB</b>	6.1	g/dL	5.8 - 6.6
<b>HCT</b>	18.6	%	17.3 - 20.3
<b>MCV</b>	80.1	μm <sup>3</sup>	74.0 - 84.0
<b>MCH</b>	26.3	pg	24.1 - 28.1
<b>MCHC</b>	32.9	g/dL	30.0 - 36.0
<b>RDW-CV</b>	14.3	%	13.0 - 21.0



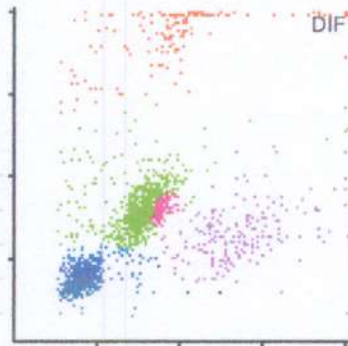
**Alarms**

			<b>Range</b>
<b>PLT</b>	83	10 <sup>3</sup> /μL	57 - 97
<b>MPV</b>	10.6	μm <sup>3</sup>	8.1 - 12.1



*Handwritten signature and date: Tu/8/22*

			<b>Range</b>
<b>WBC</b>	3.06	10 <sup>3</sup> /μL	2.50 - 3.30
	<b>#</b>	<b>Range</b>	<b>%</b>
<b>NEU</b>	1.21	0.87 - 1.57	39.4
<b>LYM</b>	1.13	0.78 - 1.44	37.0
<b>MON</b>	0.29	0.00 - 0.52	9.4
<b>EOS</b>	0.26	0.01 - 0.35	8.5
<b>BAS</b>	0.17	0.00 - 0.24	5.7



**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** 08/14/2022 10:04:49 AM

**Operator** REDCLIFFE

**Name** ABXdiffrol N

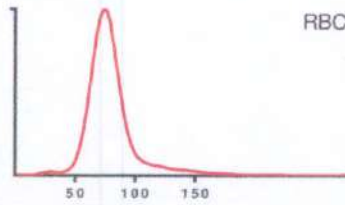
**Sample ID** PX436N

**Level** Normal

**Exp. date** 09/05/2022

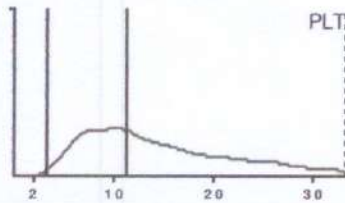
**Lot number** PX436N

			<b>Range</b>
<b>RBC</b>	4.72	10 <sup>6</sup> /μL	4.53 - 4.93
<b>HGB</b>	13.1	g/dL	12.8 - 13.8
<b>HCT</b>	40.8	%	38.9 - 42.9
<b>MCV</b>	86.4	μm <sup>3</sup>	80.0 - 90.0
<b>MCH</b>	27.7	pg	26.1 - 30.1
<b>MCHC</b>	32.1	g/dL	30.1 - 36.1
<b>RDW-CV</b>	11.2	%	10.5 - 18.5



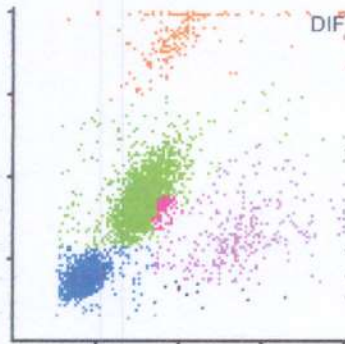
**Alarms**

			<b>Range</b>
<b>PLT</b>	270	10 <sup>3</sup> /μL	238 - 298
<b>MPV</b>	13.5	μm <sup>3</sup>	11.2 - 15.2



*Handwritten signature and date: 12/14/22*

			<b>Range</b>
<b>WBC</b>	8.28	10 <sup>3</sup> /μL	7.45 - 9.45
	<b>#</b>	<b>Range</b>	<b>%</b>
<b>NEU</b>	3.85	3.09 - 4.89	46.5
<b>LYM</b>	3.46	2.93 - 4.33	41.8
<b>MON</b>	0.46	0.00 - 0.82	5.6
<b>EOS</b>	0.33	0.01 - 0.55	3.9
<b>BAS</b>	0.18	0.00 - 0.28	2.2



**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 :

**QC - Control Run Report**

**Run Date** 08/14/2022 10:14:29 AM

**Operator** REDCLIFFE

**Name** ABXdiffrol H

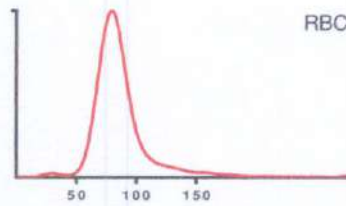
**Sample ID** PX436H

**Level** High

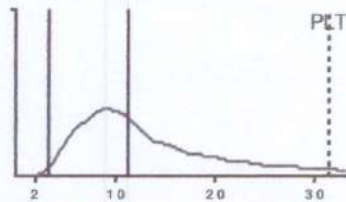
**Exp. date** 09/05/2022

**Lot number** PX436H

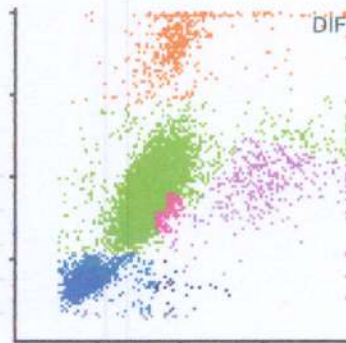
			<b>Range</b>
<b>RBC</b>	5.22	10 <sup>6</sup> /μL	4.99 - 5.49
<b>HGB</b>	15.8	g/dL	15.2 - 16.4
<b>HCT</b>	48.5	%	45.7 - 50.7
<b>MCV</b>	92.9	μm <sup>3</sup>	87.0 - 97.0
<b>MCH</b>	30.4	pg	27.7 - 32.7
<b>MCHC</b>	32.7	g/dL	29.8 - 35.8
<b>RDW-CV</b>	11.2	%	10.0 - 18.0



			<b>Range</b>
<b>PLT</b>	508	10 <sup>3</sup> /μL	470 - 570
<b>MPV</b>	12.0	μm <sup>3</sup>	9.9 - 13.9



			<b>Range</b>		<b>Range</b>
<b>WBC</b>	18.12	10 <sup>3</sup> /μL	16.20 - 20.60		
	<b>#</b>		<b>Range</b>	<b>%</b>	<b>Range</b>
<b>NEU</b>	12.71		10.89 -	70.2	59.5 - 79.5
<b>LYM</b>	3.52		2.25 - 5.25	19.4	12.4 - 28.4
<b>MON</b>	0.61		0.00 - 1.28	3.4	0.0 - 7.0
<b>EOS</b>	0.84		0.00 - 1.70	4.6	0.0 - 9.2
<b>BAS</b>	0.44		0.00 - 0.74	2.4	0.0 - 4.0



*Handwritten signature and date: 14/8/22*

**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 :