

**HORIBA**  
Medical

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CIN : U73100DL2006PTC153232

HIN/MED/2022-2023/1005835  
04<sup>th</sup> Feb 2022

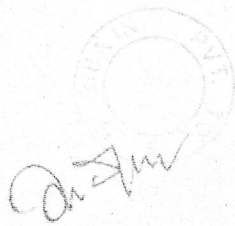
**CALIBRATION CERTIFICATE**

This is to certify that the Hematology Analyzer **ABX YUMIZEN H550** bearing serial number:  
**112YAXH03618** installed at **REDCLIFFE LIFETECH PVT. LTD., CHANDIGARH** as calibrated  
on 04<sup>th</sup> Feb 2022

Calibrator : ABX MINOCAL  
Lot No. : CX466  
Expiry Date : 05<sup>th</sup> Feb 2022

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

Next calibration cycle is due on 03<sup>rd</sup> Aug 2022.



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

**HORIBA**  
Medical

**Yumizen H 550**

(Serial no:**112YAXH03618**)

Automated Hematology Analyzer

**Performance Qualification**

For

REDCLIFFE LIFETECH PVT LTD

SCO-171, 1<sup>st</sup> Floor, SECTOR-37C, CHANDIGARH



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

Instrument Name : Yumizen H 550.  
Serial Number: 112YAXH03618

**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: 112YAXH03618

Parameters	Acceptable Range	Observed Value	Verified by Sign/Date
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.06	04/02/2022
RBC $10^6/\text{mm}^3$	$\leq 0.03 \times 10^6/\text{mm}^3$	0.00	04/02/2022
HGB g/dL	$\leq 0.3 \text{ g/dl}$	0.0	04/02/2022
PLT $10^3/\text{mm}^3$	$\leq 7 \times 10^3/\text{mm}^3$	1	04/02/2022

Conducted By: Rajesh Sharma

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

**Lot:** CX466 ; **Expiry:** 05/02/2022.

**Serial No:** 112YAXH03618

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.80	8.70	1.62	<3%	PASSED
RBC	4.51	4.18	1.32	<2%	PASSED
HGB	13.5	13.3	0.56	<1%	PASSED
HCT	39.2	36.5	1.24	<2%	PASSED
PLT	251	228	3.17	<5%	PASSED
MPV	10.2	10.2	1.55	<2%	PASSED

Conducted By: Rajesh Sharma

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 PX433L; Exp: 05/03/2022.

Serial No: 112YAXH03618

Level I: Low Control

Parameters	Range (As per Kit Insert)	Observed Value Dated 04/02/2022	Comments
RBC $10^6/\text{mm}^3$	2.2 – 2.85	2.38	Passed
HGB g/Dl	6.3 – 7.1	6.7	Passed
HCT %	18.2 – 21.2	20.2	Passed
MCV $\mu\text{m}^3$	78.5 – 88.5	85	Passed
MCH pg	26.4 – 30.4	28.4	Passed
MCHC g/Dl	31 – 37	33.4	Passed
RDW %	11.0 – 19.0	16.0	Passed
PLT $10^3/\text{mm}^3$	48 – 88	83	Passed
MPV $\mu\text{m}^3$	9.0 – 13.0	11.6	Passed
WBC $10^3/\text{mm}^3$	2.05 – 2.85	2.49	Passed
NEU %	43.5 – 63.5	55.0	Passed
NEU #	0.96 – 1.66	1.37	Passed
LYM %	18.7 – 42.7	32.4	Passed
LYM #	0.42 – 1.08	0.81	Passed
MON %	0.0 – 11.2	3.8	Passed
MON #	0.0 – 0.28	0.11	Passed
EOS %	0.0 – 15.4	7.8	Passed
EOS #	0.0 – 0.38	1.37	Passed
BAS %	0.0 – 5.0	1.0	Passed
BAS #	0.0 – 0.12	0.10	Passed


Conducted By:  Rajesh Sharma

Verified By: 



