

## MX LABS H-5PD Auto Hematology Analyzer Calibration Certificate

<b>Customer Address:</b> <b>DEEPA FORTUNE IMAGING &amp; DIAGNOSTICS PVT LTD</b> D5/517, GROUND FLOOR, 5 <sup>TH</sup> MAIN ROAD ASHOK NAGAR, VIVEKANADHA ROAD CITY, MANDYA, KARNATAKA 571401.	Model :- <b>MX LABS H-5PD</b>	
	SN :- I15A00000092	Ins Date :- 05.05.2023
	Calibration Date :- 14.03.2024	
	Calibration Due Date :- 13.03.2025	

Software version Details			
Version	V1.3.1.4	MID Sof Ver.	V1.3.0.3
Component Ver. HG	HG:1.6	LM Sof Ver.	V1.3.1.2
TM	2.16	LS1 Sof Ver.	V1.1.0.1
FG	2.4	LS2 Sof Ver.	V1.1.0.1
UP Sof. Ver.	V1.3.1.4	LS3 Sof Ver.	V1.1.0.2

### 1 Safety Inspection

Item	Standard	Inspection Result	Result
Dielectric Strength	Metal case grounding withstand voltage: 1557V/2491V 50/60Hz, diachronic6S, should be no breakdown, Flashover, corona discharge	No breakdown, Flashover, corona discharge	PASS
Ground Resistance	≤0.1Ω	0.02Ω	PASS

### 2 Appearances, Structure Inspection

Item	Result	Item	Result	Item	Result
Surface Clean, No Scratch, No Painting drop.	PASS	Label Pasted Properly	PASS	Screws Inspection	PASS
Bottom Feet Fixed properly.	PASS	Mechanical Part Co-operating Properly	PASS	Machine inside cleanness	PASS
Bottom Working properly.	PASS	Sample Probe Surface, Open side direction	PASS	Ports, grounding ports inspection	PASS
Tubing Connector Fixed Properly	PASS	Power supply interface	PASS	Appearance Chinks inspection	PASS
Tubing Screen Fixed Properly	PASS	Production processes documentation	PASS	Computer SN	PASS



### 3 Functionality Inspections

Item	Result	Item	Result	Item	Result
Motor inspection	✓	Fan function inspection	✓	Computer hardware inspection	
Software installation	✓	Default parameter inspection	✓	Debug parameter inspection	✓
Power On/Off Inspection	✓	Liquid path perfusion inspection	✓	Reagent insufficient alarming inspection	✓
Waste liquid line inspection	✓	Sample probes position inspection	✓	Syringe moving inspection	✓
Sample probe moving inspection	✓	Waste liquid pump function inspection	✓	Valves function inspection	✓
Indicating lamp inspection	✓	Room temperature inspection	✓	DIFF chamber temperature inspection	✓
Indicating sound inspection	✓	CBC gain inspection	✓	Diff gain inspection	✓
Barcode scanning inspection	✓	Optical path particle quantity inspection	✓	External printer inspection	✓

### 4 Performance Inspections

Item		Standard	Test results			Max. Test result	Result			
1. Background	WBC	$\leq 0.2 \times 10^9/L$	0.05	0.02	0.04	0.05	PASS			
	RBC	$\leq 0.02 \times 10^{12} /L$	0	0	0	0	PASS			
	HGB	$\leq 1g/L$	0	0	0	0	PASS			
	HCT	$\leq 0.5\%$	0	0	0	0	PASS			
	PLT	$\leq 10 \times 10^9/L$	3	1	1	3	PASS			
2 Carryover	Item	Standard	H1	H2	H3	L1	L2	L3	Test Result	Result
	WBC	0.5	18.83	19.25	19.63	19.63	0.02	0.01	0.02	0.00
	RBC	0.5	5.84	5.29	5.32	5.32	0.00	0.00	0.00	0.00
	HGB	0.5	166	167	167	167	0	0	0	0.00
	PLT	1	474	493	493	514	4	1	0	0.78



