

HORIBA

Medical

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CIN : U73100DL2006PTC153232

HIN/MED/2021-2022/100568

18th Dec 2021

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **YUMIZEN H550** bearing serial number: **910YAXH02773** installed at **REDCLIFFE LIFE DIAGNOSTICS, UDAIPUR** as calibrated on 18th Dec 2021.

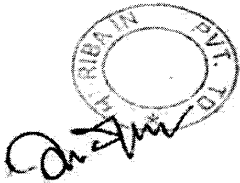
Calibrator : ABX MINOCAL

Lot No. : CX465

Expiry Date : 05th Jan 2022

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

Next calibration cycle is due on 17th Dec 2022.



Shrish Dixit

(Head- Products & Marketing)

For **Horiba India Pvt. Ltd.**

HORIBA

Medical

ABX YUMIZEN H550

(Serial no: **910YAXH02773**)

Fully Automated Hematology Analyzer

Performance Qualification

For

REDCLIFFE LIFE DIAGNOSTICS UDAIPUR

#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 : **910YAXH02773**

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: 910YAXH02773

Parameters	Acceptable Range	Observed Value	Verified by Sign/Date
WBC 10³/mm³	$\leq 0.3 \times 10^3 / \text{mm}^3$	0.0	PASSED
RBC 10⁶/mm³	$\leq 0.03 \times 10^6 / \text{mm}^3$	0.00	PASSED
HGB g/dl	$\leq 0.3 \text{ g/dl}$	0.0	PASSED
PLT 10³/mm³	$\leq 7 \times 10^3 / \text{mm}^3$	1	PASSED
LMNE	< 0.30 #	0.13	PASSED

Conducted By:

Verified By:

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

Serial No: 910YAXH02773

Parameters	CV % Acceptance	CV % Observed	Comments
RBC 10⁶/mm³	< 2.0	0.64	PASSED
HGB g/dL	< 1.5	0.32	PASSED
HCT %	< 2.0	0.90	PASSED
PLT 10³/mm³	< 5.0	2.22	PASSED
WBC 10³/mm³	< 2.5	1.61	PASSED

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) 05 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: CX465; Expiry: 5/02/2022

Serial No: 910YAXH02773

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.70	8.57	1.09	<2%	PASSED
RBC	4.51	4.21	0.74	<2%	PASSED
HGB	13.0	12.8	0.30	<1%	PASSED
HCT	37.4	34.8	0.65	<2%	PASSED
PLT	258	237	0.79	<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 PX432L; **Exp:** 05/01/2022

Serial No: 910YAXH02773

Level I: Low Control

Parameters	Range (As per Kit Insert)	Observed Value Dated 20/12/21	Comments
RBC 10 ⁶ /mm ³	2.22 – 2.54	2.40	Passed
HGB g/Dl	6.8 – 7.3	6.8	Passed
HCT %	18.7 – 21.7	19.8	Passed
MCV μm ³	80 – 90	82.3	Passed
MCH pg	27.0 – 31.0	28.2	Passed
MCHC g/Dl	31.1 – 37.1	34.3	Passed
RDW %	13.0 – 21.0	13.4	Passed
PLT 10 ³ /mm ³	55 – 95	77	Passed
MPV μm ³	9.0 – 13.0	11.2	Passed
WBC 10 ³ /mm ³	2.22 – 2.54	2.40	Passed
NEU %	40.3 – 60.3	46.9	Passed
NEU #	0.81 – 1.51	1.17	Passed
LYM %	16.4 – 40.4	33.7	Passed
LYM #	0.32 – 0.98	0.85	Passed
MON %	0.0 – 18.8	8.0	Passed
MON #	0.00 – 0.44	0.20	Passed
EOS %	0.0 – 13.4	7.5	Passed
EOS #	0.00 – 0.30	0.19	Passed
BAS %	0.0 – 13.4	7.5	Passed
BAS #	0.0 – 0.24	0.10	Passed

