

Date: 11/06/2022

CALIBRATION CERTIFICATE

This is to state that the haematology cell counter model **HORIBA MEDICAL: YUMIZEN H500**, bearing serial no: **201YOXH04453** installed at **Indiglobal Labs Pvt Ltd, Hyderabad** was calibrated with Calibrator on **11th June 2022**.

Subsequently controls were processed and found them in respective range.

Calibrator Used: **ABX MINOCAL**
Lot No.: **CX471**
Expiry Date: **05/07/2022**

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.40	8.29	2.18	<2.5%	PASSED
RBC	4.60	4.57	1.51	<2%	PASSED
HGB	13.2	12.9	0.24	<1.5%	PASSED
HCT	40.5	40.2	1.52	<2%	PASSED
PLT	251	250	2.34	<5%	PASSED

Next Calibration Due Date: **10/06/2023**



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

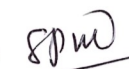
- **Calibration:** To calibrate the Instrument using calibrator (ABX Minocal) and verify the same.

Procedure: Go to Quality Assurance icon on main screen and then Calibration icon. Run Calibrator (ABX Minocal) 11 times, without taking the values of first run, calibrate the instrument using average of the last 11 runs. Run Calibrator as a sample to verify the calibration. **Lot: CX71; Expiry: 05/07/2022.**

Serial No: **201YOXH04453**

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.40	8.29	2.18	<2.5%	PASSED
RBC	4.60	4.57	1.51	<2%	PASSED
HGB	13.2	12.9	0.24	<1.5%	PASSED
HCT	40.5	40.2	1.52	<2%	PASSED
PLT	251	250	2.34	<5%	PASSED
MPV	11.8	11.6	1.88	<3%	PASSED

Conducted By: 
11/06/22

Verified By: 
11 Jun 2022

- **Control Runs:** The quality of the analyzer is checked by running three levels of Controls & getting the values in the range as per the kitinsert.

□ **Lot:** ABX Difftrol PX435; **Exp:** 05/07/2022.

Serial No: **201YOXH04453**

LEVEL	STATUS
LOW (PX435L)	PASSED
NORMAL (PX435N)	PASSED
HIGH (PX435H)	PASSED

Conducted By:

[Signature]
11/06/22

Verified By:

[Signature]
11 JUN 2022

Calibration Report

Sample ID CX471
Lot number CX471

Name MINOCAL

Exp. date 07/05/2022
Modified on

	Coefficient	WBC	RBC	HGB	HCT	PLT	MPV
New	1.098	0.936	0.981	1.046	1.060	1.028	
Current	1.098	0.936	0.981	1.046	1.060	1.028	
Target	8.40	4.60	13.2	40.5	251	11.8	
Mean	8.29	4.57	12.9	40.2	250	11.6	
CV(%)	2.18	1.51	0.24	1.52	2.34	1.88	

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

Sel.	Run Time	WBC (10 ³ /μL)	RBC (10 ⁹ /μL)	HGB (g/dL)	HCT (%)	PLT (10 ³ /μL)	MPV (μm ³)
✓	06/11/2022 12:59:50 PM	8.30	4.60	12.9	40.8	251	11.5
✓	06/11/2022 01:02:38 PM	8.06	4.48	12.9	39.4	247	11.7
✓	06/11/2022 01:03:56 PM	8.30	4.47	12.9	39.4	242	11.6
✓	06/11/2022 01:05:30 PM	8.10	4.54	12.9	40.0	243	11.8
✓	06/11/2022 01:06:52 PM	8.55	4.60	12.8	40.4	249	11.5
✓	06/11/2022 01:08:13 PM	8.43	4.57	12.9	40.4	246	12.0
✓	06/11/2022 01:09:35 PM	8.45	4.46	12.9	39.2	254	11.3
✓	06/11/2022 01:11:02 PM	8.17	4.66 h	12.9	41.0	261	11.5
✓	06/11/2022 01:12:26 PM	8.42	4.60	12.9	40.4	249	11.8
✓	06/11/2022 01:14:01 PM	8.42	4.61	12.9	40.5	256	11.9
✓	06/11/2022 01:15:24 PM	8.01	4.63	12.9	40.7	257	11.4

