HORIBA

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HIN/MED/2023-2024/100737
10th Feb 2023

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **ABX YUMIZEN H550** baring serial number: **110YAXH03533** installed at **P.H. Medical Centre, Santacruz** calibrated on **10th Feb 2023**

Calibrator : ABX MINOCAL
Lot No. : CX480
Expiry Date : 05th April 2023

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

Next calibration cycle is due on **09th Feb 2024.**

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

Blank Cycle Logs

Running Date Comments	Operator	WBC $10^3/\mu L$	RBC $10^6/\mu L$	HGB g/dL	PLT $10^3/\mu L$	Status	Technical alarms
02/10/2023 10:40:14 AM	DIPALI	0.00	0.00	0.0	4	Passed	
02/10/2023 07:29:19 PM	technician	1.56 H	0.01	0.0	12 H	Failed	
02/10/2023 07:38:29 PM	technician	0.02	0.00	0.0	8 H	Failed	
02/10/2023 07:42:59 PM	technician	0.01	0.00	0.0	4	Passed	
02/10/2023 07:47:37 PM	technician	0.00	0.00	0.0	5	Passed	

Manufactured By:
HORIBA India Private Limited
(A subsidiary of **HORIBA** Limited Japan)
Plot No.26 Sector-7, I.I.E, SIDCUL,
Haridwar-249403, Uttarakhand, India
Toll Free No.: 1800 103 4470

ABX Minocal

CE
IVD

LOT CX 480
Rev 1

CAL

(Exp.) 2023-04-05
(YYYY - MM - DD)

PARAMETRES *PARAMETERS*	UNITES *UNITS*	WHITEDIFF YUMIZEN V1.0 to V2.x H550	WHITEDIFF YUMIZEN V1.0 to V2.x H500 OT H500 CT	WHITEDIFF YUMIZEN V2.x V3 H50 OT	WHITEDIFF YUMIZEN V2.x V3 H500 CT H550	TOLERANCES *TOLERANCE*
GB WBC	$10^3/mm^3$ ou $10^9/l$	8.70	8.70	8.60	8.60	± 0.20
GR RBC	$10^6/mm^3$ ou $10^{12}/l$	4.57	4.57	4.53	4.53	± 0.06
	g/dl	13.2	13.2	13.0	13.0	± 0.2
HB HGB	g/l	132	132	130	130	± 2
	mmol/l	8.20	8.20	8.07	8.07	± 0.12
HT HCT	%	38.2	38.2	37.5	36.2	± 1.0
	l/l	0.382	0.382	0.375	0.382	± 0.010
PLA PLT	$10^3/mm^3$ ou $10^9/l$	250	250	244	274	± 10
VMP MPV	μm^3 ou fl	10.8	10.8	9.2	9.2	± 0.5

Ref. °EMP-0387 Rev.48 BACK / VERSO 130/100x208

Blood Control Vial should be dispose off as per State Government Bio-Medical Waste Management Rule.

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Repeatability Report (part 1)

Number of repeatability run report selected for statistic calculation 10/11

Coefficient	WBC ($10^3/\mu L$)	RBC ($10^6/\mu L$)	HGB (g/dL)	HCT (%)	PLT ($10^3/\mu L$)	MCV (μm^3)	RDW-CV (%)	RDW-SD (μm^3)	P-LCR (%)
Minimum	6.24	4.67	14.2	40.9	289	87.5	12.3	44.3	36.2
Maximum	6.70	4.79	14.4	42.0	317	88.1	13.2	46.6	39.8
Mean	6.41	4.72	14.3	41.5	301	87.7	12.7	45.3	37.9
Difference	0.47	0.12	0.2	1.1	28	0.6	0.9	2.3	3.6
2 SD	0.28	0.07	0.1	0.7	20	0 4	0.5	1.4	2 0
CV(%)	2.20	0.79	0.38	0.82	3.34	0.22	2.02	1.55	2.61

