

**HORIBA**

Private Limited

**HORIBA India Private Limited**

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CIN : U73100DL2006PTC153232

HIN/MED/2023-2024 /1055028  
16<sup>TH</sup> DEC 2023

## **CALIBRATION CERTIFICATE**

This is to certify that the Hematology Analyzer Horiba PENTRA XL80 bearing serial number 304YADH05693 installed at REDCLIFFE LIFETECH LAB JAMMU as calibrated on 16<sup>TH</sup> DEC 2023.

Calibrator : ABX MINOCAL  
Lot No. : CX489  
Expiry Date : 05<sup>TH</sup> JAN 2024

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

Next calibration cycle is due on 15<sup>TH</sup> DEC 2024



Shrish Dixit

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

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CIN : U73100DL2006PTC1M232

## Repeatability Report (part 1)

Number of repeatability run report selected for statistic calculation 6/7

Coefficient	WBC (10 <sup>9</sup> /mm <sup>3</sup> )	RBC (10 <sup>9</sup> /mm <sup>3</sup> )	HGB (g/dL)	PLT (10 <sup>3</sup> /mm <sup>3</sup> )	HCT (%)	MCV (fL)	RDW-CV (%)	RDW-SD (fL)	P-LCR (%)	MIC (%)
Minimum	7.18	4.60	13.4	326	42.3	92.0	13.4	53.1	36.3	1.5
Maximum	7.50	4.67	13.6	330	44.4	95.3	14.4	59.8	41.3	1.9
Mean	7.27	4.63	13.5	328	43.6	94.3	14.0	57.4	39.2	1.7
Difference	0.32	0.07	0.2	5	2.1	3.3	1.0	6.6	5.0	0.4
2 SD	0.25	0.05	0.1	3	1.6	2.5	0.7	4.7	3.7	0.3
CV(%)	1.71	0.59	0.46	0.48	1.78	1.33	2.37	4.12 H	4.66	8.75

Coefficient	MAC (%)	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	IMG% (%)	IMM% (%)
Minimum	6.1	63.3	31.1	3.0	1.0	0.0	0.3	0.0
Maximum	7.3	64.4	32.1	3.5	1.4	0.3	0.4	0.1
Mean	6.8	63.8	31.5	3.3	1.3	0.1	0.4	0.1
Difference	1.2	1.1	1.0	0.5	0.4	0.3	0.1	0.1
2 SD	1.0	1.0	0.8	0.4	0.3	0.3	0.1	0.1
CV(%)	7.46	0.76	1.31	5.36	11.89	112.92 H	10.65	77.46

Run Date & Time	WBC (10 <sup>9</sup> /mm <sup>3</sup> )	RBC (10 <sup>9</sup> /mm <sup>3</sup> )	HGB (g/dL)	PLT (10 <sup>3</sup> /mm <sup>3</sup> )	HCT (%)	MCV (fL)	RDW-CV (%)	RDW-SD (fL)	P-LCR (%)	MIC (%)
16/12/2023 04:15:43 PM	7.21	4.60	13.4	329	42.3	92.0	13.4	53.1	38.4	1.9
16/12/2023 04:16:44 PM	7.21	4.61	13.5	328	43.2	93.7	13.9	56.4	41.3	1.7
16/12/2023 04:17:44 PM	7.18	4.60	13.4	327	43.6	94.7	14.0	57.5	40.9	1.7
16/12/2023 04:18:45 PM	7.34	4.63	13.5	327	43.9	94.8	14.4	59.8	39.5	1.7
16/12/2023 04:19:46 PM	7.20	4.67	13.5	330	44.4	95.2	14.0	58.7	39.0	1.5
16/12/2023 04:20:46 PM	7.50	4.65	13.6	326	44.3	95.3	14.1	58.7	36.3	1.6
16/12/2023 04:21:47 PM	7.25	4.75	13.4	337	45.3	95.3	14.3	59.8	35.9	1.5

