

HORIBA

Explore the future

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Ref. No.: HIN/MED/2023-24/10090001

Date: Jan 4, 2023

CALIBRATION CERTIFICATE

This is to certify that the Hematology analyzer Model: **Yumizen H550** bearing. **S. No. 210YADH04025** and installed at **Redcliffe Life tech Private Limited -VIJAYAWADA** was calibrated on **Jan/04/2023**.

The CV of repeatability check, Calibration and Control values were all found in range. Done the Calibration by using the *ABXMINOCAL* Calibrator Lot No. CX477 Exp. Date – Jan/05/2023.

Calibration done and the instrument is working satisfactorily. Next Calibration Due On: Jan 03, 2024



**For HORIBA MEDICAL,
HORIBA INDIA PVT. LIMITED.**

Log

Date/Time	Operator	Section	Level	Message/Details Comments
01/04/2023 12:27:18 PM	Service	Blank	INFO	Startup passed Pass WBC: 0.01 10 ³ /mm ³ RBC: 0.00 10 ⁶ /mm ³ HGB: 0.0 g/dL PLT: 0 10 ³ /mm ³

Repeatability Report (part 1)

Number of repeatability run report selected for statistic calculation 11/11

Coefficient	WBC (10 ³ /mm ³)	RBC (10 ⁶ /mm ³)	HGB (g/dL)	PLT (10 ³ /mm ³)	HCT (%)	MCV (fL)	RDW-CV (%)	RDW-SD (fL)	P-LCR (%)	MIC (%)
Minimum	7.32	4.91	15.4	368	42.4	86.0	11.6	37.4	20.1	0.2
Maximum	7.55	5.04	15.6	379	43.6	86.6	11.9	39.7	22.1	0.3
Mean	7.46	4.98	15.5	373	43.0	86.4	11.8	39.0	20.9	0.3
Difference	0.23	0.13	0.3	12	1.2	0.6	0.3	2.3	2.0	0.1
2 SD	0.14	0.08	0.1	8	0.8	0.4	0.2	1.5	1.0	0.1
CV(%)	0.96	0.81	0.44	1.02	0.94	0.23	0.80	1.96	2.42	11.26

Coefficient	MAC (%)	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	IMG% (%)	IMM% (%)
Minimum	4.7	49.6	36.1	7.4	2.8	0.0	0.1	0.0
Maximum	5.2	52.8	38.6	9.0	3.6	0.3	0.4	0.1
Mean	5.0	51.3	37.3	8.2	3.1	0.1	0.2	0.0
Difference	0.5	3.2	2.5	1.6	0.8	0.3	0.3	0.1
2 SD	0.4	1.8	1.4	0.8	0.4	0.2	0.2	0.1
CV(%)	3.58	1.77	1.94	5.10	7.34	86.72 H	39.11	171.27 H

Sel	Run Date &Time	WBC (10 ³ /mm ³)	RBC (10 ⁶ /mm ³)	HGB (g/dL)	PLT (10 ³ /mm ³)	HCT (%)	MCV (fL)	RDW-CV (%)	RDW-SD (fL)	P-LCR (%)	MIC (%)
✓	01/04/2023 01:31:53 PM	7.48	4.98	15.4	375	42.9	86.2	11.6	37.4	21.2	0.3
✓	01/04/2023 01:33:01 PM	7.53	5.00	15.5	373	43.3	86.5	11.8	39.7	22.1	0.3
✓	01/04/2023 01:34:09 PM	7.51	4.91 *	15.5 *	368 *	42.4 *	86.3 *	11.7 *	38.6 *	20.5	0.3 *
✓	01/04/2023 01:35:16 PM	7.36	5.00	15.6	368	43.4	86.6	11.7	38.6	20.9	0.3
✓	01/04/2023 01:36:25 PM	7.32	4.96	15.6	368	42.9	86.5	11.9	39.7	20.8	0.3
✓	01/04/2023 01:37:32 PM	7.47	4.95	15.4	375	42.6	86.0	11.7	38.6	20.9	0.3
✓	01/04/2023 01:38:39 PM	7.55	5.03	15.5	373	43.6	86.6	11.9	39.7	20.9	0.2
✓	01/04/2023 01:39:46 PM	7.45	4.93	15.5	376	42.7	86.5	11.8	38.6	21.0	0.3
✓	01/04/2023 01:40:54 PM	7.49	5.04	15.5	379	43.6	86.5	11.9	39.7	20.1	0.2
✓	01/04/2023 01:42:01 PM	7.46	4.98	15.5	371	43.1	86.6	11.7	38.6	20.4	0.2
✓	01/04/2023 01:43:08 PM	7.40	5.00	15.5	375	43.2	86.3	11.9	39.7	20.7	0.3

Repeatability Report (part 1)

