HORIBA
Explore the future

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HIN/MED/2023-2024/00330
15th May 2023.

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **ABX Yumizen H550 bearing** serial number: **212YAXH05276** installed at **Redcliff lifetech Pvt Ltd, Gurugram, Haryana Calibrated** on **15th May 2023.**

Calibrator : ABX MINOCAL
Lot No. : CX482
Expiry Date : 05th June 2023.

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

Next calibration cycle is due on 14th May 2024.

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

ABX Minocal

CE

IVD

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

LOT CX 482
Rev 1

CAL

(Exp.) 2023-06-05
(YYYY - MM - DD)

PARAMETRES *PARAMETERS*	UNITES *UNITS*	WHITEDIFF								TOLERANCES *TOLERANCE*
		YUMIZEN V1.0 to V2.x			YUMIZEN since V3					
		H550	H500 OT H500 CT		H500 OT	H500 CT H550				
GB WBC	$10^3/mm^3;10^9/l$	**9.00**	**9.00**		**9.00**	**9.00**				± 0.20
GR RBC	$10^6/mm^3;10^{12}/l$	**4.42**	**4.42**		**4.43**	**4.43**				± 0.06
HB HGB	g/dl	**12.8**	**12.8**		**12.8**	**12.8**				± 0.2
	g/l	**128**	**128**		**128**	**128**				± 2
	mmol/l	**7.95**	**7.95**		**7.95**	**7.95**				± 0.12
HT HCT	%	**37.1**	**37.1**		**36.1**	**35.1**				± 1.0
	l/l	**0.371**	**0.371**		**0.361**	**0.351**				± 0.010
PLA PLT	$10^3/mm^3;10^9/l$	**255**	**255**		**275**	**280**				± 10
VMP MPV	μm^3 ; fl	**10.4**	**10.4**		**9.2**	**9.2**				± 0.5

Ref: TEMP-0387 Rev.48 BACK / VERSO 1300105208

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

ABX Minocal

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LOT CX 482
Rev 1

CAL

(Exp.) 2023-06-05
(YYYY - MM - DD)

PARAMETRES *PARAMETERS*	UNITES *UNITS*	ABX Lysebio YUMIZEN H1500 H2500									TOLERANCES *TOLERANCE*
GB WBC	$10^3/mm^3;10^9/l$	**8.80**									± 0.20
GR RBC	$10^6/mm^3;10^{12}/l$	**4.41**									± 0.06
HB HGB	g/dl	**13.3**									± 0.2
	g/l	**133**									± 2
	mmol/l	**8.26**									± 0.12
HT HCT	%	N/A									N/A
	l/l	N/A									N/A
PLA PLT	$10^3/mm^3;10^9/l$	**251**									± 10
VMP MPV	μm^3 ; fl	N/A									N/A
VGM MCV	μm^3 ; fl	**84.0**									± 4.0

1300060884

Ref: TEMP-0387 Rev.48

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

Calibration Report

Sample ID CX482 Exp. date 06/05/2023
Lot number CX482 Name ABX MINOCAL Modified on

Coefficient	WBC	RBC	HGB	HCT	PLT	MPV
New	1.141	1.042	1.020	1.038	1.136	1.060
Current	1.141	1.042	1.020	1.038	1.136	1.060
Target	9.00	4.42	12.8	37.1	255	10.4
Mean	8.95	4.38	12.7	36.5	245	10.3
CV(%)	0.95	1.08	0.40	0.98	0.74	0.71

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)
	05/15/2023 12:54:18 PM	9.07	**4.30** I	12.7	**36.0** I	246	10.4
✔	05/15/2023 12:56:08 PM	9.02	4.39	12.7	36.8	**245** I	10.3
✔	05/15/2023 12:57:38 PM	9.06	4.39	12.7	36.5	**243** I	10.4
✔	05/15/2023 12:59:20 PM	8.86	4.38	12.7	36.5	248	10.3
✔	05/15/2023 01:01:03 PM	8.93	**4.32** I	12.6	**35.9** I	247	10.4
✔	05/15/2023 01:02:54 PM	8.90	4.45	12.7	36.7	**245** I	10.4

