

HORIBA

Medical

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CIN : U73100DL2006PTC153232

HIN/MED/2022-2023/1005825

05th Feb 2022

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **YUMIZEN H550** bearing serial number: **909YAXH02687** installed at **Shradhadeep Green Cross, Gandhinagar** as calibrated on 05th Feb 2022.

Calibrator : ABX MINOCAL

Lot No. : CX466

Expiry Date : 05th Feb 2022

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

Next calibration cycle is due on 04th Feb 2023.



Shrish Dixit

(Head- Products & Marketing)

For **Horiba India Pvt. Ltd.**

HORIBA

Explore the future

Notification No. _____

Work Order No. _____

**HORIBA CARE**

Toll Free No.: 1800-103-4470

SERVICE REPORT

CUSTOMER COPY

HIN-M02-15249

CUSTOMER DETAILS		INSTRUMENT DETAILS			SERVICE STATUS	
NAME: Shradhadeep Greenross Lab.		MODEL: 4H-550			VISITING PURPOSE:	
ADDRESS: Sect - 7 Ginagas		EQUIP. SL. No.: 909VA XH02687			<input type="checkbox"/> REPAIR <input type="checkbox"/> DATA ERROR	
PIN CODE		VERSION: 1.2.1.1d			<input type="checkbox"/> INSTALLATION <input checked="" type="checkbox"/> MAINTENANCE	
CITY Gandhinagar		NOTIFICATION No. _____			<input type="checkbox"/> UPGRADE <input type="checkbox"/> CUSTOMER TRAINING	
STATE Gujarat		CALL DETAILS			<input type="checkbox"/> COURTESY VISIT <input type="checkbox"/> DEMO	
TEL. NO.:		DATE			<input type="checkbox"/> OTHERS	
CONTACT PERSON: Dr. Dinesh Rathod		TIME			CUSTOMER STATUS	
COMPLAINT RECD.		START 5/2/22 04:30			<input checked="" type="checkbox"/> R.R. <input type="checkbox"/> WARRANTY	
START		COMPLETED 5/2/22 07:55			<input type="checkbox"/> AMC <input type="checkbox"/> CMC	
TRAVEL TIME (Eng. 1) 2 HOURS		TRAVEL TIME (Eng. 2) 2 HOURS			<input type="checkbox"/> DEMO <input type="checkbox"/> FREE SERVICE	
TRAVEL TIME (Eng. 2) 2 HOURS		DAILY WORKLOAD 20			<input type="checkbox"/> CHARGEABLE CALL <input type="checkbox"/> OTHERS	
WORKS CARRIED OUT AT		<input type="checkbox"/> SITE <input type="checkbox"/> SERVICE CENTRE				

PROBLEM REPORTED: Due to preventive maintenance

OBSERVATIONS: - Changing Reagent - Did visual cleaning

- Changed pm kit as per protocol - Prime Reagent

ACTION TAKEN: - Run start up - Did all mech. gain

adjustment - Run start up - Run Donorability

- Run calibration (CY 466 - Lot) 11 times

- Run control - all working well

 FOLLOWING PARTS HAVE BEEN REPLACED FOLLOWING PARTS NEED TO BE REPLACED PLEASE APPROVE

PART CODE.	DESCRIPTION (Replaced)	QTY.	COST	TAX	TOTAL
0500020086 1300033061	Yumizen Maintenance KIT	1			

PART CODE.	DESCRIPTION (Trouble Shooting)	QTY.	TOTAL RS.		
					*Replaced for Trouble Shooting Need to be returned after Trouble Shooting.

FOLLOW-UP ACTION (Spare need to replaced, if any)

TO BE FILLED IN BY CUSTOMER

- FAULT RECTIFIED & INSTRUMENT IS WORKING SATISFACTORILY
 FAULT IS NOT COMPLETED, ENGINEER NEED TO COME AGAIN
 WE HEREBY APPROVE Rs.
 COMMENTS (IF ANY)

ENGINEER'S NAME-1:

DHARMIK R.

SIGNATURE:

DATE & TIME: 5.2.22

ENGINEER'S NAME-2:

NILESH SAPPA

SIGNATURE:

DATE & TIME: 5/2/22

CUSTOMER SIGNATURE:

NAME:

SEAL:

Calibration Report

Sample ID CX466
Lot number CX466

Name ABX MINOCAL

Exp. date 02/06/2022
Modified on

Coefficient	WBC	RBC	HGB	HCT	PLT	MPV
New	1.120	0.998	0.984	1.046	1.084	1.063
Current	1.120	0.998	0.984	1.046	1.084	1.063
Target	8.80	4.51	13.5	39.2	251	10.2
Mean	9.09	4.57	13.5	39.1	236	9.8
CV(%)	1.50	1.51	0.67	1.63	3.48	1.07