Item	Standard	Test Results											CV (%)	Result
3 Repeatability	WBC	≤2.0	8.01	7.78	7.75	7.82	7.75	7.97	8	7.98	7.94	7.8	1.38	PASS
	RBC	≤1.5	5.19	5.18	5.16	5.14	5.18	5.21	5.23	5.17	5.18	5.16	0.50	PASS
	HGB	≤1.5	166	164	163	164	163	164	165	164	164	165	0.56	PASS
	MCV	≤1.0	92.3	91.8	91.9	91.5	91.6	91.5	91.5	91.7	91.3	91.2	0.35	PASS
	PLT	≤4.0	228	222	232	224	217	228	237	238	221	214	3.55	PASS
	MPV	≤4.0	9.1	9.3	9.3	9.2	9.3	9.3	9.2	9.6	9.3	9.4	1.43	PASS
	NEU%	NEU%	57.4	58.7	56.8	57.9	57.5	57.3	58.3	57.6	57.7	56.2	1.34	PASS
	LYM%	LYM%	37	35.5	37	35.9	36.6	37.1	35.3	36.4	35.8	37	1.06	PASS
	MON%	MON%	4.1	4.2	4.1	4.7	4.2	4.2	4.2	4.2	4.2	4.8	0.51	PASS
	EOS%	EOS%	1.2	1.4	2	1.4	1.5	1.3	1.8	1.5	1.8	1.7	0.44	PASS
	BAS%	BAS%	0.3	0.2	0.1	0.1	0.2	0.1	0.4	0.3	0.5	0.3	0.25	PASS

Item	Standard	Target value	CBC+Diff Mode Test Result	Mean Value	CV%	Result	
4 Comparability	WBC	≤±3%	4.64	4.73	4.71	1.51	PASS
				4.62			
				4.68			
				4.83			
				4.69			
	RBC	≤±2%	5.17	5.22	5.22	0.97	PASS
				5.29			
				5.18			
				5.22			
				5.19			
	HGB	≤±2%	155	158	157.80	1.81	PASS
				158			
				157			
				159			
				157			
	MCV	≤±2%	88.5	88.2	87.96	-0.61	PASS
				87.4			
				88.3			
				87.9			
				88			
PLT	≤±5%	208	213	212.20	2.02	PASS	
			220				
			212				
			207				
			209				



Sample No	NEU %											Result
	Testing results of standard analyzer				Acceptable Range		Testing results of inspecting analyzer					
	Test 1	Test 2	Test 3	Mean V.	Lower Limit	Upper limit	Test 1	Test 2	Test 3	Mean V.		
1	46.1	45.8	46.4	46.10	37.04	55.16	48.5	48.9	48.8	48.73	PASS	
2	58.5	58.2	58.8	58.50	49.55	67.45	61	60.5	60.1	60.53	PASS	
3	58.3	58.6	58	58.30	49.34	67.26	57.4	58.7	56.8	57.63	PASS	
Sample No	LYM %											Result
	Testing results of standard analyzer				Acceptable Range		Testing results of inspecting analyzer					
	Test 1	Test 2	Test 3	Mean V.	Lower Limit	Upper limit	Test 1	Test 2	Test 3	Mean V.		
1	43.1	42.5	43.7	43.10	34.10	52.10	40.7	39.8	41.1	40.53	PASS	
2	34.8	34.5	35.1	34.80	26.14	43.46	31.4	32.6	32.7	32.23	PASS	
3	35.8	35.6	36	35.80	27.09	44.51	37	35.5	37	36.50	PASS	
Sample No	MON%											Result
	Testing results of standard analyzer				Acceptable Range		Testing results of inspecting analyzer					
	Test 1	Test 2	Test 3	Mean V.	Lower Limit	Upper limit	Test 1	Test 2	Test 3	Mean V.		
1	5.9	5.4	6.4	5.90	1.62	10.18	4.8	4.5	5.1	4.80	PASS	
2	5.5	5.3	5.7	5.50	1.36	9.64	5.7	4.8	5.4	5.30	PASS	
3	4.5	4.8	4.2	4.50	0.73	8.27	4.1	4.2	4.1	4.13	PASS	
Sample No	ESO%											Result
	Testing results of standard analyzer				Acceptable Range		Testing results of inspecting analyzer					
	Test 1	Test 2	Test 3	Mean V.	Lower Limit	Upper limit	Test 1	Test 2	Test 3	Mean V.		
1	4.6	4.2	5	4.60	0.79	8.41	5.9	6.3	4.9	5.70	PASS	
2	0.9	0.5	1.3	0.90	0.00	2.62	1.8	2	1.7	1.83	PASS	
3	1.2	1	1.4	1.20	0.00	3.18	1.2	1.4	2	1.53	PASS	
Sample No	BAS%											Result
	Testing results of standard analyzer				Acceptable Range		Testing results of inspecting analyzer					
	Test 1	Test 2	Test 3	Mean V.	Lower Limit	Upper limit	Test 1	Test 2	Test 3	Mean V.		
1	0.3	0.2	0.4	0.30	0.00	1.29	0.1	0.5	0.1	0.23	PASS	
2	0.3	0.5	0.1	0.30	0.00	1.29	0.1	0.1	0.1	0.10	PASS	
3	0.2	0.2	0.2	0.20	0.00	1.01	0.3	0.2	0.1	0.20	PASS	