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Repeatability Report (part 1)

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

Coefficient	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	HCT (%)	PLT (10 ³ /μL)	MCV (μm ³)	RDW-CV (%)	RDW-SD (μm ³)	P-LCR (%)
Minimum	7.27	4.84	15.9	42.9	277	88.6	12.2	48.7	18.0
Maximum	7.51	4.96	16.0	44.3	297	89.5	13.3	52.1	19.6
Mean	7.38	4.90	16.0	43.8	290	89.3	12.5	49.6	18.7
Difference	0.24	0.12	0.1	1.4	19	1.0	1.1	3.4	1.6
2 SD	0.15	0.07	0.1	0.8	12	0.5	0.6	1.9	1.0
CV(%)	1.05	0.76	0.25	0.92	2.15	0.27	2.57	1.92	2.75

Sel	Run Date &Time	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	HCT (%)	PLT (10 ³ /μL)	MCV (μm ³)	RDW-CV (%)	RDW-SD (μm ³)	P-LCR (%)	Operator
✓	06/11/2022 12:10:11 PM	7.33	4.84	15.9	42.9	285	88.6	13.3	52.1	18.2	technician
✓	06/11/2022 12:11:46 PM	7.38	4.92	15.9	44.0	293	89.3	12.5	49.6	18.4	technician
✓	06/11/2022 12:13:20 PM	7.34	4.88	15.9	43.6	290	89.4	12.3	49.6	19.3	technician
✓	06/11/2022 12:14:38 PM	7.28	4.93	15.9	44.0	286	89.2	12.7	50.4	18.0	technician
✓	06/11/2022 12:16:13 PM	7.35	4.87	15.9	43.5	277	89.3	12.4	49.6	18.1	technician
✓	06/11/2022 12:17:34 PM	7.36	4.96	16.0	44.3	296	89.3	12.4	49.6	19.6	technician
✓	06/11/2022 12:18:56 PM	7.46	4.95	15.9	44.2	293	89.3	12.3	49.6	19.0	technician
✓	06/11/2022 12:20:24 PM	7.37	4.91	15.9	43.8	285	89.2	12.3	49.6	18.7	technician
✓	06/11/2022 12:22:22 PM	7.47	4.91	16.0	44.0	297	89.5	12.3	48.7	18.6	technician
✓	06/11/2022 12:24:09 PM	7.27	4.87	16.0	43.5	297	89.4	12.2	48.7	19.1	technician
✓	06/11/2022 12:25:31 PM	7.51	4.90	15.9	43.7	285	89.3	12.2	48.7	18.5	technician

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Repeatability Report (part 2)

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

Coefficient	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	LIC% (%)
Minimum	44.8	42.2	5.4	3.2	1.0	0.2
Maximum	46.9	44.3	6.1	4.4	1.5	0.4
Mean	45.9	43.3	5.8	3.7	1.3	0.3
Difference	2.2	2.1	0.7	1.2	0.5	0.2
2 SD	1.4	1.4	0.4	0.6	0.4	0.1
CV(%)	1.48	1.65	3.69	8.58	14.47	22.67

Sel	Run Date &Time	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	LIC% (%)	Operator
✓	06/11/2022 12:10:11 PM	46.9	42.6	5.6	3.9	1.0	0.4	technician
✓	06/11/2022 12:11:46 PM	45.5	43.4	6.0	3.6	1.5	0.3	technician
✓	06/11/2022 12:13:20 PM	44.8	44.3	5.8	3.7	1.4	0.2	technician
✓	06/11/2022 12:14:38 PM	46.3	42.3	5.6	4.4	1.4	0.2	technician
✓	06/11/2022 12:16:13 PM	46.4	42.2	6.1	3.8	1.5	0.4	technician
✓	06/11/2022 12:17:34 PM	45.0	44.1	5.8	3.8	1.3	0.4	technician
✓	06/11/2022 12:18:56 PM	46.0	43.4	5.9	3.4	1.3	0.3	technician
✓	06/11/2022 12:20:24 PM	45.9	43.7	5.4	3.5	1.5	0.3	technician
✓	06/11/2022 12:22:22 PM	45.6	44.0	5.6	3.7	1.1	0.3	technician
✓	06/11/2022 12:24:09 PM	45.6	43.5	5.8	4.0	1.1	0.3	technician
✓	06/11/2022 12:25:31 PM	46.7	43.0	6.0	3.2	1.1	0.3	technician

