

HORIBA

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HIN/MED/2022-2023/100647

04th July 2022

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **ABX YUMIZEN H550** bearing serial number: **205YAXH03775** installed at **Redcliff lifetech Pvt.Ltd., Jaipur** as calibrated on 04th July 2022

Calibrator : ABX MINOCAL

Lot No. : CX471

Expiry Date : 05th Aug 2022

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

Next calibration cycle is due on 03rd July 2023.



Shrish Dixit

(Head- Products & Marketing)

For **Horiba India Pvt. Ltd.**

HORIBA

Medical

YUMIZEN H550

(Serial no: **205YAXH03775**)

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.

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

Instrument Name : YUMIZEN H550.

Serial Number : 205YAXH03775

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: 205YAXH03775

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: CX471; **Expiry:** 05/07/2020.

Serial No: 205YAXH03775

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.90	8.93	1.18	<3%	PASSED
RBC	4.52	3.98	1.30	<2%	PASSED
HGB	13.0	12.7	0.79	<1.5%	PASSED
HCT	38.0	33.6	1.47	<2%	PASSED
PLT	251	220	1.57	<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 PX436; **Exp:** 05/09/2022.

Serial No: 205YAXH03775

Level I: Low Control

Parameters	Range	Observed Value Dated 04/07/2022	Comments
RBC 10 ⁶ /mm ³	2.22-2.54	2.36	Passed
HGB g/dl	5.8-6.6	6.2	Passed
HCT %	17.3-20.3	18.4	Passed
MCV μm ³	74.0-84.0	77.9	Passed
MCH pg	24.1-28.1	26.1	Passed
MCHC g/dL	30.0-26.0	33.5	Passed
RDW %	13.0-21.0	13.5	Passed
PLT 10 ³ /mm ³	57-97	85	Passed
MPV μm ³	8.1-12.1	10.8	Passed
WBC 10 ³ /mm ³	2.50-3.30	3.24	Passed
NEU %	32.1-52.1	44.7	Passed
NEU#	0.87-1.57	1.45	Passed
LYM%	26.4-50.4	37.4	Passed
LYM #	0.78-1.44	1.21	Passed
MON %	0.1-11.9	7.9	Passed
MON #	0.00-0.35	0.25	Passed
EOS%	0.7-11.9	7.3	Passed
EOS#	0.01-0.35	0.24	Passed
BAS%	0.2-8.2	2.7	Passed
BAS#	0.00-0.24	0.09	Passed

Level II: Normal Control

Parameters	Range	Observed Value Dated 04/07/2022	Comments
RBC $10^6/\text{mm}^3$	4.53-4.93	4.71	Passed
HGB g/dL	12.8-13.8	13.2	Passed
HCT %	38.9-42.9	40.5	Passed
MCV μm^3	80.0-90.0	85.9	Passed
MCH pg	26.1-30.1	28.0	Passed
MCHC g/dL	30.1-36.1	32.6	Passed
RDW %	10.5-18.5	11.6	Passed
PLT $10^3/\text{mm}^3$	238-298	267	Passed
MPV μm^3	11.2-15.2	13.2	Passed
WBC $10^3/\text{mm}^3$	7.45-9.45	8.35	Passed
NEU %	37.2-57.2	49.5	Passed
NEU #	3.09-4.89	4.13	Passed
LYM %	34.9-50.9	40.3	Passed
LYM #	2.93-4.33	3.37	Passed
MON %	0.1-9.7	4.8	Passed
MON #	0.00-0.82	0.40	Passed
EOS%	0.1-6.5	4.4	Passed
EOS#	0.01-0.55	0.37	Passed
BAS%	0.0-3.4	1.0	Passed
BAS#	0.00-0.28	0.08	Passed