Run Date & Time	MAC (%)	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	IMG% (%)	IMM% (%)	Operator
16/12/2023 04:15:43 PM	6.1	64.4	31.1	3.3	1.2	0.0	0.4	0.1	Service Technician
16/12/2023 04:16:44 PM	6.4	63.4	31.4	3.5	1.4	0.3	0.4	0.1	Service Technician
16/12/2023 04:17:44 PM	6.8	63.4	31.9	3.4	1.0	0.3	0.4	0.1	Service Technician

## Repeatability Report (part 1)

Sel	Run Date & Time	MAC (%)	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	IMG% (%)	IMM% (%)	Operator
✓	16/12/2023 04:18:45 PM	7.2	64.2	31.1	3.2	1.3	0.2	0.4	0.1	Service Technician
✓	16/12/2023 04:19:46 PM	7.2	63.3	32.1	3.2	1.4	0.0	0.3	0.0	Service Technician
✓	16/12/2023 04:20:46 PM	7.3	64.1	31.6	3.0	1.3	0.0	0.4	0.0	Service Technician
	16/12/2023 04:21:47 PM	7.1	64.9	30.3	3.4	1.3	0.1	0.2	0.0	Service Technician

## Repeatability Report (part 2)

Number of repeatability run report selected for statistic calculation 6/7

Coefficient	IML% (%)	LIC% (%)	ALY% (%)
Minimum	0.0	0.4	0.6
Maximum	0.0	0.7	1.2
Mean	0.0	0.6	0.8
Difference	0.0	0.3	0.6
2 SD	0.0	0.3	0.4
CV(%)	0.00	21.08	27.39

Sel	Run Date &Time	IML% (%)	LIC% (%)	ALY% (%)	Operator
✓	16/12/2023 04:15:43 PM	0.0	0.7	0.8	Service Technician
✓	16/12/2023 04:16:44 PM	0.0	0.6	1.2	Service Technician
✓	16/12/2023 04:17:44 PM	0.0	0.7	0.8	Service Technician
✓	16/12/2023 04:18:45 PM	0.0	0.7	0.8	Service Technician
✓	16/12/2023 04:19:46 PM	0.0	0.4	0.6	Service Technician
✓	16/12/2023 04:20:46 PM	0.0	0.5	0.6	Service Technician
	16/12/2023 04:21:47 PM	0.0	0.4	0.6	Service Technician

## Calibration Report

Sample ID CX489  
Lot number CX489

Name MINOCAL

Exp. date 05/01/2024  
Modified on

Coefficient	WBC	RBC	HGB	HCT	PLT
New	1.114	1.046	0.930	0.940	1.129
Current	1.114	1.046	0.930	0.840	1.129
Target	8.80	4.45	13.1	37.8	259
Mean	8.79	4.49	13.2	37.8	264
CV(%)	1.11	0.84	0.41	0.86	1.97

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

Seq.	Run Time	WBC (10 <sup>3</sup> /mm <sup>3</sup> )	RBC (10 <sup>6</sup> /mm <sup>3</sup> )	HGB (g/dL)	HCT (%)	PLT (10 <sup>3</sup> /mm <sup>3</sup> )
✓	16/12/2023 04:44:17 PM	8.79	4.55 h	13.2	38.4	268
✓	16/12/2023 04:45:29 PM	8.89	4.45	13.2	37.6	267
✓	16/12/2023 04:47:02 PM	8.85	4.50	13.2	37.9	260
✓	16/12/2023 04:48:13 PM	8.62	4.46	13.1	37.5	265
✓	16/12/2023 04:49:34 PM	8.76	4.51	13.2	38.0	268
✓	16/12/2023 04:50:50 PM	8.84	4.47	13.2	37.6	255