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QC - Control Run Report

Run Date 06/11/2022 01:19:59 PM

Operator technician

Name ABXdifftrol L

Sample ID PX435L

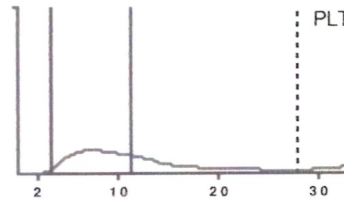
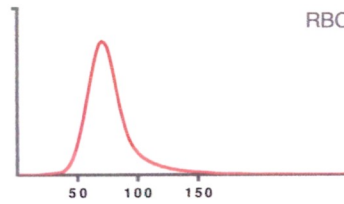
Level Low

Exp. date 07/05/2022

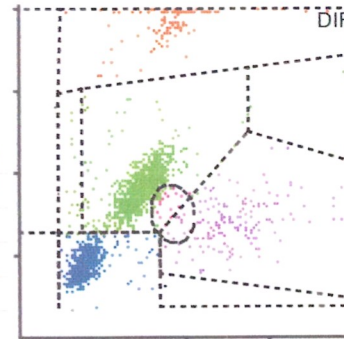
Lot number PX435L

			Range
RBC	2.48	10 ⁶ /μL	2.29 - 2.61
HGB	6.3	g/dL	5.9 - 6.7
HCT	19.7	%	18.1 - 21.1
MCV	79.5	μm ³	75.0 - 85.0
MCH	25.4	pg	23.7 - 27.7
MCHC	31.9	g/dL	29.1 - 35.1
RDW-CV	13.7	%	13.0 - 21.0
RDW-SD	47.0	μm ³	37.0 - 53.0
Range			
PLT	85	10 ³ /μL	59 - 99
MPV	10.6	μm ³	8.6 - 12.6

Alarms



			Range		Range
WBC	2.93	10 ³ /μL	2.60 - 3.40		
	#		Range	%	Range
NEU	1.40		0.94 - 1.64	47.8	33.0 - 53.0
LYM	1.09		0.84 - 1.50	37.0	27.0 - 51.0
MON	0.23		0.00 - 0.52	8.0	0.0 - 17.4
EOS	0.19		0.00 - 0.34	6.5	0.0 - 11.0
BAS	0.02		0.00 - 0.22	0.7	0.0 - 7.6



Raw Data

PLT counts (by sections)

S1	S2	S3	S4	S5	S6
106	103	114	127	139	122
S7	S8	S9	S10	S11	S12
114	111	149	152	150	155

RBC counts (by sections)

S1	S2	S3	S4	S5	S6
2356	2465	2405	2405	2360	2419
S7	S8	S9	S10	S11	S12
2441	2442	2382	2454	2468	2404

WBC counts (by sections) and others

S1	S2	S3	S4	S5	S6
211	202	181	184	193	180
S7	S8	S9	S10	S11	
202	203	195	226	199	

HGB measures (Optical intensity)

LI1	LI2	LI3	LI4	LI5	LI6
3859	3859	3859	1854	1854	1854
LI7	LI8	LI9	LI10	LI11	LI12
1854	1855	1855	1855	1855	1855
LI13					
1855					

