

HORIBA

Explore the future

HORIBA India Private Limited

246, Okhla Industrial Estate, Phase-III,

New Delhi 110020, India

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

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

http : //www.horiba.com

Ref. No.: HIN/MED/2022-23/114024

Date: December 29, 2022.

CALIBRATION CERTIFICATE

This is to certify that the Hematology analyzer Model Yumizen H 550 bearing S.No. 210YADH04024 and installed at Redcliffe Lifetech Pvt Ltd, Visakhapatnam. Was calibrated on 29.12.2022.

The CV of repeatability check, Calibration and Control values were all found in range. Done the Calibration by using the *ABX MINOCAL* Calibrator Lot No: CX477 Exp. Date – 2023/01/05.

Calibration done and the instrument are working satisfactorily. Next Calibration Due On: **December 28, 2023.**



For HORIBA MEDICAL,
HORIBA INDIA PVT. LIMITED.

Log

Date/Time	Operator	Section	Level	Message/Details Comments
12/29/2022 10:54:47 AM	REDCLIFF	Blank	INFO	Startup passed Pass WBC: 0.04 10 ³ /mm ³ RBC: 0.00 10 ⁶ /mm ³ HGB: 0.0 g/dL PLT: 0 10 ³ /mm ³
12/29/2022 11:40:26 AM	Lab Manager	Blank	INFO	Startup passed Pass WBC: 0.04 10 ³ /mm ³ RBC: 0.00 10 ⁶ /mm ³ HGB: 0.0 g/dL PLT: 0 10 ³ /mm ³

Calibration Report

Sample ID CX477
Lot number CX477

Name ABX MINOCAL

Exp. date 01/05/2023
Modified on

Coefficient	WBC	RBC	HGB	HCT	PLT
New	1.151	0.910	0.976	0.793 L	0.919
Current	1.180	0.859	0.962	0.866 L	0.942
Target	9.16	4.66	13.7	38.3	275
Mean	9.39	4.40	13.5	39.5	282
CV(%)	1.39	1.26	0.61	1.22	4.13

Number of calibration run selected for coefficient calculation (minimum 5) 6/7

Sel.	Run Time	WBC (10 ³ /mm ³)	RBC (10 ⁶ /mm ³)	HGB (g/dL)	HCT (%)	PLT (10 ³ /mm ³)
✓	12/29/2022 12:59:18 PM	9.32	4.41 <i>l</i>	13.5 <i>l</i>	39.6 <i>h</i>	266
✓	12/29/2022 01:01:17 PM	9.46 <i>h</i>	4.44 <i>l</i>	13.6	39.8 <i>h</i>	283
✓	12/29/2022 01:03:11 PM	9.20	4.38 <i>l</i>	13.4 <i>l</i>	39.4 <i>h</i>	276
✓	12/29/2022 01:05:05 PM	9.57 <i>h</i>	4.35 <i>l</i>	13.5 <i>l</i>	39.0	281
	12/29/2022 01:06:31 PM	9.52 <i>h</i>	4.42 <i>l</i>	13.5 <i>l</i>	39.4 <i>h</i>	304 <i>h</i>
✓	12/29/2022 01:08:15 PM	9.46 <i>h</i>	4.49 <i>l</i>	13.5 <i>l</i>	40.1 <i>h</i>	301 <i>h</i>
✓	12/29/2022 01:09:21 PM	9.34	4.34 <i>l</i>	13.4 <i>l</i>	38.8	283

Calibration Report

Sample ID CX477
Lot number CX477

Name ABX MIINOAL

Exp. date 01/05/2023
Modified on

Coefficient	WBC	RBC	HGB	HCT	PLT
New	1.129	0.922	0.976	0.793 L	0.929
Current	1.151	0.910	0.976	0.793 L	0.919
Target	9.16	4.66	13.7	38.3	275
Mean	9.34	4.60	13.7	37.8	272
CV(%)	----	----	----	----	----