Level II: Normal Control

Parameters	Range (As per Kit Insert)	Observed Value Dated 04/02/2022	Comments
RBC 10 <sup>6</sup> /mm <sup>3</sup>	4.4-4.88	4.72	Passed
HGB g/Dl	13.1-14.1	13.8	Passed
HCT %	37.6-41.6	41.1	Passed
MCV μm <sup>3</sup>	81-91	87.0	Passed
MCH pg	27.6-31.6	29.2	Passed
MCHC g/dL	31.4-37.4	33.5	Passed
RDW %	10-18	14.9	Passed
PLT 10 <sup>3</sup> /mm <sup>3</sup>	243-303	267	Passed
MPV μm <sup>3</sup>	8.9-12.9	11.3	Passed
WBC 10 <sup>3</sup> /mm <sup>3</sup>	6.20-8.20	6.89	Passed
NEU %	46.0- 66.0	56.7	Passed
NEU #	3.08-4.88	3.91	Passed
LYM %	26.5-42.5	35.3	Passed
LYM #	1.75 -3.15	2.43	Passed
MON %	0.0-9.0	2.5	Passed
MON #	0.00-0.64	0.17	Passed
EOS %	0.0-6.6	4.2	Passed
EOS #	0.00-0.46	0.29	Passed
BAS %	0.0-3.4	1.3	Passed
BAS #	0.00-0.24	0.09	Passed

Conducted By:  Rajesh Shrama

Verified By: 

## Level III: High Control

Parameters	Range (As per Kit Insert)	Observed Value Dated 04/02/2022	Comments
RBC 10 <sup>6</sup> /mm <sup>3</sup>	5.03-5.53	5.38	Passed
HGB g/Dl	15.9-17.1	16.6	Passed
HCT %	45.0-50.0	48.3	Passed
MCV $\mu$ m <sup>3</sup>	85.0-95.0	89.7	Passed
MCH pg	28.8-33.8	30.8	Passed
MCHC g/dL	31.7-37.7	34.3	Passed
RDW %	9.5-17.5	11.4	Passed
PLT 10 <sup>3</sup> /mm <sup>3</sup>	475-575	508	Passed
MPV $\mu$ m <sup>3</sup>	9.0-13.0	9.8	Passed
WBC 10 <sup>3</sup> /mm <sup>3</sup>	15.0-19.40	17.27	Passed
NEU %	55.3-75.3	71.7	Passed
NEU #	9.33-13.13	12.40	Passed
LYM %	8.5-24.5	15.6	Passed
LYM #	1.34-4.34	2.70	Passed
MON %	0.0-19.0	6.7	Passed
MON #	0.00-3.26	1.15	Passed
EOS %	0.0-9.6	5.2	Passed
EOS #	0.00-1.66	0.89	Passed
BAS %	0.0-7.8	0.8	Passed
BAS #	0.00-1.34	0.13	Passed

  
Conducted By: Rajesh Sharma

  
Verified By:

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

Serial No: 112YAXH03618

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	1.10	PASSED
HGB g/dL	< 1.0	1.09	PASSED
HCT %	< 2.0	1.43	PASSED
PLT $10^3/\text{mm}^3$	< 5.0	3.34	PASSED
WBC $10^3/\text{mm}^3$	< 2.0	2.0	PASSED



Conducted By: Rajesh Sharma



Verified By:



**QC - Control Run Report**

Run Date 08/05/2022 01:16:27 PM

Operator technician

Name ABXdiffrol H

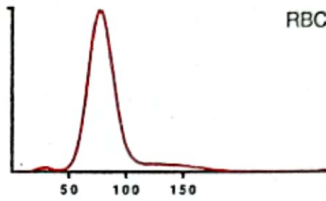
Sample ID PX436H

Level High

Exp. date 09/05/2022

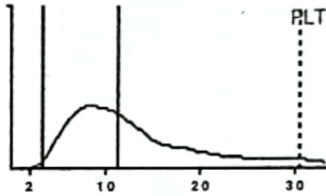
Lot number PX436H

			Range
RBC	5.31	10 <sup>6</sup> /μL	4.99 - 5.49
HGB	15.8	g/dL	15.2 - 16.4
HCT	49.8	%	45.7 - 50.7
MCV	93.7	μm <sup>3</sup>	87.0 - 97.0
MCH	29.8	pg	27.7 - 32.7
MCHC	31.9	g/dL	29.8 - 35.8
RDW-CV	14.0	%	10.0 - 18.0