RMeasured : 2045
Correlated : 2033
Optical intensity 184

QC - Control Run Report

Run Date 06/11/2022 01:17:23 PM

Operator technician

Name ABXdiffrol N

Sample ID PX435N

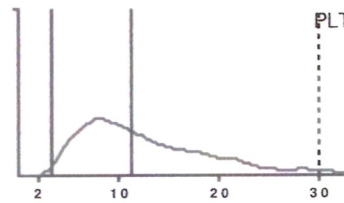
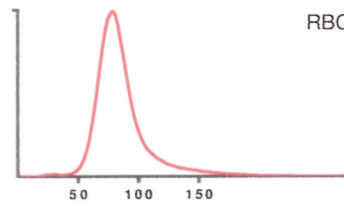
Level Normal

Exp. date 07/05/2022

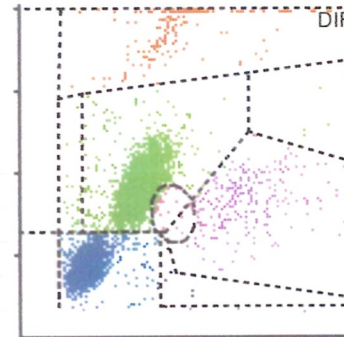
Lot number PX435N

			Range
RBC	4.55	10 ⁶ /μL	4.40 - 4.80
HGB	13.2	g/dL	12.7 - 13.7
HCT	40.0	%	38.5 - 42.5
MCV	88.0	μm ³	83.0 - 93.0
MCH	29.1	pg	26.7 - 30.7
MCHC	33.0	g/dL	29.6 - 35.6
RDW-CV	12.0	%	10.5 - 18.5
RDW-SD	46.2	μm ³	34.0 - 50.0
Range			
PLT	274	10 ³ /μL	221 - 281
MPV	11.6	μm ³	9.8 - 13.8

Alarms



			Range
WBC	8.45	10 ³ /μL	7.40 - 9.40
	#	Range	%
NEU	4.07	3.08 - 4.88	48.2
LYM	3.63	2.85 - 4.25	42.9
MON	0.39	0.00 - 0.88	4.6
EOS	0.33	0.00 - 0.56	3.9
BAS	0.03	0.00 - 0.30	0.4



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11/06/22

Raw Data

PLT counts (by sections)

S1	S2	S3	S4	S5	S6
242	250	271	254	276	276
S7	S8	S9	S10	S11	S12
226	266	222	239	275	258

RBC counts (by sections)

S1	S2	S3	S4	S5	S6
4174	4054	4165	4263	4224	4120
S7	S8	S9	S10	S11	S12
4145	4117	4043	4095	4001	4155

WBC counts (by sections) and others

S1	S2	S3	S4	S5	S6
582	552	563	538	565	587
S7	S8	S9	S10	S11	
591	592	566	536	580	

HBG measures (Optical intensity)

LI1	LI2	LI3	LI4	LI5	LI6
3855	3855	3856	871	871	871
LI7	LI8	LI9	LI10	LI11	LI12
871	871	871	871	870	871
LI13					
871					

RMeasured : 5434
Correlated : 5401
Optical intensity 191

QC - Control Run Report

Run Date 06/11/2022 01:21:29 PM

Operator technician

Name ABXdiffrol H

Sample ID PX435H

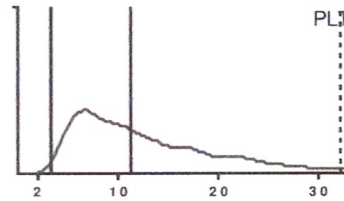
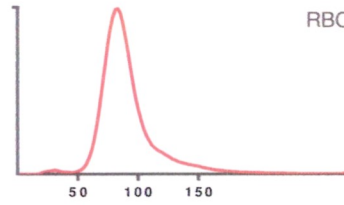
Level High