Sel	Run Date &Time	WBC ($10^3/\mu L$)		RBC ($10^6/\mu L$)	HGB (g/dL)	HCT (%)	PLT ($10^3/\mu L$)	MCV (μm^3)	RDW-CV (%)	RDW-SD (μm^3)	P-LCR (%)	Operator
	02/10/2023 07:49:12 PM	6.43		4.82	14.3	42.4	305	87.9	12.8	45.9	39.0	ABX
✔	02/10/2023 07:50:43 PM	6.49		4.79	14.4	42.0	307	87.7	12.6	45.1	38.3	ABX
✔	02/10/2023 07:52:19 PM	6.29		4.70	14.3	41.4	291	88.1	13.2	46.6	38.7	ABX
✔	02/10/2023 07:53:51 PM	6 57		4.75	14 4	41.6	317	87 6	12.9	45.9	39 8	ABX
✔	02/10/2023 07:55:26 PM	6.39		4.72	14.3	41.5	292	87.9	12.8	45.9	36.2	ABX
✔	02/10/2023 07:57:01 PM	6.70	*	4.75	14.3	41.8	289	87.9	12.7	45.1	38.0	ABX
✔	02/10/2023 07:58:34 PM	6.33		4.67	14.3	40.9	310	87.6	12.4	44.3	37.9	ABX
✔	02/10/2023 08:00:06 PM	6.24		4.73	14.3	41.5	299	87.7	12.6	45.1	38.2	ABX
✔	02/10/2023 08:01:42 PM	6.45		4.74	14.2	41.4	310	87.5	12.3	44.3	37.9	ABX
✔	02/10/2023 08:03:14 PM	6.34		4.67	14.3	41.0	301	87.6	12.7	45.1	37.5	ABX
✔	02/10/2023 08:04:44 PM	6.35		4.72	14.3	41.4	290	87.7	12.7	45.1	36.8	ABX

Repeatability Report (part 2)

Number of repeatability run report selected for statistic calculation 10/11

Coefficient	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	LIC% (%)
Minimum	60 6	23.1	4.2	7.4	0 5	0.5
Maximum	62.9	26.4	5.1	8.5	1.1	0.9
Mean	61.7	25.0	4.6	7.9	0.8	0.7
Difference	2.3	3.3	0.9	1.1	0.6	0.4
2 SD	1.9	2.0	0.5	0.9	0.3	0.3
CV(%)	1.50	3.93	5.08	5.46	21.67	19.43

Sel	Run Date &Time	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	LIC% (%)	Operator
	02/10/2023 07:49:12 PM	61.6	25.5	4.6	7.3	1.0	0.9	ABX
✔	02/10/2023 07:50:43 PM	62.2	24.2	4.2	8.3	1.1	0.7	ABX
✔	02/10/2023 07:52:19 PM	60.6	26.4	4.7	7.4	0.9	0.6	ABX
✔	02/10/2023 07:53:51 PM	62.5	24.8	4.6	7.4	0.7	0.5	ABX
✔	02/10/2023 07:55:26 PM	62.7	24.5	4.4	7.7	0.7	0.9	ABX
✔	02/10/2023 07:57:01 PM	62.5	24.6	4.7	7.5	0.7	0.6	ABX
✔	02/10/2023 07:58:34 PM	61.1	26.0	4.6	7.7	0.6	0.7	ABX
✔	02/10/2023 08:00:06 PM	62.9	23.1	4.7	8.5	0.8	0.8	ABX
✔	02/10/2023 08:01:42 PM	61.1	25.2	5.1	7.8	0.8	0.7	ABX
✔	02/10/2023 08:03:14 PM	60.6	25.6	4.5	8.5	0.8	0.9	ABX
✔	02/10/2023 08:04:44 PM	60.9	25.8	4.7	8.1	0 5	0.9	ABX

Calibration Report

Sample ID CX480 | Exp. date 04/05/2023
Lot number CX480 | Name ABX MINOCAL | Modified on

Coefficient	WBC	RBC	HGB	HCT	PLT	MPV
New	1.118	0.936	0.988	1.023	1.012	1.075
Current	1.150	0.930	0.988	1.027	0.988	1.065
Target	8.70	4.57	13.2	38.2	250	10.8
Mean	8.95	4.54	13.2	38.1	244	10.7
CV(%)	1.37	0.52	0.28	0.42	3.56	1.62