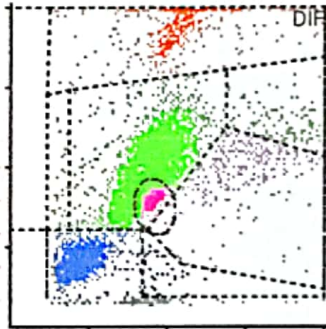


**Alarms**

			Range
PLT	520	10 <sup>3</sup> /μL	470 - 570
MPV	11.5	μm <sup>3</sup>	9.9 - 13.9



			Range
WBC	18.34	10 <sup>3</sup> /μL	16.20 - 20.60
	#	Range	%
NEU	12.59	10.89 -	68.6
LYM	3.55	2.25 - 5.25	19.4
MON	0.51	0.00 - 1.28	2.8
EOS	0.99	0.00 - 1.70	5.4
BAS	0.70	0.00 - 0.74	3.8



**Raw Data**

**PLT counts (by sections)**

S1	S2	S3	S4	S5	S6	S1	S2	S3	S4	S5	S6
429	421	438	433	480	524	4465	4392	4420	4575	4516	4335
S7	S8	S9	S10	S11	S12	S7	S8	S9	S10	S11	S12
407	459	434	417	406	447	4444	4405	4416	4441	4391	4311

**RBC counts (by sections)**

**WBC counts (by sections) and others**

S1	S2	S3	S4	S5	S6
1171	1137	1127	1216	1176	1149
S7	S8	S9	S10	S11	S12
1156	1176	1125	1180	1198	

**HGB measures (Optical intensity)**

LI1	LI2	LI3	LI4	LI5	LI6
3853	3852	3853	685	684	685
LI7	LI8	LI9	LI10	LI11	LI12
685	685	685	685	685	685
LI13					
684					

RMeasured : 10593  
Correlated : 10236  
Optical intensity 197

*John*  
5/8/22

QC - Control Run Report

Run Date 08/05/2022 01:14:34 PM

Operator technician

Name ABXdifftrol L

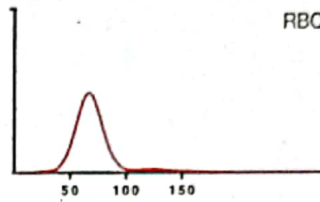
Sample ID PX436L

Level Low

Exp. date 09/05/2022

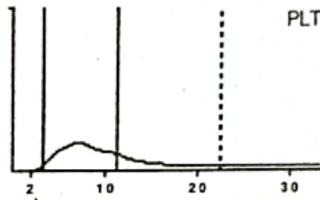
Lot number PX436L

			Range
RBC	2.41	10 <sup>6</sup> /μL	2.22 - 2.54
HGB	6.1	g/dL	5.8 - 6.6
HCT	19.4	%	17.3 - 20.3
MCV	80.7	μm <sup>3</sup>	74.0 - 84.0
MCH	25.3	pg	24.1 - 28.1
MCHC	31.3	g/dL	30.0 - 36.0
RDW-CV	19.4	%	13.0 - 21.0

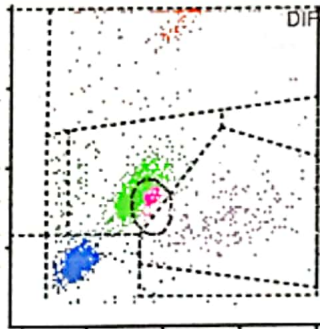


Alarms

			Range
PLT	81	10 <sup>3</sup> /μL	57 - 97
MPV	9.2	μm <sup>3</sup>	8.1 - 12.1



			Range		Range
WBC	3.25	10 <sup>3</sup> /μL	2.50 - 3.30		
	#		Range	%	Range
NEU	1.31		0.87 - 1.57	40.1	32.1 - 52.1
LYM	1.18		0.78 - 1.44	36.3	26.4 - 50.4
MON	0.30		0.00 - 0.52	9.3	0.1 - 17.9
EOS	0.31		0.01 - 0.35	9.6	0.7 - 11.9
BAS	0.15		0.00 - 0.24	4.7	0.2 - 8.2