Exp. date 07/05/2022

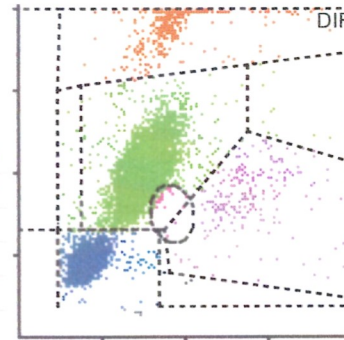
Lot number PX435H

			Range
RBC	5.08	10 ⁶ /μL	4.84 - 5.34
HGB	15.6	g/dL	14.9 - 16.1
HCT	47.3	%	44.8 - 49.8
MCV	93.2	μm ³	88.0 - 98.0
MCH	30.7	pg	28.0 - 33.0
MCHC	32.9	g/dL	29.7 - 35.7
RDW-CV	11.9	%	8.0 - 16.0
RDW-SD	48.7	μm ³	36.0 - 52.0
Range			
PLT	542	10 ³ /μL	455 - 555
MPV	11.8	μm ³	9.7 - 13.7

Alarms



			Range			Range
WBC	17.02	10 ³ /μL	15.20 - 19.60			
	#		Range	%		Range
NEU	12.09		10.16 -	71.0		59.3 - 79.3
LYM	3.80		2.33 - 5.33	22.3		14.0 - 30.0
MON	0.37		0.00 - 0.84	2.2		0.0 - 4.8
EOS	0.73		0.00 - 1.54	4.3		0.0 - 8.8
BAS	0.03		0.00 - 0.66	0.2		0.0 - 3.8



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Raw Data

PLT counts (by sections)

S1	S2	S3	S4	S5	S6
436	456	455	494	449	477
S7	S8	S9	S10	S11	S12
393	453	480	436	439	426

RBC counts (by sections)

S1	S2	S3	S4	S5	S6
4545	4570	4566	4436	4563	4574
S7	S8	S9	S10	S11	S12
4594	4502	4590	4463	4480	4596

WBC counts (by sections) and others

S1	S2	S3	S4	S5	S6
1154	1221	1103	1110	1093	1154
S7	S8	S9	S10	S11	
1116	1115	1171	1164	1118	

HBG measures (Optical intensity)

L1	L2	L3	L4	L5	L6
3855	3855	3855	683	683	683
L7	L8	L9	L10	L11	L12
683	683	683	683	683	683
L13					
683					

RMeasured : 9819
 Correlated : 9795
 Optical intensity 183

LOT CX 471
Rev 1

CAL

 (Exp.) 2022-07-05
(YYYY - MM - DD)

PARAMETRES PARAMETERS	UNITES UNITS	WHITEDIFF								TOLERANCES TOLERANCE
		YUMIZEN		YUMIZEN						
		H550	H500 OT H500 CT							
GB WBC	10 ⁹ /mm ³ ; 10 ⁹ /l	8.40	8.40							± 0.20
GR RBC	10 ⁶ /mm ³ ; 10 ¹² /l	4.60	4.60							± 0.06
HB HGB	g/dl	13.2	13.2							± 0.2
	g/l	132	132							± 2
	mmol/l	8.20	8.20							± 0.12
HT HCT	%	40.5	40.5							± 1.0
	l/l	0.405	0.405							± 0.010
PLAQ. PLTS	10 ³ /mm ³ ; 10 ⁹ /l	251	251							± 10
VPM MPV	µm ³ ; fl	11.8	11.8							± 0.5

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11/08/22

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

ABX Difftrol



LOT PX 435
Rev 1

CONTROL

(Exp.) 2022-07-05
(YY - MM - DD)