Level II: Normal Control

Parameters	Range (As per Kit Insert)	Observed Value Dated 20/12/21	Comments
RBC 10⁶/mm³	4.36 – 4.76	4.58	Passed
HGB g/Dl	12.5-13.5	12.7	Passed
HCT %	35.8 – 39.8	37.1	Passed
MCV μm^3	78 – 88	81.1	Passed
MCH pg	26.5 – 30.5	27.7	Passed
MCHC g/Dl	31.3 – 37.3	34.2	Passed
RDW %	11.0 – 19.0	14.3	Passed
PLT 10³/mm³	235 – 295	274	Passed
MPV μm^3	7.7 – 11.7	9.8	Passed
WBC 10³/mm³	6.15 – 8.15	7.28	Passed
NEU %	41.1 – 61.1	49.0	Passed
NEU #	2.75 – 4.55	3.56	Passed
LYM %	23.4 – 39.4	35.0	Passed
LYM #	1.55 – 2.95	2.55	Passed
MON %	0.0 - 24.4	11.1	Passed
MON #	0.00 – 1.74	0.81	Passed
EOS %	0.0 – 7.4	3.8	Passed
EOS #	0.00 – 0.52	0.28	Passed
BAS %	0.0 – 3.2	1.1	Passed
BAS #	0.00 – 0.22	0.08	Passed

Level III: High Control

Parameters	Range (As per Kit Insert)	Observed Value Dated 20/12/21	Comments
RBC 10⁶/mm³	4.88 – 5.38	5.07	Passed
HGB g/Dl	15.2 – 16.4	15.5	Passed
HCT %	43.2 – 48.2	45.2	Passed
MCV μm^3	84.0 – 94.0	89.1	Passed
MCH pg	28.3 – 33.3	30.5	Passed
MCHC g/Dl	31.6 – 37.6	34.3	Passed
RDW %	9.5 – 17.5	13.6	Passed
PLT 10³/mm³	484 – 584	524	Passed
MPV μm^3	8.9 – 12.9	10.6	Passed
WBC 10³/mm³	14.80 - 19.20	16.90	Passed
NEU %	54.7 – 74.7	64.9	Passed
NEU #	9.10 -12.90	10.97	Passed
LYM %	7.7 – 23.7	17.3	Passed
LYM #	1.17 – 4.17	2.92	Passed
MON %	0.0 – 25.6	12.3	Passed
MON #	0.00 – 4.36	2.07	Passed
EOS %	0.0 – 9.8	4.2	Passed
EOS #	0.00 – 1.66	0.72	Passed
BAS %	0.00 – 3.8	1.3	Passed
BAS #	0.00 – 0.64	0.22	Passed

QC - Control Run Report

Run Date 08/14/2022 11:05:55 AM

Operator REDCLIFFE

Name ABXdifftrol L

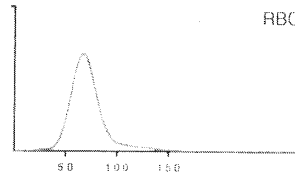
Sample ID PX436L

Level Low

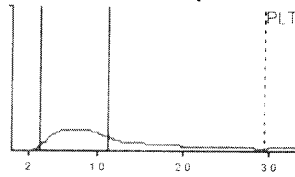
Exp. date 09/05/2022

Lot number PX436L

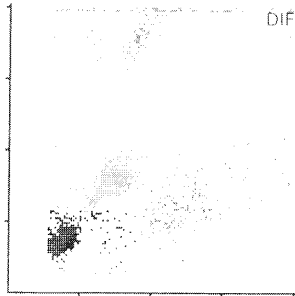
			Range
RBC	2.34	10 ⁶ /μL	2.22 - 2.54
HGB	6.3	g/dL	5.8 - 6.6
HCT	19.0	%	17.3 - 20.3
MCV	81.2	μm ³	74.0 - 84.0
MCH	26.8	pg	24.1 - 28.1
MCHC	33.0	g/dL	30.0 - 36.0
MW-CV	16.1	%	13.0 - 21.0



			Range
PLT	91	10 ³ /μL	57 - 97
MPV	11.3	μm ³	8.1 - 12.1



			Range		Range
WBC	3.29	10 ³ /μL	2.50 - 3.30		
	#			%	
NEU	1.44	0.87 - 1.57	43.8	32.1 - 52.1	
LYM	1.23	0.78 - 1.44	37.4	26.4 - 50.4	
MON	0.28	0.00 - 0.52	8.5	0.1 - 17.9	
EOS	0.28	0.01 - 0.35	8.5	0.7 - 11.9	
BAS	0.06	0.00 - 0.24	1.8	0.2 - 8.2	