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
05/15/2023 11:12:43 AM	technician	0.07	0.00	0.0	2	Passed	
05/15/2023 11:14:12 AM	technician	0.08	0.00	0.0	1	Passed	
05/15/2023 11:15:51 AM	technician	0.11	0.01	0.0	0	Passed	
05/15/2023 11:31:28 AM	technician	0.07	0.00	0.0	0	Passed	
05/15/2023 11:33:03 AM	technician	0.07	0.00	0.0	0	Passed	

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	5.30	4.86	14.8	44.1	251	90.6	14.2	50.4	26.1
Maximum	5.74	5.18	15.3	47.2	281	91.3	15.0	52.9	28.3
Mean	5.58	4.99	15.1	45.4	268	90.9	14.6	51.7	27.1
Difference	0.44	0.32	0.5	3.1	30	0.7	0.8	2.5	2.3
2 SD	0.27	0.19	0.2	1.8	17	0.5	0.5	1.4	1.3
CV(%)	2.43	1.93	0.78	1.99	3.20	0.28	1.77	1.38	2.48

Sel	No. 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
	05/15/2023 11:52:22 AM	5.53	4.98	15.3	45.7	276	91.8	15.2	53.8	24.5	technician
✔	05/15/2023 11:54:37 AM	5.53	5.06	15.3	46.0	281	90.9	14.2	50.4	27.5	technician
✔	05/15/2023 11:56:11 AM	5.73	5.03	15.1	45.6	271	90.7	14.8	52.1	26.1	technician
✔	05/15/2023 11:57:53 AM	5.71	4.97	15.2	45.4	269	91.3	14.3	51.2	28.3	technician
✔	05/15/2023 11:59:43 AM	5.47	4.88	15.1	44.2	266	90.6	14.8	52.1	27.4	technician
✔	05/15/2023 12:01:12 PM	5.58	4.95	15.0	45.1	277	91.1	14.4	51.2	26.6	technician
✔	05/15/2023 12:03:17 PM	5.30	4.86	14.8	44.1	266	90.7	14.8	52.1	27.2	technician
✔	05/15/2023 12:04:48 PM	5.66	5.05	15.1	45.8	275	90.7	14.4	51.2	27.2	technician
✔	05/15/2023 12:06:37 PM	5.52	5.03	15.1	45.9	269	91.1	14.4	51.2	26.5	technician
✔	05/15/2023 12:08:08 PM	5.57	4.93	15.0	45.0	259	91.2	14.7	52.1	27.6	technician
✔	05/15/2023 12:09:54 PM	5.74	5.18 *	15.1	47.2 *	251	91.0 *	15.0 *	52.9 *	26.6	technician

Repeatability Report (part 2)

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

Coefficient	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	LIC% (%)
Minimum	49.0	40.2	4.7	1.3	1.0	0.1
Maximum	51.4	43.9	5.4	1.9	1.6	0.4
Mean	50.4	41.7	5.0	1.6	1.4	0.3
Difference	2.4	3.7	0.7	0.6	0.6	0.3
2 SD	1.8	2.5	0.4	0.4	0.4	0.2
CV(%)	1.82	2.98	4.00	14.10	13.88	43.20