QC - Control Run Report

Run Date 16/12/2023 05:37:50 PM

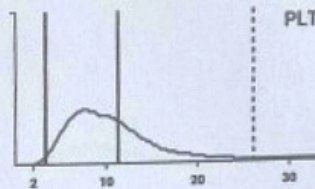
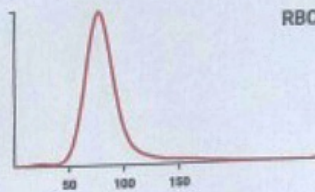
Operat. Service Technician

Name DIFFTROL N  
Level Normal  
Lot number PX445N

Sample ID PX445N  
Exp. date 05/03/2024

CBC

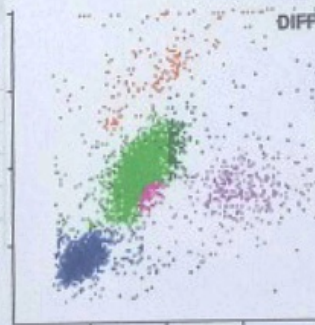
			Range
WBC	8.47	10 <sup>3</sup> /mm <sup>3</sup>	7.47 - 9.47
RBC	4.55	10 <sup>6</sup> /mm <sup>3</sup>	4.42 - 4.82
HGB	13.1	g/dL	12.9 - 13.9
HCT	39.8	%	37.6 - 42.6
MCV	87.6	fL	81.3 - 91.3
MCH	28.9	pg	26.1 - 30.1
MCHC	32.9	g/dL	30.4 - 40.4
W-CV	11.7	%	8.1 - 24.1
RDW-SD	41.0	fL	32.0 - 48.0
PLT	239	10 <sup>3</sup> /mm <sup>3</sup>	217 - 277
MPV	10.6	fL	8.8 - 12.8



Alarms  
Expired reagent

DIF

	%	Range	10 <sup>3</sup> /mm <sup>3</sup>	Range
NEU	47.0	36.2 - 56.2	3.98	3.00 - 4.80
LYM	42.2	34.3 - 50.3	3.58	2.90 - 4.30
MON	5.3	0.6 - 10.6	0.45	0.08 - 0.92
EOS	3.3	0.0 - 6.4	0.28	0.00 - 0.52
BAS	2.2	0.0 - 5.6	0.18	0.02 - 0.44
IMG	3.3	0.0 - 8.0	0.28	0.00 - 0.68



QC - Control Run Report

Run Date 16/12/2023 05:44:46 PM

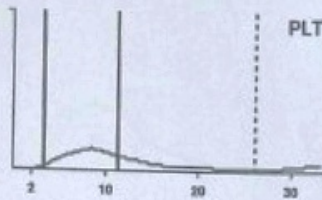
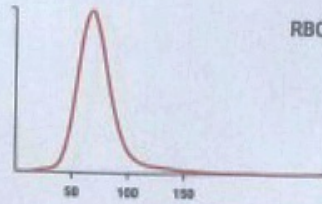
Operat. Service Technician

Name DIFFTROL L  
 Level Low  
 Lot number PX445L

Sample ID PX445L  
 Exp. date 05/03/2024

CBC

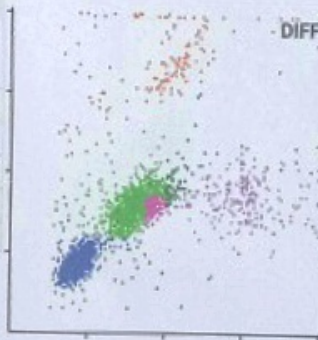
			Range
WBC	3.20	10 <sup>3</sup> /mm <sup>3</sup>	2.63 - 3.43
RBC	2.32	10 <sup>6</sup> /mm <sup>3</sup>	2.16 - 2.48
HGB	5.8	g/dL	5.5 - 6.3
HCT	18.3	%	15.9 - 20.9
MCV	78.7	fL	74.8 - 84.8
MCH	25.0	pg	24.1 - 28.1
MCHC	31.7	g/dL	28.1 - 38.1
W-CV	14.1	%	8.8 - 24.8
RDW-SD	44.3	fL	32.7 - 48.7
PLT	76	10 <sup>3</sup> /mm <sup>3</sup>	59 - 99
MPV	11.0	fL	9.1 - 13.1