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

Redcliffe
14/08/22

Reviewed on _____ by _____ Signature :

QC - Control Run Report

Run Date 08/14/2022 10:47:10 AM

Operator REDCLIFFE

Name ABXdifftrol N

Sample ID PX436N

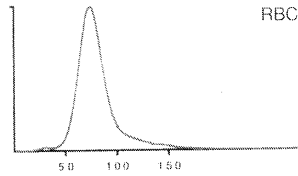
Level Normal

Exp. date 09/05/2022

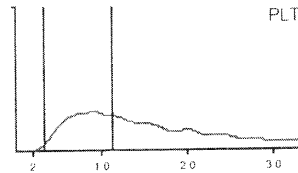
Lot number PX436N

Alarms

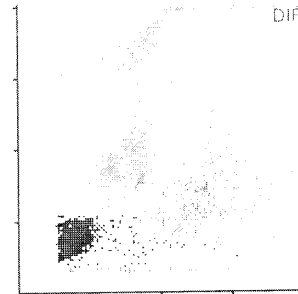
			Range
RBC	4.71	10 ⁶ /μL	4.53 - 4.93
HGB	13.5	g/dL	12.8 - 13.8
HCT	42.1	%	38.9 - 42.9
MCV	89.4	μm ³	80.0 - 90.0
MCH	28.6	pg	26.1 - 30.1
MCHC	32.0	g/dL	30.1 - 36.1
RDW-CV	14.0	%	10.5 - 18.5



			Range
PLT	295	10 ³ /μL	238 - 298
MPV	14.0	μm ³	11.2 - 15.2



			Range		Range
WBC	8.51	10 ³ /μL	7.45 - 9.45		
	#		Range	%	Range
NEU	4.20		3.09 - 4.89	49.3	37.2 - 57.2
LYM	3.53		2.93 - 4.33	41.5	34.9 - 50.9
MON	0.39		0.00 - 0.82	4.6	0.1 - 9.7
EOS	0.31		0.01 - 0.55	3.6	0.1 - 6.5
BAS	0.08		0.00 - 0.28	1.0	0.0 - 3.4



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 :

P. Shukla
14/08/22

QC - Control Run Report

Run Date 08/14/2022 10:49:49 AM

Operator REDCLIFFE

Name ABXdifftrol H

Sample ID PX436H

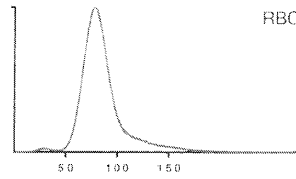
Level High

Exp. date 09/05/2022

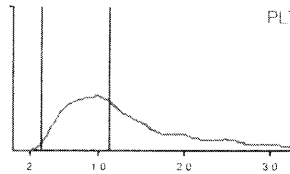
Lot number PX436H

			Range
RBC	5.16	10 ⁶ /μL	4.99 - 5.49
HGB	16.0	g/dL	15.2 - 16.4
HCT	48.9	%	45.7 - 50.7
MCV	94.7	μm ³	87.0 - 97.0
MCH	30.9	pg	27.7 - 32.7
MCHC	32.6	g/dL	29.8 - 35.8
RDW-CV	13.5	%	10.0 - 18.0

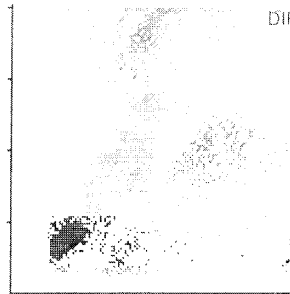
Alarms



			Range
PLT	558	10 ³ /μL	470 - 570
MPV	12.2	μm ³	9.9 - 13.9



			Range		Range
WBC	17.91	10 ³ /μL	16.20 - 20.60		
	#		Range	%	Range
NEU	12.92		10.89 -	72.1	59.5 - 79.5
LYM	3.36		2.25 - 5.25	18.8	12.4 - 28.4
MON	0.54		0.00 - 1.28	3.0	0.0 - 7.0
EOS	0.90		0.00 - 1.70	5.0	0.0 - 9.2
BAS	0.19		0.00 - 0.74	1.1	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

Push/Ka
14/08/22

Reviewed on _____ by _____ Signature :