Sel	Date &Time	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	LIC% (%)	Operator
	05/15/2023 11:52:22 AM	49.5	42.2	5.9	1.4	1.0	0.2	technician
✔	05/15/2023 11:54:37 AM	49.0	43.9	4.7	1.4	1.0	0.4	technician
✔	05/15/2023 11:56:11 AM	51.4	40.4	5.1	1.6	1.5	0.4	technician
✔	05/15/2023 11:57:53 AM	51.2	41.0	5.0	1.4	1.4	0.2	technician
✔	05/15/2023 11:59:43 AM	49.3	43.0	4.8	1.3	1.6	0.3	technician
✔	05/15/2023 12:01:12 PM	50.9	41.1	5.1	1.3	1.6	0.1	technician
✔	05/15/2023 12:03:17 PM	49.7	42.5	5.1	1.5	1.2	0.1	technician
✔	05/15/2023 12:04:48 PM	50.2	42.0	4.8	1.7	1.3	0.3	technician
✔	05/15/2023 12:06:37 PM	49.5	42.3	5.0	1.8	1.4	0.2	technician
✔	05/15/2023 12:08:08 PM	50.8	40.5	5.4	1.9	1.4	0.3	technician
✔	05/15/2023 12:09:54 PM	51.4	40.2	5.0	1.8	1.6	0.2	technician

CARRYOVER STUDY						
YUMIZEN H550		212YAXH05276				
HB	H1	15.7		L1	2.1	-0.74
	H2	15.6		L2	2.1	
	H3	15.7		L3	2.2	
RBC	H1	5.11		L1	0.69	0.67
	H2	5.05		L2	0.68	
	H3	5.16		L3	0.66	
PLATELETS	H1	496		L1	38	-0.43
	H2	493		L2	41	
	H3	502		L3	40	
WBC	H1	18.6		L1	0.77	0.29
	H2	18.4		L2	0.76	
	H3	18.23		L3	0.72	

Parameters	WBC 103/mm3	RBC 106/mm3	HGB g/dL	PLT 103/mm3
Carry Over (%)	0.29	0.67	-0.74	-0.43
Manufacturer acceptable CV%	0.5	1	1	0.5
Status	Passed	Passed	Passed	Passed

Source: User Manual , Summary of performance data, Carryover

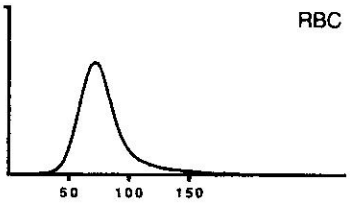
QC - Control Run Report

Run Date 03/06/2024 11:19:07 AM
Operator technician

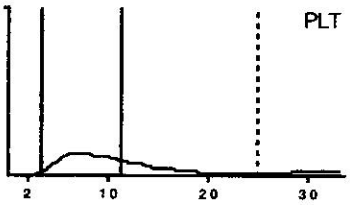
Name ABXdifftrol L
Level Low
Lot number PX445L
Sample ID PX445L
Exp. date 04/05/2024

			Range
RBC	2.33	$10^6/\mu L$	2.17 - 2.49
HGB	5.8	g/dL	5.5 - 6.3
HCT	18.6	%	16.6 - 19.6
MCV	79.9	μm^3	72.5 - 82.5
MCH	25.0	pg	23.3 - 27.3
MCHC	31.3	g/dL	29.7 - 35.7
RDW-CV	17.7	%	14.0 - 22.0

Alarms

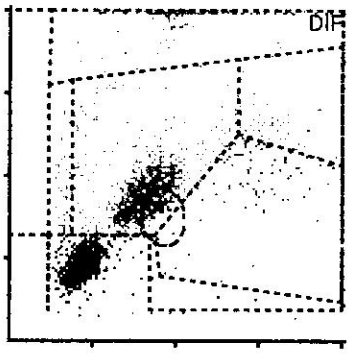


			Range
PLT	71	$10^3/\mu L$	49 - 89
MPV	10.5	μm^3	7.5 - 11.5



			Range
WBC	3.22	$10^3/\mu L$	2.60 - 3.40

	#	Range	%	Range
NEU	1.55	0.92 - 1.62	48.6	32.3 - 52.3
LYM	1.15	0.83 - 1.49	35.6	26.5 - 50.5
MON	0.13	0.00 - 0.52	3.9	0.0 - 17.4
EOS	0.31	0.00 - 0.34	9.5	0.0 - 11.4
BAS	0.08	0.00 - 0.28	2.4	0.0 - 9.6