Level III: High Control

Parameters	Range	Observed Value Dated 04/07/2022	Comments
RBC 10 ⁶ /mm ³	4.99-5.49	5.20	Passed
HGB g/dL	15.2-16.4	15.7	Passed
HCT %	45.7-50.7	48.4	Passed
MCV μm ³	87.0-97.0	93.0	Passed
MCH pg	27.7-32.7	30.1	Passed
MCHC g/dL	29.8-35.8	32.4	Passed
RDW %	10-18	12.4	Passed
PLT 10 ³ /mm ³	470-570	543	Passed
MPV μm ³	9.9-13.9	12.4	Passed
WBC 10 ³ /mm ³	16.2-20.6	17.77	Passed
NEU %	59.5-79.5	70.3	Passed
NEU #	10.89-18.9	12.48	Passed
LYM %	12.4-28.4	20.1	Passed
LYM #	2.25-5.25	3.57	Passed
MON %	0.0-7.0	3.2	Passed
MON #	0.00-1.28	0.57	Passed
EOS%	0.0-9.2	5.1	Passed
EOS#	0.00-1.70	0.92	Passed
BAS%	0.0-4.0	1.3	Passed
BAS#	0.00-0.74	0.23	Passed

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

Serial No: 205YAXH03775

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	1.34	PASSED
HGB g/Dl	< 1.5	0.79	PASSED
HCT %	< 2.0	1.38	PASSED
PLT $10^3/\text{mm}^3$	< 5.0	1.89	PASSED
WBC $10^3/\text{mm}^3$	< 3.0	1.27	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 % = $(L1-L3) \times 100 / (H3-L3)$.

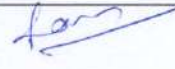
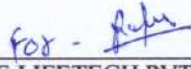
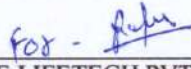


Serial No: 205YAXH03775

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 : 205YAXH03775
Customer Details : REDCLIFFE LIFETECH PVT LTD.
With complete address # 1ST FLOOR BLOCK 2/9 , CHITRAKOOT , GANDHI
PATH , VAISHALI NAGAR , JAIPUR
Installation Date : 04/07/2022
Warranty expires on : RR

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Ram Chandra Rewar		
Title:	Sign:		
Engineer Customer Support			
Reviewed by:	REDCLIFFE LIFETECH PVT LTD.		
Name:	Dr. Meenakshyee Joshi		
Title:	Sign:		Date:
		For - 	4/7/2022
Approved by:	REDCLIFFE LIFETECH PVT LTD.		
Name:	Dr. Meenakshyee Joshi		
Title:	Sign:		Date:
		For - 	4/7/22

Deviation:

Conclusion: Instrument has been qualified for Performance.

QC - Control Run Report

Run Date 08/14/2022 09:32:29 AM

Operator REDCLIFFE

Name ABXdifftrol L

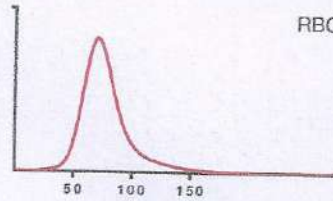
Sample ID PX436L

Level Low

Exp. date 09/05/2022

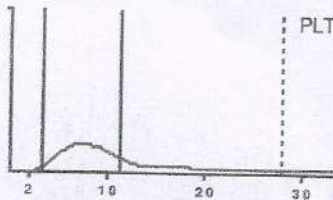
Lot number PX436L

			Range
RBC	2.41	10 ⁶ /μL	2.22 - 2.54
HGB	6.1	g/dL	5.8 - 6.6
HCT	19.0	%	17.3 - 20.3
MCV	78.7	μm ³	74.0 - 84.0
MCH	25.5	pg	24.1 - 28.1
MCHC	32.4	g/dL	30.0 - 36.0
RDW-CV	14.5	%	13.0 - 21.0



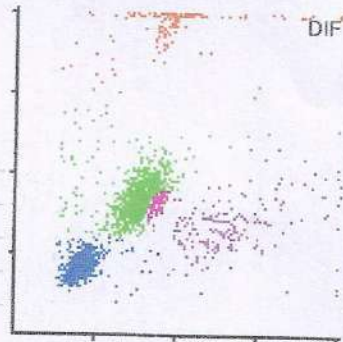
Alarms

			Range
PLT	91	10 ³ /μL	57 - 97
MPV	11.0	μm ³	8.1 - 12.1



Handwritten: 14/8/22

			Range
WBC	2.94	10 ³ /μL	2.50 - 3.30
	#	Range	%
NEU	1.22	0.87 - 1.57	41.7
LYM	1.13	0.78 - 1.44	38.2
MON	0.25	0.00 - 0.52	8.5
EOS	0.24	0.01 - 0.35	8.1
BAS	0.10	0.00 - 0.24	3.5