PARAMETRES PARAMETERS	UNITS	Whitediff											
		CONTROL			TOLERANCES TOLERANCE	CONTROL			TOLERANCES TOLERANCE	CONTROL			
		YUMIZEN		H500 OT H500 CT		YUMIZEN		H500 OT H500 CT		YUMIZEN		H500 OT H500 CT	TOLERANCES TOLERANCE
		H550	H500 OT H500 CT			H550	H500 OT H500 CT			H550	H500 OT H500 CT		
GB WBC	10 ⁹ /mm ³ · 10 ⁹ /L	3.00	3.00	± 0.40	8.40	8.40	± 1.00	17.40	17.40	± 2.20			
GR RBC	10 ¹² /mm ³ · 10 ¹² /L	2.45	2.45	± 0.16	4.60	4.60	± 0.20	5.09	5.09	± 0.25			
HB HGB	g/dl	6.3	6.3	± 0.4	13.2	13.2	± 0.5	15.5	15.5	± 0.6			
	g/l	63	63	± 4	132	132	± 5	155	155	± 6			
	mmol/l	3.91	3.91	± 0.25	8.20	8.20	± 0.31	9.63	9.63	± 0.37			
HT HCT	%	19.6	19.6	± 1.5	40.5	40.5	± 2.0	47.3	47.3	± 2.5			
	l/l	0.196	0.196	± 0.015	0.405	0.405	± 0.020	0.473	0.473	± 0.025			
VGM MCV	µm ³ · fl	80.0	80.0	± 5.0	88.0	88.0	± 5.0	93.0	93.0	± 5.0			
TCMP ² MCH	pg	25.7	25.7	± 2.0	26.7	28.7	± 2.0	30.5	30.5	± 2.5			
	fmol	1.60	1.60	± 0.12	1.78	1.78	± 0.12	1.89	1.89	± 0.16			
CCMH ² MCHC	g/dl	32.1	32.1	± 3.0	32.6	32.6	± 3.0	32.7	32.7	± 3.0			
	g/l	321	321	± 30	326	326	± 30	327	327	± 30			
	mmol/l	19.93	19.93	± 1.86	20.24	20.24	± 1.86	20.31	20.31	± 1.86			
IDR-CV RDW-CV	%	17.0	17.0	± 4.0	14.5	14.5	± 4.0	12.0	12.0	± 4.0			
PLAQ PLTS	10 ⁹ /mm ³ · 10 ⁹ /L	79	79	± 20	251	251	± 30	505	505	± 50			
VPM MPV	µm ³ · fl	10.6	10.6	± 2.0	11.8	11.8	± 2.0	11.7	11.7	± 2.0			
NEUT	#	1.29	1.29	± 0.35	3.98	3.98	± 0.90	12.06	12.06	± 1.90			
	%	43.0	43.0	± 10.0	47.4	47.4	± 10.0	69.3	69.3	± 10.0			
LYMPHO	#	1.17	1.17	± 0.33	3.55	3.55	± 0.70	3.83	3.83	± 1.50			
	%	39.0	39.0	± 12.0	42.3	42.3	± 8.0	22.0	22.0	± 8.0			
MCNC	#	0.26	0.26	± 0.26	0.44	0.44	± 0.44	0.42	0.42	± 0.42			
	%	8.7	8.7	± 8.7	5.2	5.2	± 5.2	2.4	2.4	± 2.4			
EOS	#	0.17	0.17	± 0.17	0.28	0.28	± 0.28	0.77	0.77	± 0.77			
	%	5.5	5.5	± 5.5	3.3	3.3	± 3.3	4.4	4.4	± 4.4			
BASC	#	0.11	0.11	± 0.11	0.15	0.15	± 0.15	0.33	0.33	± 0.33			
	%	3.8	3.8	± 3.8	1.8	1.8	± 1.8	1.9	1.9	± 1.9			
ICR-SD RDW-SD	fl	45.0	45.0	± 8.0	42.0	42.0	± 8.0	44.0	44.0	± 8.0			

Ref: TEMP-0821 Rev.45 FRONT / RECTO 1300074625

Handwritten signature and date: 19/08/22

Blank Cycle Logs

Running Date Comments	Operator	WBC 10 ³ /μL	RBC 10 ⁶ /μL	HGB g/dL	PLT 10 ³ /μL	Status	Technical alarms
06/11/2022 10:46:23 AM	technician	0.07	0.00	0.0	5	Passed	
06/11/2022 12:04:26 PM	technician	0.06	0.00	0.0	1	Passed	

Amal
11/06/2022