Sathya 06/03/24

Raw Data

PLT counts (by sections)

S1	S2	S3	S4	S5	S6
84	95	100	90	103	111
S7	S8	S9	S10	S11	S12
92	85	92	91	91	99

RBC counts (by sections)

S1	S2	S3	S4	S5	S6
2181	2130	2140	2232	2160	2160
S7	S8	S9	S10	S11	S12
2196	2118	2100	2110	2121	2125

WBC counts (by sections) and others

S1	S2	S3	S4	S5	S6
213	217	234	220	241	222
S7	S8	S9	S10	S11	
217	202	245	203	214	

RMeasured : 2296
Correlated : 2262
Optical intensity 179

HBG measures (Optical intensity)

LI1	LI2	LI3	LI4	LI5	LI6
3855	3854	3853	1981	1981	1980
LI7	LI8	LI9	LI10	LI11	LI12
1980	1980	1979	1979	1978	1977
LI13					
1975					

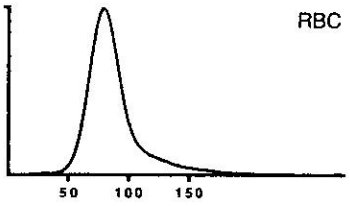
QC - Control Run Report

Run Date 03/06/2024 11:21:32 AM
Operator technician

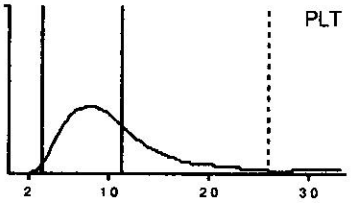
Name ABXdifftrol N
Level Normal
Lot number PX445N
Sample ID PX445N
Exp. date 04/05/2024

			Range
RBC	4.53	$10^6/\mu L$	4.37 - 4.77
HGB	13.1	g/dL	12.6 - 13.6
HCT	39.8	%	37.8 - 41.8
MCV	87.9	μm^3	82.0 - 92.0
MCH	28.9	pg	26.7 - 30.7
MCHC	32.8	g/dL	29.9 - 35.9
RDW-CV	14.6	%	11.0 - 19.0

Alarms

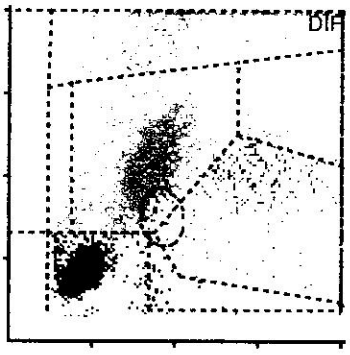


			Range
PLT	254	$10^3/\mu L$	203 - 263
MPV	10.2	μm^3	7.5 - 11.5



			Range
WBC	8.45	$10^3/\mu L$	7.50 - 9.50

	#	Range	%	Range
NEU	4.15	3.02 - 4.82	49.2	36.1 - 56.1
LYM	3.50	2.94 - 4.34	41.4	34.8 - 50.8
MON	0.33	0.00 - 0.90	3.9	0.0 - 10.6
EOS	0.40	0.04 - 0.60	4.7	0.0 - 7.6
BAS	0.07	0.00 - 0.34	0.8	0.0 - 4.0



Sadiya
06/03/24

Raw Data

PLT counts (by sections)

S1	S2	S3	S4	S5	S6
238	225	250	224	231	257
S7	**S8**	**S9**	**S10**	**S11**	**S12**
217	239	252	252	233	241

RBC counts (by sections)