Number of calibration run selected for coefficient calculation (minimum 5) 1/1

Sel.	Run Time	WBC (10 ³ /mm ³)	RBC (10 ⁹ /mm ³)	HGB (g/dL)	HCT (%)	PLT (10 ³ /mm ³)
✓	12/29/2022 01:30:20 PM	9.34	4.60	13.7	37.8	272

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	9.66	5.09	13.7	277	39.4	76.9	14.6	44.1	27.2	4.0
Maximum	10.18	5.22	14.1	293	40.7	78.0	14.9	45.3	29.8	5.2
Mean	9.93	5.14	14.0	283	39.9	77.7	14.7	44.6	28.5	4.5
Difference	0.51	0.13	0.3	16	1.3	1.0	0.3	1.2	2.6	1.2
2 SD	0.28	0.07	0.2	11	0.7	0.6	0.2	1.2	1.8	0.6
CV(%)	1.43	0.72	0.72	1.94	0.83	0.39	0.58	1.36	3.12	7.12

Coefficient	MAC (%)	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	IMG% (%)	IMM% (%)
Minimum	3.8	53.6	26.3	3.9	13.4	0.0	0.2	0.0
Maximum	4.1	55.2	27.7	4.2	14.9	0.1	0.3	0.1
Mean	3.9	54.7	27.0	4.0	14.3	0.0	0.3	0.0
Difference	0.3	1.6	1.4	0.3	1.5	0.1	0.1	0.1
2 SD	0.2	0.9	0.9	0.2	1.0	0.1	0.1	0.1
CV(%)	2.14	0.86	1.66	2.85	3.44	331.66 H	20.52	331.66 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 (%)
✓	12/29/2022 12:10:14 PM	9.87	5.12	14.0	278	39.4	76.9	14.8	44.1	27.2	5.2
✓	12/29/2022 12:11:13 PM	9.84	5.17	14.0	286	40.0	77.4	14.7	44.1	27.6	4.8
✓	12/29/2022 12:12:12 PM	10.08	5.14	13.8	277	39.8	77.5	14.7	44.1	28.9	4.6
✓	12/29/2022 12:13:11 PM	10.18	5.15	14.1	281	40.0	77.6	14.6	44.1	27.2	4.3
✓	12/29/2022 12:14:09 PM	10.04	5.11	14.0	278	39.8	77.8	14.7	45.3	28.7	4.3
✓	12/29/2022 12:15:10 PM	9.83	5.14	14.0	293	39.9	77.7	14.7	44.1	27.7	4.4
✓	12/29/2022 12:16:08 PM	9.94	5.09	13.9	283	39.6	77.8	14.8	45.3	29.8	4.3
✓	12/29/2022 12:17:07 PM	9.87	5.22	13.9	287	40.7	77.9	14.9	45.3	29.1	4.3
✓	12/29/2022 12:18:06 PM	9.92	5.14	14.1	280	40.0	77.8	14.7	45.3	29.4	4.3
✓	12/29/2022 12:19:05 PM	9.66	5.09	13.7	290	39.7	77.9	14.8	45.3	28.5	4.4
✓	12/29/2022 12:20:04 PM	10.04	5.15	14.0	278	40.1	78.0	14.6	44.1	29.0	4.0

Repeatability Report (part 1)

Sel	Run Date & Time	MAC (%)	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	IMG% (%)	IMM% (%)	Operator
✓	12/29/2022 12:10:14 PM	4.1	55.2	27.1	3.9	13.8	0.0	0.3	0.0	Lab Manager
✓	12/29/2022 12:11:13 PM	3.9	54.7	27.4	3.9	14.0	0.0	0.3	0.0	Lab Manager
✓	12/29/2022 12:12:12 PM	3.8	54.9	26.7	4.1	14.3	0.0	0.2	0.1	Lab Manager
✓	12/29/2022 12:13:11 PM	4.0	54.6	27.2	4.1	14.1	0.0	0.2	0.0	Lab Manager
✓	12/29/2022 12:14:09 PM	3.9	55.2	27.2	3.9	13.7	0.0	0.3	0.0	Lab Manager
✓	12/29/2022 12:15:10 PM	3.9	53.6	27.7	3.9	14.7	0.1	0.3	0.0	Lab Manager
✓	12/29/2022 12:16:08 PM	3.9	55.2	27.5	3.9	13.4	0.0	0.2	0.0	Lab Manager
✓	12/29/2022 12:17:07 PM	4.0	54.8	26.5	4.0	14.7	0.0	0.2	0.0	Lab Manager
✓	12/29/2022 12:18:06 PM	3.9	54.8	26.3	4.2	14.7	0.0	0.3	0.0	Lab Manager
✓	12/29/2022 12:19:05 PM	3.9	54.4	27.2	3.9	14.5	0.0	0.3	0.0	Lab Manager
✓	12/29/2022 12:20:04 PM	3.9	54.4	26.6	4.1	14.9	0.0	0.2	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	0.2	1.0
Maximum	0.0	0.5	1.5
Mean	0.0	0.4	1.3
Difference	0.0	0.3	0.5
2 SD	0.0	0.2	0.3
CV(%)	0.00	24.15	12.71