5. Precision





<b>6. Whole blood mode calibration coefficient</b>	WBC	101.88	RBC	106.57	HGB	123.62	PLT	162.65	MCV	89.57	MPV	112.1
<b>7. Pre Diluted Mode Calibration Certificate</b>	WBC	73.50	RBC	84.30	HGB	88.23	PLT	118.75	MCV	88.06	MPV	111.6
<b>8. Linearity (Random Inspection)</b>	<b>Item</b>	<b>Standard</b>	<b>Test point</b>	<b>Test 1</b>	<b>Test 2</b>	<b>Linearity result</b>	<b>Result</b>					
	<b>WBC</b>	(1.0~10.0) X10 <sup>9</sup> /L±0.5x10 <sup>9</sup> /L, (10.1~99.9) X10 <sup>9</sup> /L±0.5%	100%	97.24	97.05	0.8 %	PASS					
			80%	77.13	76.07	-0.7 %						
			60%	57.09	56.87	-1.6 %						
			40%	39.22	38.92	1.0 %						
			20%	19.84	19.49	1.0 %						
			10%	9.9	9.98	0.074						
	<b>RBC</b>	(0.3~1.0) X10 <sup>12</sup> /L±0.05x10 <sup>12</sup> /L (1.01~7.0) X10 <sup>12</sup> /L±0.5%	100%	6.66	6.69	1.2 %	PASS					
			80%	5.25	5.22	-0.7 %						
			60%	3.86	3.86	-2.3 %						
			40%	2.6	2.63	-0.4 %						
			20%	1.32	1.31	0.8 %						
			10%	0.67	0.66	0.022						
	<b>HGB</b>	20~70g/L±2 g/L 71~240g/L±0.3%	100%	239	239	1.1 %	PASS					
			80%	189	187	-0.6 %						
			60%	138	140	-2.0 %						
			40%	95	93	-0.6 %						
			20%	48	48	0.8						
			10%	24	25	0.9						
	<b>PLT</b>	(20~100) X10 <sup>9</sup> /L±10x10 <sup>9</sup> /L, 101~999X10 <sup>9</sup> /L±10%	100%	981	994	0.3 %	PASS					
			80%	790	795	0.7 %						
			60%	567	584	-2.3 %						
			40%	406	380	0.4 %						
			20%	188	196	-0.9 %						
10%			97	92	-0.5							



## 5 Other inspection before packing

Item	Result	Item	Result	Item	Result
Background	✓	Perform Probe Cleanser Soak	✓	Liquid path perfusion	✓
Original data export	✓	Parameters back-up	✓	Perform analyzer draining	✓
Data delete	✓	Optional functions setting	✓	User management setting	✓

## 6 Packing inspection

Item	Standard	Result
Packing	Conformed with FQC inspection Spec(V1.0)	✓

## 7 Equipment/Reagents used for Inspection

Equipment			Reagents				
Withstand voltage Meter	Code	WMQ014	Calibrator	Lot No.	E5173-1	W-6LD Lyse	211018
Ground resistance Meter		WMQ015	Normal value QC		E5173-2	W-6LH Lyse	211005
Pipette 1		WMQ008	High value QC		E5173-2	W-6D Diluents	211018
Pipette 2		WMQ009					

## 8 Whole Machine Evaluations:

Qualified       Unqualified

**Checked By:**

**Name: - PRADEEP N**

**Designation: - ENGINEER – CUSTOMER SUPPORT**

**Signature: -**

**Date: - 05.05.2023**

*N. Pradeep*

**Approved By:**

**Name:-**

**Signature: -**

**Date: -**