S1	S2	S3	S4	S5	S6
3948	3828	3804	4035	3884	3980
S7	**S8**	**S9**	**S10**	**S11**	**S12**
3856	3929	3889	3891	3826	3835

WBC counts (by sections) and others

S1	S2	S3	S4	S5	S6
570	606	599	548	566	553
S7	**S8**	**S9**	**S10**	**S11**	
607	591	617	541	558	

RMeasured : 5813
Correlated : 5782
Optical intensity 179

HBG measures (Optical Intensity)

LI1	LI2	LI3	LI4	LI5	LI6
3821	3843	3851	902	902	902
LI7	**LI8**	**LI9**	**LI10**	**LI11**	**LI12**
903	903	903	904	905	906
LI13					
907					

QC - Control Run Report

Run Date 03/06/2024 11:16:07 AM

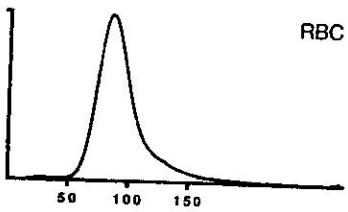
Operator technician

Name ABCdifftrol H
Level High
Lot number PX445H

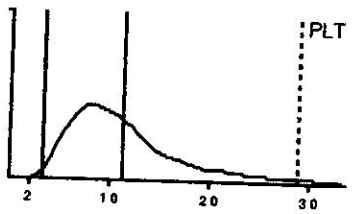
Sample ID PX445H
Exp. date 04/05/2024

			Range
RBC	5.07	$10^6/\mu L$	4.76 - 5.26
HGB	15.5	g/dL	14.9 - 16.1
HCT	48.3	%	44.6 - 49.6
MCV	95.3	μm^3	89.0 - 99.0
MCH	30.5	pg	28.4 - 33.4
MCHC	32.0	g/dL	29.9 - 35.9
RDW-CV	14.8	%	10.0 - 18.0

Alarms

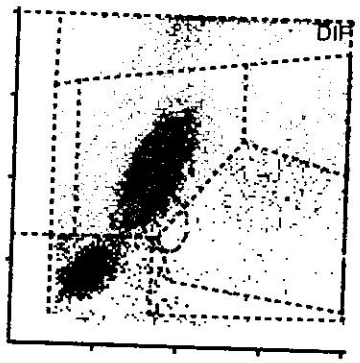


			Range
PLT	500	$10^3/\mu L$	425 - 525
MPV	11.0	μm^3	8.2 - 12.2



			Range
WBC	17.73	$10^3/\mu L$	16.20 - 20.60

	#	Range	%	Range
NEU	12.50	10.50 -	70.6	57.4 - 77.4
LYM	3.74	2.49 - 5.49	21.1	13.7 - 29.7
MON	0.44	0.00 - 1.18	2.5	0.0 - 6.4
EOS	0.81	0.06 - 1.64	4.5	0.3 - 8.9
BAS	0.24	0.00 - 1.14	1.3	0.0 - 6.2



Sathya 06/03/24

Raw Data

PLT counts (by sections)

S1	S2	S3	S4	S5	S6
426	424	395	430	430	429
S7	**S8**	**S9**	**S10**	**S11**	**S12**
386	421	395	410	460	418

WBC counts (by sections) and others

S1	S2	S3	S4	S5	S6
1244	1199	1206	1133	1139	1241
S7	**S8**	**S9**	**S10**	**S11**	
1262	1203	1167	1199	1259	

RMeasured : 11236
Correlated : 11150
Optical intensity 179

RBC counts (by sections)

S1	S2	S3	S4	S5	S6
4287	4197	4327	4329	4246	4437
S7	**S8**	**S9**	**S10**	**S11**	**S12**
4189	4335	4352	4248	4317	4192

HBG measures (Optical intensity)

LI1	LI2	LI3	LI4	LI5	LI6
3856	3843	3786	711	711	711
LI7	**LI8**	**LI9**	**LI10**	**LI11**	**LI12**
710	710	710	710	710	711
LI13					
710					