Sel	Run Date &Time	IML% (%)	LIC% (%)	ALY% (%)	Operator
✓	12/29/2022 12:10:14 PM	0.0	0.5	1.4	Lab Manager
✓	12/29/2022 12:11:13 PM	0.0	0.4	1.5	Lab Manager
✓	12/29/2022 12:12:12 PM	0.0	0.4	1.1	Lab Manager
✓	12/29/2022 12:13:11 PM	0.0	0.4	1.3	Lab Manager
✓	12/29/2022 12:14:09 PM	0.0	0.4	1.2	Lab Manager
✓	12/29/2022 12:15:10 PM	0.0	0.5	1.4	Lab Manager
✓	12/29/2022 12:16:08 PM	0.0	0.2	1.4	Lab Manager
✓	12/29/2022 12:17:07 PM	0.0	0.3	1.2	Lab Manager
✓	12/29/2022 12:18:06 PM	0.0	0.5	1.1	Lab Manager
✓	12/29/2022 12:19:05 PM	0.0	0.4	1.0	Lab Manager
✓	12/29/2022 12:20:04 PM	0.0	0.3	1.4	Lab Manager

QC - Control Run Report

Run Date 12/29/2022 01:44:29 PM

Operator Lab Manager

Name DIFFTROL L

Sample ID PX439L

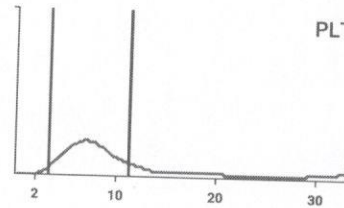
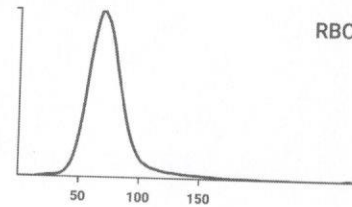
Level Low

Exp. date 03/05/2023

Lot number PX439L

CBC

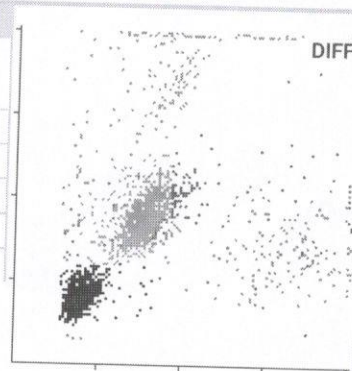
			Range
WBC	3.31	10 ³ /mm ³	2.63 - 3.43
RBC	2.36	10 ⁶ /mm ³	2.23 - 2.55
HGB	6.1	g/dL	5.7 - 6.5
HCT	17.3	%	15.8 - 18.8
MCV	73.1	fL	67.2 - 77.2
MCH	25.7	pg	23.5 - 27.5
MCHC	35.2	g/dL	32.4 - 38.4
RDW-CV	15.3	%	10.9 - 18.9
RDW-SD	41.8	fL	29.1 - 45.1
PLT	89	10 ³ /mm ³	67 - 107
MPV	9.8	fL	8.4 - 12.4