Alarms  
 Expired reagent

DIF

	%	Range	10 <sup>3</sup> /mm <sup>3</sup>	Range
NEU	39.7	27.8 - 47.8	1.28	0.79 - 1.49
LYM	38.2	25.3 - 49.3	1.22	0.86 - 1.52
MON	9.2	3.3 - 16.1	0.29	0.14 - 0.46
EOS	6.2	0.0 - 10.6	0.20	0.00 - 0.32
BAS	6.7	4.1 - 11.9	0.21	0.12 - 0.36
IMG	3.6	1.0 - 5.0	0.12	0.00 - 0.18



QC - Control Run Report

Run Date 16/12/2023 05:54:20 PM

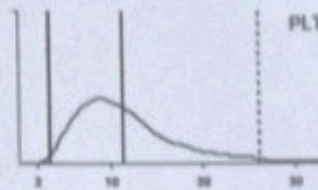
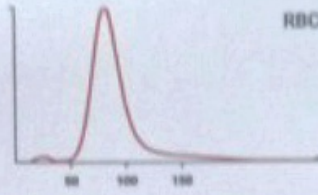
Operat. Service Technician

Name DIFFTROL H  
 Level High  
 Lot number PX445H

Sample ID PX445H  
 Exp. date 05/03/2024

CBC

			Range
WBC	18.58	10 <sup>3</sup> /mm <sup>3</sup>	15.95 - 20.35
RBC	4.88	10 <sup>6</sup> /mm <sup>3</sup>	4.87 - 5.57
HGB	15.3	g/dL	14.8 - 16.0
HCT	46.0	%	45.1 - 51.1
MCV	94.4	fL	87.0 - 97.0
MCH	31.3	pg	26.1 - 34.1
MCHC	33.1	g/dL	27.2 - 37.2
V-CV	10.9	%	6.6 - 22.6
RDW-SD	41.0	fL	30.6 - 46.6
PLT	478	10 <sup>3</sup> /mm <sup>3</sup>	433 - 533
MPV	11.3	fL	9.3 - 13.3

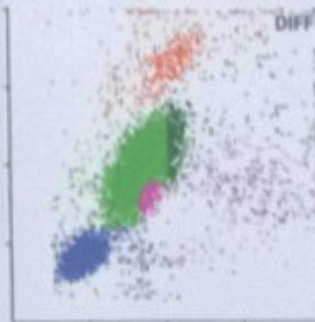


Alarms

Expired reagent

DIF

	%	Range	10 <sup>3</sup> /mm <sup>3</sup>	Range
NEU	67.9	57.0 - 77.0	12.62	10.25 - 14...
LYM	21.6	13.7 - 29.7	4.01	2.44 - 5.44
MON	3.2	1.4 - 6.0	0.60	0.00 - 1.34
EOS	4.4	0.0 - 7.6	0.81	0.00 - 1.38
BAS	2.9	0.0 - 7.6	0.54	0.00 - 1.36
IMG	4.6	0.0 - 12.2	0.86	0.00 - 2.26





QC - Control Run Report

Run Date 14/03/2024 04:12:06 PM

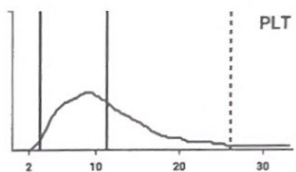
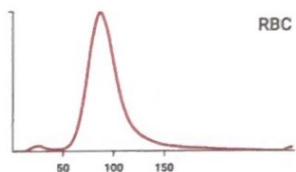
Operat. REDCLIFFELAB