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

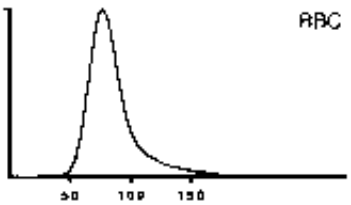
Sel.	Run Time	WBC ($10^3/\mu L$)	RBC ($10^6/\mu L$)	HGB (g/dL)	HCT (%)	PLT ($10^3/\mu L$)	MPV (μm^3)
✔	02/10/2023 08:08:31 PM	8.81	4.57	13.2	38.1	254	10.8
	02/10/2023 08:10:02 PM	**9.06** h	4.51	13.3	37.8	244	11.0
✔	02/10/2023 08:11:34 PM	**9.14** h	4.55	13.2	38.0	252	10.7
✔	02/10/2023 08:13:06 PM	**8.94** h	**4.51** l	13.2	38.0	242	10.7
✔	02/10/2023 08:14:37 PM	**8.97** h	4.52	13.2	38.0	**235** l	10.7
✔	02/10/2023 08:16:11 PM	8.90	4.54	13.1	38.4	**237** l	10.4

QC - Control Run Report

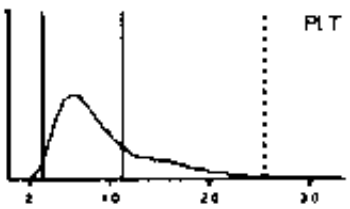
Run Date 02/10/2023 08:19:44 PM **Operator** ABX

Name NORMAL CONTROL **Sample ID** PX439N
Level Normal **Exp. date** 03/31/2023
Lot number PX439N

			Range	Alarms
RBC	4.66	$10^6/\mu L$	4.42 - 4.82	
HGB	13.3	g/dL	12.9 - 13.9	
HCT	40.4	%	38.2 - 42.2	
MCV	86.7	μm^3	82.0 - 92.0	
MCH	28.6	pg	27.0 - 31.0	
MCHC	33.0	g/dL	30.3 - 36.3	
RDW-CV	12.5	%	10.0 - 18.0	

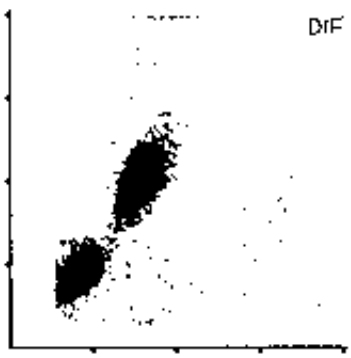


			Range
PLT	264	$10^3/\mu L$	226 - 286
MPV	9.4	μm^3	7.1 - 11.1



			Range
WBC	8.54	$10^3/\mu L$	7.20 - 9.20

	#	Range	%	Range
NEU	4.07	2.98 - 4.78	47.8	37.3 - 57.3
LYM	3.70	2.85 - 4.25	43.3	35.3 - 51.3
MON	0.38	0.00 - 0.86	4.5	0.0 - 10.4
EOS	0.34	0.00 - 0.50	3.9	0.0 - 6.2
BAS	0.05	0.00 - 0.18	0.5	0.0 - 2.2



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

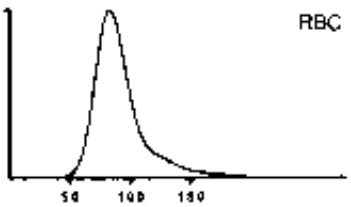
Reviewed on _____ by _____ Signature :

QC - Control Run Report

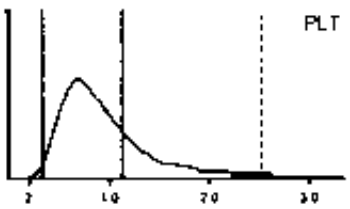
Run Date 02/10/2023 08:22:59 PM **Operator** ABX

Name HIGH CONTROL **Sample ID** PX439H
Level High **Exp. date** 03/31/2023
Lot number PX439H