Alarms

DIF

	%	Range	10 ³ /mm ³	Range
NEU	45.3	34.8 - 54.8	1.50	1.01 - 1.71
LYM	37.6	26.1 - 50.1	1.24	0.82 - 1.48
MON	7.3	0.2 - 15.2	0.24	0.02 - 0.44
EOS	7.4	1.2 - 11.2	0.25	0.05 - 0.33
BAS	2.4	2.1 - 4.3	0.08	0.07 - 0.13
IMG	4.6	0.0 - 8.0	0.15	0.00 - 0.24



QC - Control Run Report

Run Date 12/29/2022 01:45:27 PM

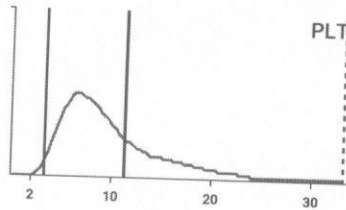
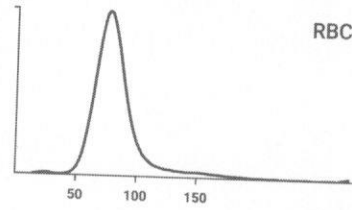
Operator Lab Manager

Name DIFFTROL N
Level Normal
Lot number PX439N

Sample ID PX439N
Exp. date 03/05/2023

CBC

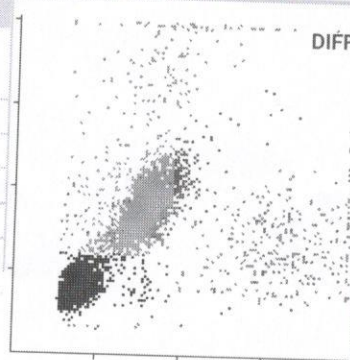
			Range
WBC	8.74	10 ³ /mm ³	7.55 - 9.55
RBC	4.65	10 ⁶ /mm ³	4.50 - 4.90
HGB	13.8	g/dL	13.0 - 14.0
HCT	37.4	%	36.2 - 40.2
MCV	80.5	fL	76.4 - 86.4
MCH	29.6	pg	26.7 - 30.7
MCHC	36.7	g/dL	32.3 - 38.3
RDW-CV	13.1	%	8.8 - 16.8
RDW-SD	39.5	fL	29.5 - 45.5
PLT	271	10 ³ /mm ³	233 - 293
MPV	8.9	fL	7.2 - 11.2



Alarms

DIF

	%	Range	10 ³ /mm ³	Range
NEU	47.9	35.5 - 55.5	4.19	2.99 - 4.79
LYM	41.8	35.1 - 51.1	3.65	2.99 - 4.39
MON	5.5	0.3 - 10.7	0.48	0.04 - 0.90
EOS	2.6	0.1 - 6.3	0.23	0.02 - 0.52
BAS	2.2	1.6 - 3.8	0.19	0.14 - 0.32
IMG	3.3	0.0 - 7.4	0.28	0.00 - 0.64



QC - Control Run Report

Run Date 12/29/2022 01:46:26 PM

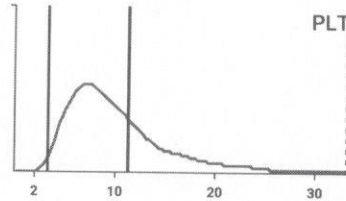
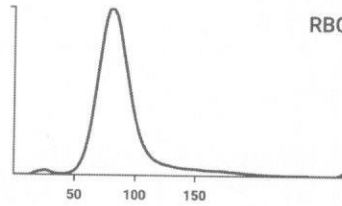
Operator Lab Manager