Sel	Run Date & Time	MAC (%)	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	IMG% (%)	IMM% (%)	Operator
✓	01/04/2023 01:31:53 PM	4.8	50.4	37.5	9.0	3.0	0.1	0.3	0.0	Lab Manager
✓	01/04/2023 01:33:01 PM	5.2	50.4	38.1	8.6	2.9	0.0	0.4	0.0	Lab Manager
✓	01/04/2023 01:34:09 PM	5.0 *	51.1	37.2	8.5	3.2	0.0	0.3	0.1	Lab Manager
✓	01/04/2023 01:35:16 PM	5.1	51.7	37.3	8.0	2.8	0.2	0.2	0.1	Lab Manager
✓	01/04/2023 01:36:25 PM	5.0	51.7	37.3	8.1	2.8	0.1	0.2	0.0	Lab Manager
✓	01/04/2023 01:37:32 PM	4.7	51.2	37.6	8.0	3.2	0.0	0.1	0.0	Lab Manager
✓	01/04/2023 01:38:39 PM	5.0	49.6	38.6	8.5	3.1	0.2	0.3	0.0	Lab Manager
✓	01/04/2023 01:39:46 PM	5.1	52.0	36.4	8.3	3.0	0.3	0.2	0.0	Lab Manager
✓	01/04/2023 01:40:54 PM	5.1	51.3	37.4	7.4	3.6	0.3	0.3	0.1	Lab Manager
✓	01/04/2023 01:42:01 PM	5.2	52.8	36.1	8.0	3.0	0.1	0.2	0.0	Lab Manager
✓	01/04/2023 01:43:08 PM	4.8	52.1	36.6	8.1	3.1	0.1	0.1	0.0	Lab Manager

Repeatability Report (part 2)

Number of repeatability run report selected for statistic calculation 11/11

Coefficient	IML% (%)	LIC% (%)	ALY% (%)
Minimum	0.0	0.3	1.4
Maximum	0.0	0.6	1.9
Mean	0.0	0.5	1.7
Difference	0.0	0.3	0.5
2 SD	0.0	0.2	0.3
CV(%)	0.00	25.19	9.84

Sel	Run Date &Time	IML% (%)	LIC% (%)	ALY% (%)	Operator
✓	01/04/2023 01:31:53 PM	0.0	0.6	1.7	Lab Manager
✓	01/04/2023 01:33:01 PM	0.0	0.6	1.8	Lab Manager
✓	01/04/2023 01:34:09 PM	0.0	0.6	1.4	Lab Manager
✓	01/04/2023 01:35:16 PM	0.0	0.4	1.4	Lab Manager
✓	01/04/2023 01:36:25 PM	0.0	0.3	1.7	Lab Manager
✓	01/04/2023 01:37:32 PM	0.0	0.3	1.8	Lab Manager
✓	01/04/2023 01:38:39 PM	0.0	0.6	1.8	Lab Manager
✓	01/04/2023 01:39:46 PM	0.0	0.5	1.6	Lab Manager
✓	01/04/2023 01:40:54 PM	0.0	0.5	1.8	Lab Manager
✓	01/04/2023 01:42:01 PM	0.0	0.4	1.9	Lab Manager
✓	01/04/2023 01:43:08 PM	0.0	0.4	1.8	Lab Manager

Calibration Report

Sample ID CX477
Lot number CX477

Name MINOCAL

Exp. date 01/05/2023
Modified on

Coefficient	WBC	RBC	HGB	HCT	PLT
New	1.156	0.955	0.947	0.844	1.043
Current	1.156	0.955	0.947	0.844	1.043
Target	9.16	4.66	13.7	38.3	275
Mean	9.02	4.55	13.9	37.0	275
CV(%)	0.98	0.40	0.52	0.69	2.63

Number of calibration run selected for coefficient calculation (minimum 5) 11/11

Sel.	Run Time	WBC (10 ³ /mm ³)	RBC (10 ⁶ /mm ³)	HGB (g/dL)	HCT (%)	PLT (10 ³ /mm ³)
✓	01/04/2023 01:51:46 PM	8.81 <i>l</i>	4.52 <i>l</i>	13.8	37.4	260 <i>l</i>
✓	01/04/2023 01:52:57 PM	9.13	4.57 <i>l</i>	14.0 <i>h</i>	37.3	279
✓	01/04/2023 01:54:04 PM	9.10	4.53 <i>l</i>	13.9	36.8 <i>l</i>	278
✓	01/04/2023 01:55:12 PM	9.07	4.55 <i>l</i>	14.0 <i>h</i>	37.1 <i>l</i>	272
✓	01/04/2023 01:56:19 PM	9.02	4.53 <i>l</i>	14.0 <i>h</i>	36.8 <i>l</i>	283
✓	01/04/2023 01:57:25 PM	8.97	4.55 <i>l</i>	13.8	36.8 <i>l</i>	273
✓	01/04/2023 01:58:32 PM	9.05	4.53 <i>l</i>	13.9 <i>h</i>	36.8 <i>l</i>	275
✓	01/04/2023 01:59:40 PM	9.05	4.57 <i>l</i>	13.9 <i>h</i>	37.2 <i>l</i>	278
✓	01/04/2023 02:00:46 PM	8.98	4.57 <i>l</i>	13.8	37.1 <i>l</i>	280
✓	01/04/2023 02:01:53 PM	9.06	4.54 <i>l</i>	13.9	36.8 <i>l</i>	264 <i>l</i>
✓	01/04/2023 02:03:01 PM	8.94 <i>l</i>	4.53 <i>l</i>	13.8	36.6 <i>l</i>	282