Name DIFFTROL H  
 Level High  
 Lot number PX446H

Sample ID PX446H  
 Exp. date 05/05/2024

CBC

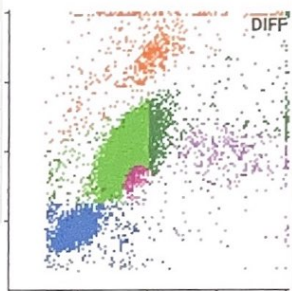
			Range
WBC	19.41	10 <sup>9</sup> /mm <sup>3</sup>	16.20 - 20.60
RBC	5.06	10 <sup>6</sup> /mm <sup>3</sup>	4.67 - 5.17
HGB	15.9	g/dL	14.9 - 16.1
HCT	45.3	%	41.0 - 46.0
MCV	89.4	fL	83.4 - 93.4
MCH	31.5	pg	29.0 - 34.0
MCHC	35.2	g/dL	32.6 - 38.6
RDW-CV	11.7	%	9.9 - 17.9
RDW-SD	41.8	fL	30.1 - 46.1
PLT	503	10 <sup>3</sup> /mm <sup>3</sup>	448 - 548
MPV	10.6	fL	7.3 - 11.3



Alarms  
 Startup failed

DIF

	%	Range	10 <sup>3</sup> /mm <sup>3</sup>	Range
NEU	67.5	56.5 - 76.5	13.09	10.34 - 14...
LYM	21.9	14.6 - 30.6	4.25	2.66 - 5.66
MON	2.9	0.3 - 6.7	0.57	0.05 - 1.23
EOS	4.8	0.0 - 8.6	0.93	0.00 - 1.58
BAS	2.9	0.0 - 6.2	0.57	0.00 - 1.14
IMG	6.8	0.0 - 9.6	1.32	0.00 - 1.76



*(Signature)*  
 14/3/24

QC - Control Run Report

Run Date 14/03/2024 04:08:48 PM

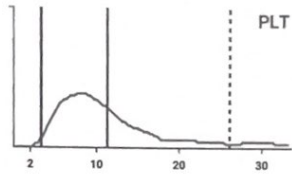
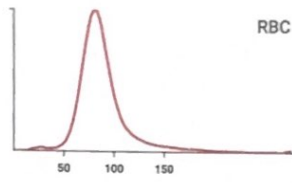
Operat. REDCLIFFELAB

Name DIFFTROL N  
 Level Normal  
 Lot number PX446N

Sample ID PX446N  
 Exp. date 05/05/2024

CBC

			Range
WBC	9.40	10 <sup>3</sup> /mm <sup>3</sup>	7.50 - 9.50
RBC	4.55	10 <sup>6</sup> /mm <sup>3</sup>	4.38 - 4.78
HGB	13.0	g/dL	12.7 - 13.7
HCT	37.7	%	35.3 - 39.3
MCV	82.8	fL	76.5 - 86.5
MCH	28.5	pg	26.8 - 30.8
MCHC	34.5	g/dL	32.4 - 38.4
RDW-CV	12.7	%	12.1 - 20.1
RDW-SD	42.7	fL	31.8 - 47.8
PLT	274	10 <sup>3</sup> /mm <sup>3</sup>	222 - 282
MPV	10.2	fL	7.4 - 11.4

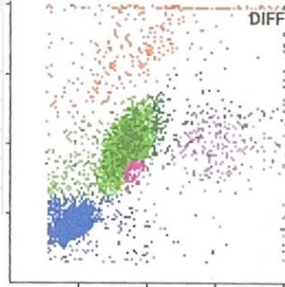


Alarms

Startup failed

DIF

	%	Range	10 <sup>3</sup> /mm <sup>3</sup>	Range
NEU	46.5	35.1 - 55.1	4.37	2.93 - 4.73
LYM	41.4	36.0 - 52.0	3.89	3.04 - 4.44
MON	4.5	0.3 - 10.9	0.42	0.03 - 0.93
EOS	5.6	0.0 - 6.6	0.53	0.00 - 0.56
BAS	2.0	0.0 - 4.0	0.19	0.00 - 0.34
IMG	4.1	0.0 - 8.0	0.39	0.00 - 0.68



*Handwritten signature and date:*  
 14/3/24