Name DIFFTROL H
Level High
Lot number PX439H

Sample ID PX439H
Exp. date 03/05/2023

CBC

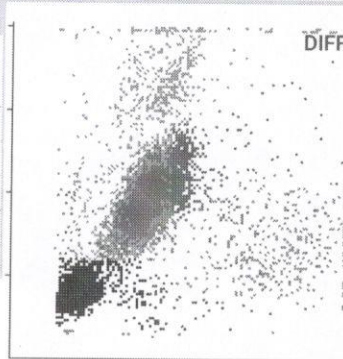
			Range
WBC	19.43	10 ³ /mm ³	16.50 - 20.90
RBC	5.15	10 ⁶ /mm ³	4.99 - 5.49
HGB	16.4	g/dL	15.5 - 16.7
HCT	43.9	%	42.9 - 47.9
MCV	85.3	fL	81.7 - 91.7
MCH	31.8	pg	28.2 - 33.2
MCHC	37.3	g/dL	32.4 - 38.4
RDW-CV	12.9	%	8.5 - 16.5
RDW-SD	41.8	fL	31.3 - 47.3
PLT	525	10 ³ /mm ³	467 - 567
MPV	9.0	fL	7.3 - 11.3



Alarms

DIF

	%	Range	10 ³ /mm ³	Range
NEU	69.1	58.5 - 78.5	13.42	10.91 - 14...
LYM	20.6	12.6 - 28.6	4.01	2.35 - 5.35
MON	3.7	0.5 - 7.7	0.71	0.11 - 1.43
EOS	4.1	0.1 - 7.1	0.80	0.03 - 1.31
BAS	2.5	1.9 - 4.5	0.49	0.36 - 0.84
IMG	6.1	0.1 - 10.9	1.18	0.09 - 1.97



QC - Control Run Report

Run Date 08/23/2023 09:06:27 AM

Operator EDC LIFFE

Name DIFFTROL L

Sample ID X-42L

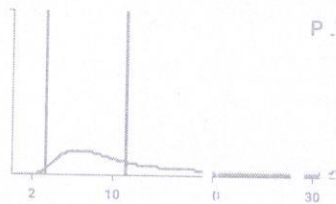
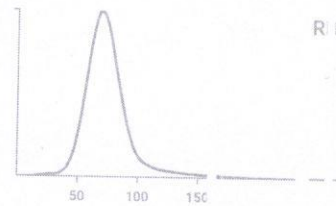
Level Low

Exp date 9/30/2023

Lot number PX442L

CBC

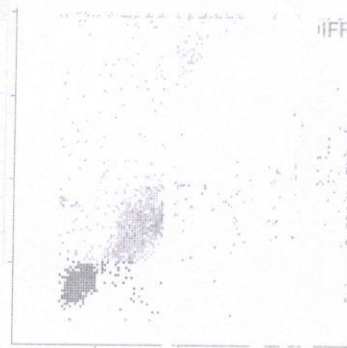
			Range
WBC	3.23	10 ³ /mm ³	2.55 - 3.35
RBC	2.42	10 ⁶ /mm ³	2.19 - 2.51
HGB	6.1	g/dL	5.6 - 6.4
HCT	17.8	%	15.7 - 18.7
MCV	73.5	fL	68.0 - 78.0
MCH	25.4	pg	23.5 - 27.5
MCHC	34.6	g/dL	32.0 - 38.0
RDW-CV	15.6	%	11.4 - 19.4
RDW-SD	36.7	fL	29.5 - 45.5
PLT	79	10 ³ /mm ³	62 - 102
MPV	10.4	fL	8.3 - 12.3



Alarms

DIF

	%	Range	10 ³ /mm ³	Range
NEU	45.9	34.5 - 54.5	1.48	0.96 - 1.66
LYM	35.0	26.0 - 50.0	1.13	0.79 - 1.45
MON	4.9	0.3 - 13.1	0.16	0.01 - 0.39
EOS	10.0	0.3 - 12.7	0.32	0.01 - 0.37
BAS	4.2	0.0 - 8.6	0.14	0.00 - 0.26
IMG	4.0	0.0 - 5.2	0.13	0.00 - 0.16