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

Sel.	Run Time	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	HCT (%)	PLT (10 ³ /μL)	MPV (μm ³)
✓	02/05/2022 06:38:02 PM	9.27 h	4.61 h	13.7	39.8	235	9.8
✓	02/05/2022 06:39:37 PM	9.26 h	4.63 h	13.6	39.7	247	9.7
✓	02/05/2022 06:41:32 PM	9.08 h	4.66 h	13.5	39.8	238	9.8
✓	02/05/2022 06:43:04 PM	8.99	4.61 h	13.5	39.6	232	9.8
✓	02/05/2022 06:44:33 PM	9.13 h	4.64 h	13.5	39.5	235	10.0
✓	02/05/2022 06:46:29 PM	8.92	4.52	13.5	38.6	238	9.7
✓	02/05/2022 06:48:05 PM	9.12 h	4.54	13.5	38.8	252	9.8
✓	02/05/2022 06:49:35 PM	8.89	4.50	13.5	38.5	221	9.7
✓	02/05/2022 06:51:07 PM	9.18 h	4.57	13.5	38.9	235	9.9
✓	02/05/2022 06:52:35 PM	8.93	4.55	13.4	39.0	237	9.8
✓	02/05/2022 06:54:04 PM	9.19 h	4.44	13.3	37.8	228	10.0

A. Kethel
02/5/22

QC - Control Run Report

Run Date 02/05/2022 06:57:41 PM

Operator technician

Name ABXdiffrol H

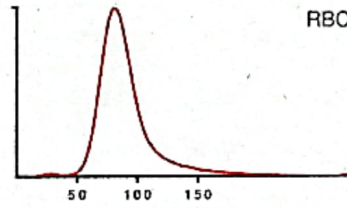
Sample ID PX433H

Level High

Exp. date 03/05/2022

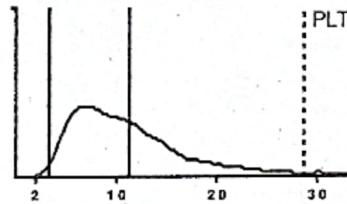
Lot number PX433H

			Range
RBC	5.18	10 ⁶ /μL	4.95 - 5.45
HGB	16.0	g/dL	15.8 - 17.0
HCT	47.7	%	44.8 - 49.8
MCV	92.0	μm ³	86.0 - 96.0
MCH	30.9	pg	29.0 - 34.0
MCHC	33.6	g/dL	31.7 - 37.7
RDW-CV	12.7	%	10.0 - 18.0

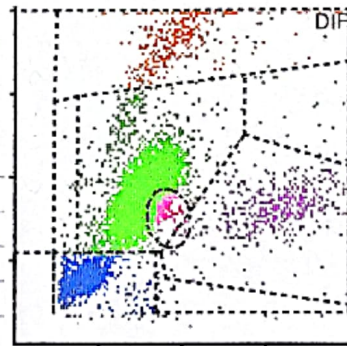


Alarms

			Range
PLT	524	10 ³ /μL	486 - 586
MPV	10.7	μm ³	8.4 - 12.4



WBC	16.47	10 ³ /μL	14.20 - 18.60
	#	Range	%
NEU	11.76	9.89 - 13.69	71.4
LYM	2.90	1.34 - 4.34	17.6
MON	0.79	0.00 - 1.48	4.8
EOS	0.60	0.00 - 1.32	3.6
BAS	0.42	0.00 - 0.76	2.6



Raw Data

PLT counts (by sections)						RBC counts (by sections)					
S1	S2	S3	S4	S5	S6	S1	S2	S3	S4	S5	S6
401	412	440	467	464	418	4397	4377	4455	4395	4479	4279
S7	S8	S9	S10	S11	S12	S7	S8	S9	S10	S11	S12
410	397	444	463	459	450	4383	4304	4334	4328	4387	4381
WBC counts (by sections) and others						HBG measures (Optical intensity)					
S1	S2	S3	S4	S5	S6	LI1	LI2	LI3	LI4	LI5	LI6
1055	1093	1118	1120	1075	1101	3829	3829	3828	653	653	653
S7	S8	S9	S10	S11		LI7	LI8	LI9	LI10	LI11	LI12
1040	1050	1044	1092	1095		653	653	652	652	652	652
RMeasured :	9963					LI13					
Correlated :	9954					653					
Optical intensity	196										

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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	7.22	4.49	13.0	37.5	216	83.5	11.4	42.8	17.5
Maximum	7.44	4.71	13.1	39.4	233	84.3	11.9	43.7	20.6
Mean	7.33	4.63	13.0	38.8	226	83.8	11.7	43.1	19.1
Difference	0.22	0.22	0.1	1.8	17	0.8	0.5	0.8	3.1
2 SD	0.13	0.12	0.1	1.0	11	0.4	0.3	0.8	1.8
CV(%)	0.89	1.31	0.34	1.31	2.41	0.25	1.19	0.91	4.65