QC - Control Run Report

Run Date 08/21/2023 09:13:33 AM

Operator REDCLIFFE

Name DIFFTROL H

Sample ID PX443H

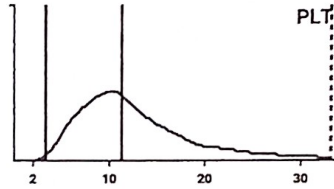
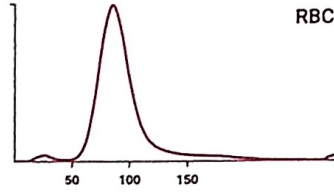
Level High

Exp. date 11/05/2023

Lot number PX443H

CBC

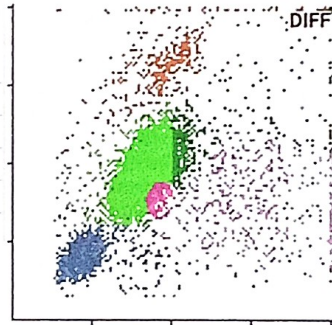
			Range
WBC	18.92	10 ³ /mm ³	16.10 - 20.50
RBC	5.43	10 ⁶ /mm ³	5.03 - 5.53
HGB	16.2	g/dL	15.6 - 16.8
HCT	47.8	%	44.7 - 49.7
MCV	88.0	fL	84.4 - 94.4
MCH	29.9	pg	28.2 - 33.2
MCHC	34.0	g/dL	31.3 - 37.3
RDW-CV	12.8	%	9.9 - 17.9
RDW-SD	43.1	fL	30.6 - 46.6
PLT	509	10 ³ /mm ³	478 - 578
MPV	10.5	fL	8.3 - 12.3



Alarms

DIF

	%	Range	10 ³ /mm ³	Range
NEU	68.5	56.8 - 76.8	12.95	10.32 - 14...
LYM	20.0	12.8 - 28.8	3.79	2.31 - 5.31
MON	4.3	0.4 - 8.2	0.81	0.08 - 1.50
EOS	3.9	0.1 - 8.1	0.74	0.02 - 1.48
BAS	3.3	0.0 - 8.0	0.63	0.00 - 1.46
IMG	4.6	0.0 - 10.0	0.88	0.00 - 1.84



performed by
T-sandhya

QC - Control Run Report

Run Date 08/21/2023 09:15:56 AM

Operator REDCLIFFE

Name DIFFTROL L

Sample ID PX443L

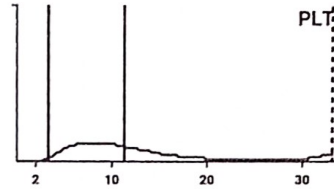
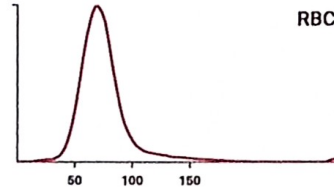
Level Low

Exp. date 11/05/2023

Lot number PX443L

CBC

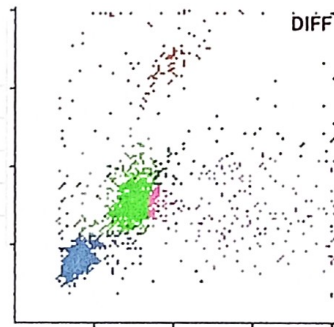
			Range
WBC	3.21	10 ³ /mm ³	2.60 - 3.40
RBC	2.35	10 ⁶ /mm ³	2.08 - 2.40
HGB	5.7	g/dL	5.3 - 6.1
HCT	16.9	%	14.8 - 17.8
MCV	71.9	fL	67.8 - 77.8
MCH	24.2	pg	23.4 - 27.4
MCHC	33.6	g/dL	32.0 - 38.0
RDW-CV	16.5	%	14.3 - 22.3
RDW-SD	45.3	fL	32.7 - 48.7
PLT	79	10 ³ /mm ³	62 - 102
MPV	10.9	fL	8.7 - 12.7



Alarms

DIF

	%	Range	10 ³ /mm ³	Range
NEU	43.0	34.0 - 54.0	1.38	0.97 - 1.67
LYM	38.7	28.3 - 52.3	1.24	0.88 - 1.54
MON	8.5	0.0 - 15.8	0.27	0.00 - 0.48
EOS	5.8	0.0 - 8.6	0.19	0.00 - 0.26
BAS	4.0	0.0 - 7.0	0.13	0.00 - 0.22
IMG	2.9	0.0 - 5.2	0.09	0.00 - 0.16



performed by
T-Sandhya