Doneley
T. J.
23/8/23

QC - Control Run Report

Run Date 08/23/2023 01:46:58 PM

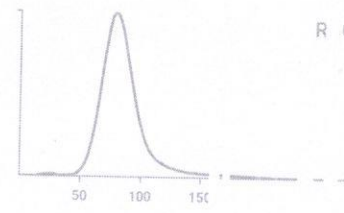
Operator E. CLIFFE

Name DIFFTROL N
Level Normal
Lot number PX442N

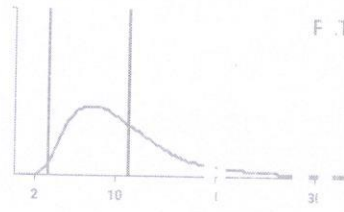
Sample ID X 42N
Exp date 9/01/2023

CBC

			Range
WBC	9.00	10 ³ /mm ³	7.30 - 9.30
RBC	4.74	10 ⁶ /mm ³	4.48 - 4.88
HGB	13.8	g/dL	13.0 - 14.0
HCT	39.4	%	36.9 - 40.9
MCV	83.0	fL	78.1 - 88.1
MCH	29.2	pg	26.8 - 30.8
MCHC	35.1	g/dL	31.7 - 37.7
RDW-CV	13.5	%	9.1 - 17.1
RDW-SD	36.7	fL	29.4 - 45.4
PLT	278	10 ³ /mm ³	243 - 303
MPV	9.3	fL	7.2 - 11.2



R C



F T

Alarms

DIF

	%	Range	10 ³ /mm ³	Range
NEU	50.5	37.4 - 57.4	4.56	3.03 - 4.83
LYM	37.8	32.5 - 48.5	3.40	2.66 - 4.06
MON	5.2	0.4 - 11.2	0.46	0.03 - 0.93
EOS	4.6	0.3 - 5.9	0.41	0.03 - 0.49
BAS	1.9	0.0 - 6.4	0.17	0.00 - 0.54
IMG	3.9	0.0 - 8.6	0.35	0.00 - 0.72



DIFF

Done by
T. S.
23/08/23

QC - Control Run Report

Run Date 08/23/2023 01:45:59 PM

Operator E. CLIFFE

Name DIFFTROL H

Sample ID X 42H

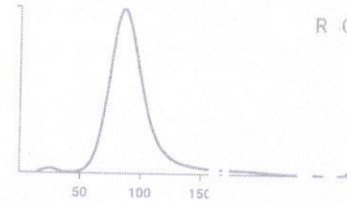
Level High

Exp date 9/30/2023

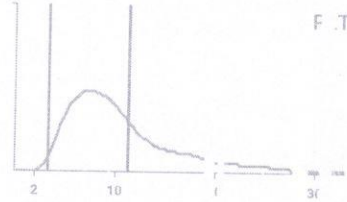
Lot number PX442H

CBC

			Range
WBC	18.93	10 ³ /mm ³	15.40 - 19.80
RBC	5.23	10 ⁶ /mm ³	5.08 - 5.58
HGB	16.9	g/dL	15.9 - 17.1
HCT	47.4	%	45.1 - 50.1
MCV	90.7	fL	84.3 - 94.3
MCH	32.3	pg	28.5 - 33.5
MCHC	35.6	g/dL	31.7 - 37.7
RDW-CV	13.3	%	8.6 - 16.6
RDW-SD	39.6	fL	30.2 - 46.2
PLT	487	10 ³ /mm ³	458 - 558
MPV	9.3	fL	7.2 - 11.2



R.C

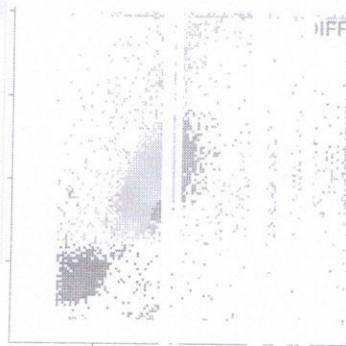


F.T

Alarms

DIF

	%	Range	10 ³ /mm ³	Range
NEU	71.1	59.9 - 79.9	13.48	10.4 - 14.2
LYM	17.7	10.3 - 26.3	3.35	1.72 - 4.72
MON	2.8	0.6 - 6.6	0.52	0.10 - 1.16
EOS	5.0	0.1 - 9.1	0.94	0.02 - 1.60
BAS	3.4	0.0 - 7.2	0.64	0.00 - 1.26
IMG	6.9	0.0 - 12.8	1.31	0.00 - 2.22



(Handwritten mark)

Done by
T. [Signature]
28/08/23