Raw Data

PLT counts (by sections)

S1	S2	S3	S4	S5	S6	S1	S2	S3	S4	S5	S6
120	102	110	111	116	131	2188	2128	2150	2156	2222	2225
S7	S8	S9	S10	S11	S12	S7	S8	S9	S10	S11	S12
126	122	121	134	114	141	2250	2170	2218	2235	2171	2216

RBC counts (by sections)

WBC counts (by sections) and others

S1	S2	S3	S4	S5	S6	L11	L12	L13	L14	L15	L16
205	183	213	226	193	217	3859	3849	3842	1923	1922	1922
S7	S8	S9	S10	S11		L17	L18	L19	L110	L111	L112
209	206	223	224	194		1922	1922	1921	1921	1921	1922

HBG measures (Optical Intensity)

L113					
1922					

RMeasured : 2161  
Correlated : 2054  
Optical intensity 197

*Signature*  
5/8/22



**QC - Control Run Report**

Run Date 08/05/2022 01:11:58 PM

Operator technician

Name ABXdiffrol N

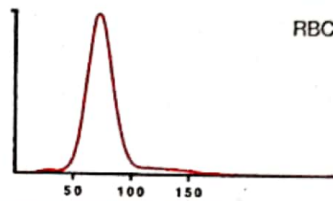
Sample ID PX436N

Level Normal

Exp. date 09/05/2022

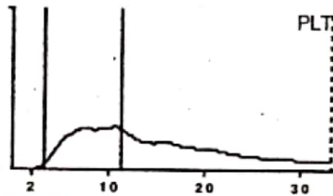
Lot number PX436N

			Range
RBC	4.83	10 <sup>6</sup> /μL	4.53 - 4.93
HGB	13.2	g/dL	12.8 - 13.8
HCT	41.9	%	38.9 - 42.9
MCV	86.8	μm <sup>3</sup>	80.0 - 90.0
MCH	27.3	pg	26.1 - 30.1
MCHC	31.5	g/dL	30.1 - 36.1
RDW-CV	15.2	%	10.5 - 18.5

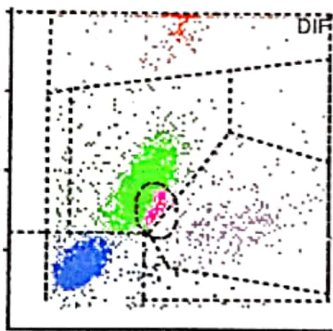


**Alarms**

			Range
PLT	277	10 <sup>3</sup> /μL	238 - 298
MPV	13.6	μm <sup>3</sup>	11.2 - 15.2



WBC	8.46	10 <sup>3</sup> /μL	7.45 - 9.45	
	#	Range	%	Range
NEU	3.86	3.09 - 4.89	45.6	37.2 - 57.2
LYM	3.58	2.93 - 4.33	42.3	34.9 - 50.9
MON	0.43	0.00 - 0.82	5.1	0.1 - 9.7
EOS	0.33	0.01 - 0.55	4.0	0.1 - 6.5
BAS	0.26	0.00 - 0.28	3.0	0.0 - 3.4



**Raw Data**

**PLT counts (by sections)**

S1	S2	S3	S4	S5	S6
231	240	224	231	255	266
S7	S8	S9	S10	S11	S12
243	262	248	275	255	278

**RBC counts (by sections)**

S1	S2	S3	S4	S5	S6
4077	4063	4184	4033	4060	4094
S7	S8	S9	S10	S11	S12
3994	4083	4014	4119	4075	4119

**WBC counts (by sections) and others**

S1	S2	S3	S4	S5	S6
538	514	528	505	522	577
S7	S8	S9	S10	S11	
560	555	522	584	536	

**HGB measures (Optical Intensity)**

L1	L2	L3	L4	L5	L6
3853	3854	3854	895	895	895
L7	L8	L9	L10	L11	L12
895	895	895	895	894	895
L13					
895					

RMeasured : 5396  
Correlated : 5168  
Optical intensity 197

*John*  
5/8/22