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
✓	02/05/2022 05:46:16 PM	7.32	4.60	13.0	38.6	224	83.9	11.8	43.7	19.0	technician
✓	02/05/2022 05:48:28 PM	7.30	4.58	13.0	38.4	233	83.8	11.5	42.8	18.0	technician
✓	02/05/2022 05:50:13 PM	7.39	4.61	13.0	38.9	229	84.3	11.8	43.7	19.8	technician
✓	02/05/2022 05:52:05 PM	7.22	4.65	13.0	39.0	219	83.9	11.4	42.8	17.5	technician
✓	02/05/2022 05:53:42 PM	7.36	4.65	13.0	38.9	232	83.7	11.6	42.8	19.1	technician
✓	02/05/2022 05:55:53 PM	7.44	4.64	13.0	38.8	223	83.7	11.6	42.8	19.4	technician
✓	02/05/2022 05:57:40 PM	7.27	4.65	13.0	39.0	230	83.8	11.6	42.8	18.5	technician
✓	02/05/2022 05:59:26 PM	7.35	4.69	13.0	39.4	229	84.0	11.9	43.7	20.6	technician
✓	02/05/2022 06:00:54 PM	7.39	4.66	13.1	39.0	228	83.7	11.6	42.8	19.2	technician
✓	02/05/2022 06:02:34 PM	7.33	4.71	13.0	39.3	222	83.5	11.7	42.8	20.0	technician
✓	02/05/2022 06:04:22 PM	7.26	4.49	13.0	37.5	216	83.7	11.6	42.8	19.5	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	69.8	14.9	7.9	2.4	0.6	0.2
Maximum	72.8	17.4	9.2	3.3	1.2	0.6
Mean	71.2	16.3	8.8	2.9	0.9	0.4
Difference	3.0	2.5	1.3	0.9	0.6	0.4
2 SD	1.9	1.5	0.8	0.6	0.4	0.2
CV(%)	1.35	4.60	4.27	11.12	21.80	27.39

Sel	Run Date & Time	NEU% (%)	LYM% (%)	MON% (%)	EOS% (%)	BAS% (%)	LIC% (%)	Operator
✓	02/05/2022 05:46:16 PM	71.1	16.3	8.9	2.5	1.2	0.4	technician
✓	02/05/2022 05:48:28 PM	72.8	14.9	9.2	2.5	0.6	0.3	technician
✓	02/05/2022 05:50:13 PM	71.6	15.9	8.9	2.7	0.9	0.4	technician
✓	02/05/2022 05:52:05 PM	70.2	17.3	9.0	2.9	0.6	0.2	technician
✓	02/05/2022 05:53:42 PM	70.7	16.4	9.2	3.0	0.7	0.5	technician
✓	02/05/2022 05:55:53 PM	72.6	15.6	7.9	3.0	0.9	0.4	technician
✓	02/05/2022 05:57:40 PM	71.2	15.8	8.6	3.3	1.1	0.3	technician
✓	02/05/2022 05:59:26 PM	70.7	16.2	9.1	3.1	0.9	0.4	technician
✓	02/05/2022 06:00:54 PM	69.8	17.0	9.1	3.3	0.8	0.5	technician
✓	02/05/2022 06:02:34 PM	71.8	16.1	8.8	2.4	0.9	0.6	technician
✓	02/05/2022 06:04:22 PM	70.3	17.4	8.6	2.7	1.0	0.4	technician

Blank Cycle Logs

Running Date Comments	Operator	WBC 10 ³ /μL	RBC 10 ⁹ /μL	HGB g/dL	PLT 10 ⁹ /μL	Status	Technical alarms
02/05/2022 08:52:44 AM	SGPL	0.00	0.00	0.0	0	Passed	
02/05/2022 05:26:49 PM	technician	0.09	0.01	0.0	19 H	Failed	
02/05/2022 05:38:21 PM	technician	0.04	0.01	0.0	8 H	Failed	
02/05/2022 05:42:38 PM	technician	0.02	0.01	0.0	3	Passed	

Method

Calibration Report

Sample ID CX454
Lot number CX454

Name ABX MINOCAL

Exp. date 02/05/2021
Modified on

Coefficient	WBC	RBC	HGB	HCT	PLT	MPV
New	1.157	1.011	0.984	0.972	1.019	1.021
Current	1.157	1.011	0.984	1.030	1.019	1.021
Target	8.75	4.58	13.3	38.7	255	11.3
Mean	8.67	4.44	13.5	37.2	265	10.7
CV(%)	1.14	1.05	0.54	1.10	2.44	1.15

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

Sel.	Run Time	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	HCT (%)	PLT (10 ³ /μL)	MPV (μm ³)
	01/16/2021 08:39:08 PM	8.97 h	4.50 l	13.7 h	37.9	262	10.9
✓	01/16/2021 08:40:39 PM	8.75	4.49 l	13.4	37.6 l	270 h	10.7 l
✓	01/16/2021 08:42:12 PM	8.66	4.41 l	13.5	37.0 l	258	10.6 l
✓	01/16/2021 08:43:47 PM	8.71	4.43 l	13.5 h	37.0 l	270 h	10.9
✓	01/16/2021 08:45:21 PM	8.72	4.38 l	13.6 h	36.7 l	258	10.7 l
✓	01/16/2021 08:46:55 PM	8.50 l	4.49 l	13.5	37.6 l	268 h	10.6 l