			Range	Alarms
RBC	5.22	10^6/µL	4.99 - 5.49	
HGB	15.9	g/dL	15.4 - 16.6	
HCT	48.3	%	46.0 - 51.0	
MCV	92.6	µm³	87.5 - 97.5	
MCH	30.4	pg	28.0 - 33.0	
MCHC	32.9	g/dL	30.0 - 36.0	
RDW-CV	13.0	%	10.5 - 18.5	

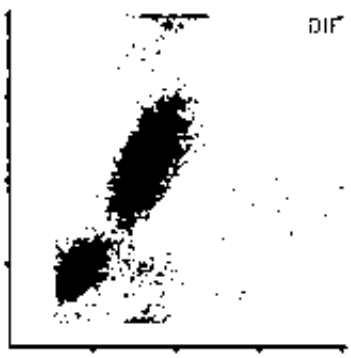


			Range
PLT	525	10^3/µL	448 - 548
MPV	9.4	µm³	7.5 - 11.5



			Range
WBC	18.39	10^3/µL	16.10 - 20.50

	#	Range	%	Range
NEU	13.21	11.07 -	71.8	60.9 - 80.9
LYM	3.79	2.29 - 5.29	20.6	12.7 - 28.7
MON	0.60	0.00 - 1.32	3.3	0.0 - 7.2
EOS	0.70	0.00 - 1.28	3.8	0.0 - 7.0
BAS	0.09	0.00 - 0.48	0.5	0.0 - 2.6



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 :

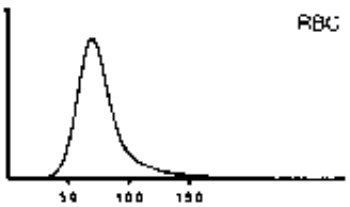
QC - Control Run Report

Run Date 02/10/2023 08:24:48 PM
Operator ABX

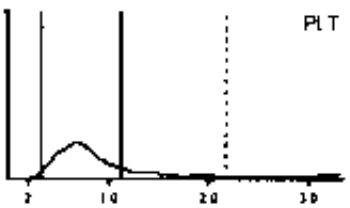
Name LOW CONTROL
Level Low
Lot number PX439L
Sample ID PX439L
Exp. date 03/31/2023

			Range
RBC	2.36	$10^6/\mu L$	2.22 - 2.54
HGB	5.9	g/dL	5.6 - 6.4
HCT	18.6	%	16.8 - 19.8
MCV	79.0	μm^3	72.0 - 82.0
MCH	25.1	pg	23.2 - 27.2
MCHC	31.8	g/dL	29.7 - 35.7
RDW-CV	14.9	%	10.0 - 18.0

Alarms
Control failed
EOS# above tolerance

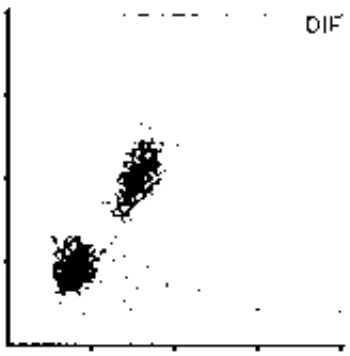


			Range
PLT	77	$10^3/\mu L$	51 - 91
MPV	8.9	μm^3	6.9 - 10.9



			Range
WBC	3.14	$10^3/\mu L$	2.40 - 3.20

	#	Range	%	Range
NEU	1.51	0.97 - 1.67	47.9	37.0 - 57.0
LYM	1.14	0.77 - 1.43	36.2	27.4 - 51.4
MON	0.19	0.00 0.42	6.2	0.0 - 15.0
EOS	0.29	0.00 - 0.28	9.3	0.0 - 10.0
BAS	0.01	0.00 - 0.06	0.4	0.0 - 2.2



Slide Review

Neutrophil	Myeloblast	Anisocytosis
Lymphocyte	Promyelocyte	Hypochromia
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Basophil	Blast	Microcytosis
Atypical Lymphocyte	Target Cell	Macrocytosis
Other	Sickle Cell	Platelet Clumps

Reviewed on _____ by _____ Signature :