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

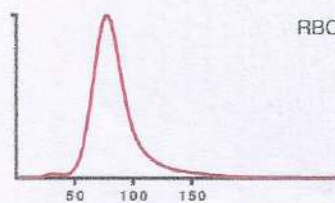
Run Date 08/14/2022 09:31:07 AM

Operator REDCLIFFE

Name ABXdifftrol N
Level Normal
Lot number PX436N

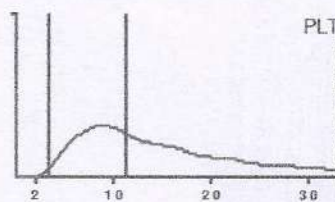
Sample ID PX436N
Exp. date 09/05/2022

			Range
RBC	4.70	10 ⁶ /μL	4.53 - 4.93
HGB	13.1	g/dL	12.8 - 13.8
HCT	40.2	%	38.9 - 42.9
MCV	85.4	μm ³	80.0 - 90.0
MCH	27.8	pg	26.1 - 30.1
MCHC	32.6	g/dL	30.1 - 36.1
RDW-CV	11.9	%	10.5 - 18.5



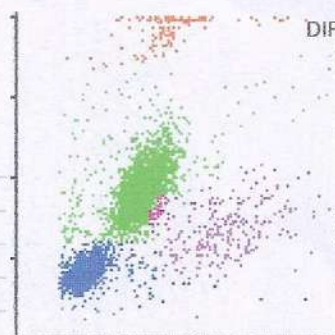
Alarms

			Range
PLT	295	10 ³ /μL	238 - 298
MPV	13.8	μm ³	11.2 - 15.2



Handwritten signature and date: 14/8/22

			Range	
WBC	8.15	10 ³ /μL	7.45 - 9.45	
	#		Range	%
NEU	4.04		3.09 - 4.89	49.7
LYM	3.39		2.93 - 4.33	41.5
MON	0.37		0.00 - 0.82	4.5
EOS	0.26		0.01 - 0.55	3.2
BAS	0.09		0.00 - 0.28	1.1



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 09:29:31 AM

Operator REDCLIFFE

Name ABXdifftrol H

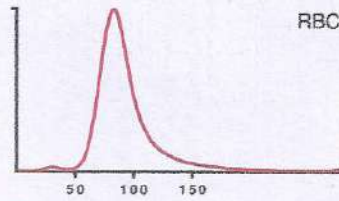
Sample ID PX436H

Level High

Exp. date 09/05/2022

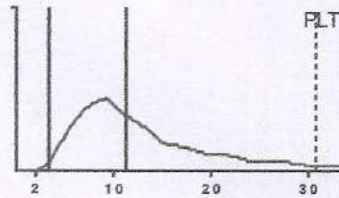
Lot number PX436H

			Range
RBC	5.29	10 ⁶ /μL	4.99 - 5.49
HGB	15.5	g/dL	15.2 - 16.4
HCT	48.8	%	45.7 - 50.7
MCV	92.1	μm ³	87.0 - 97.0
MCH	29.4	pg	27.7 - 32.7
MCHC	31.9	g/dL	29.8 - 35.8
RDW-CV	11.8	%	10.0 - 18.0



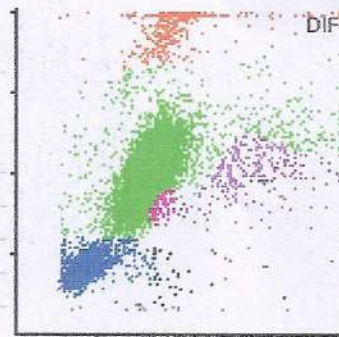
Alarms

			Range
PLT	529	10 ³ /μL	470 - 570
MPV	12.0	μm ³	9.9 - 13.9



Handwritten signature and date: 14/8/22

			Range		Range
WBC	17.77	10 ³ /μL	16.20 - 20.60		
	#		Range	%	Range
NEU	12.75		10.89 -	71.7	59.5 - 79.5
LYM	3.46		2.25 - 5.25	19.5	12.4 - 28.4
MON	0.45		0.00 - 1.28	2.5	0.0 - 7.0
EOS	0.83		0.00 - 1.70	4.7	0.0 - 9.2
BAS	0.28		0.00 - 0.74	1.6	0.0 - 4.0



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 :