

CALIBRATION CERTIFICATE

Certificate no. 0106

Customer: LIKHITHA DIAGNOSTICS
Ecil,hyderabad

Date of Calibration: 30-10-2021
Working Temperature: $25^{\circ} \pm 1^{\circ}$
Due Date: 29-10-2022

Instrument: Automated 3 Part Haematology Analyzer Serial no. DM10011813072.

Model: "DH 36"

Manufacturer: SHENZHEN DYMIND BIOTECHNOLOGY CO. LTD.

Acu Medica Lab Systems Pvt. Limited is an organization dealing with Dymind Auto Haematology Analyzer. It has a technically qualified Technical team to ensure trouble free operation. The Described instrument has been checked and calibrated under the ambient conditions stated above.

Power Supply			
UPS Supply	Expected Reading	Measured Reading	Remarks
Phase to Neutral	230 ± 10 VAC	232 VAC	Within Limits
Phase to Earth	230 ± 10 VAC	234 VAC	
Neutral to Earth	0 - 5 VAC	2 VAC	

Test Point Voltages	Measured Reading	Remarks
5 ± 0.15 VDC	5.0 VDC	Values are within Limits
12 ± 0.25 VDC	11.52 VDC	
-12 ± 0.25 VDC	-11.71 VDC	
56 ± 6.0 VDC	55.60 VDC	
3.3 ± 0.13 VDC	3.26 VDC	

	Measured Value	Range	Remarks
HGB Zero (V)	0.0	0.0 – 0.20	Within Range
HGB Blank (V)	4.56	3.4 – 4.8	
Vacuum	184	175 – 205	

Test Point Voltages	Status	Remarks
Pressure	Normal	All Parts are working well & Adjustment not required.
Vacuum	Normal	
Filter	Normal	
Syringe Motor Check	Normal	
Rotation Motor Check	Normal	
Elevator Motor Check	Normal	
Printer/Recorder Check	Normal	

	Status	Remarks
System Initialization	Okay	Working Well.
Key Board Check	Okay	
Display Check	Okay	

Acu Medica Lab Systems (P) Ltd.

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Parameters Tested	Target Values	Acceptable Range	Units
White Blood Cells (WBC)	9.10	± 0.20	$10^3/\mu\text{L}$
Red Blood Cells (RBC)	4.73	± 0.08	$10^6/\mu\text{L}$
Haemoglobin (HGB)	13.5	± 0.20	g / dL
Mean Cell Volume (MCV)	91.8	± 2.0	fL
Platelet (PLT)	254	± 12	$10^3/\mu\text{L}$

This Instrument and the above measuring parameters are calibrated with R & D Systems Inc. **CBC-CAL PLUS** Haematology Calibrator. Lot no. PLUS1121 Exp. Date : 5/12/2021 The estimated uncertainty to be associated with the results is at a confidence level of approximately 99%.

REMARKS/DEVIATIONS IF ANY:

1. The calibration interval should be determined based on the user's requirements.
2. The user should be determining the stability of the instrument for its intended use.
3. The results stated in this certificate related only to the instrument calibrated.

Calibrated By:




UPPUTHOLLA ANKARAO
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Traceability

CBC-CAL PLUS Hematology Calibrator

DYMIND CBC-CAL PLUS Hematology Calibrator, manufactured by R&D Systems Inc., is traceable to standard reference methods.

Hematology analyzers in R&D Systems' Quality Assurance Laboratory are whole blood calibrated to values obtained using these standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

WBC: A 1:500 dilution is prepared using a 100 mL Class A volumetric flask filled with isotonic diluent. 1.2 mL of diluent is removed. Sample is added to the flask using a 200 µL calibrated positive displacement pipette, followed by 1.0 mL lysing agent. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

RBC: A 1:50,000 dilution is prepared using a 1000 mL Class A volumetric flask filled with isotonic diluent. Sample is added to the flask using a 20 µL T.C. micropipet. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

HGB: A 1:251 dilution is prepared using a 50 mL Class A volumetric flask filled with the CLSI recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method (1). Sample is added to the flask using a 200 µL calibrated positive displacement pipette. The sample is filtered with a 0.2 µm filter immediately before reading. Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations (1).

HCT: Plain glass microhematocrit tubes (not coated with anticoagulant) are filled with sample, sealed with sealing putty and centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H07-A3 document (2). After centrifugation, the length of the whole column including the plasma, and the length of the red blood cell column, are viewed and measured using a microscope with graduated stage and an ocular micrometer. The hematocrit (packed cell volume) is calculated as the ratio of the two measurements. No correction is made for trapped plasma.

MCV: On some instruments MCV is the calibrated parameter instead of the HCT. The MCV is calculated from the HCT and RBC using the formula: $MCV = HCT \times 10/RBC$

PLT: A 1:126 dilution is prepared using a 50 mL Class A volumetric flask filled with filtered 1% ammonium oxalate. Sample is added to the flask using a 400 µL calibrated positive displacement pipette. The dilution is plated onto a clean, dry Neubauer ruled phase type hemocytometer. The hemocytometer is left for 10 minutes in a humidified chamber. Using phase contrast optics, the platelets in the entire central square millimeter on both sides of the hemocytometer are counted. The two counts are averaged and multiplied by 1260 (dilution factor 126 × volume factor 10 = 1260).

BIBLIOGRAPHY

1. Clinical Laboratory Standards Institute. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood: Approved Standard-Third Edition. CLSI document H15-A3.
2. Clinical Laboratory Standards Institute. Procedure for Determining Packed Cell Volume by the Microhematocrit Method: Approved Standard-Third Edition. CLSI document H07-A3.

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CBC-CAL

HEMATOLOGY CALIBRATOR

Assay values and ranges provided by DYMIND

CALIBRATOR

LOT PLUS1121

2021-10-07

2021-12-05

Instrument	Parameter	Unit	Reference Value	Deviation
DH31, DH33, DH36 (Technical File Version A5.0 or higher) DH31Vet, DH36Vet (Technical File Version A1.0 to A4.0)	WBC	$\times 10^9/L$	9.10	± 0.20
	RBC	$\times 10^{12}/L$	4.73	± 0.08
	HGB	g/L	135	± 2
	MCV	fL	91.8	± 2.0
	PLT	$\times 10^9/L$	254	± 12
DH20, DH21, DH22 DH23, DH25, DH26 (Technical File Version A1.0 or higher)	WBC	$\times 10^9/L$	9.10	± 0.20
	RBC	$\times 10^{12}/L$	4.68	± 0.08
	HGB	g/L	135	± 2
	MCV	fL	84.8	± 2.0
	PLT	$\times 10^9/L$	259	± 12
DH31Vet, DH36Vet (Technical File Version A5.0 or higher)	WBC	$\times 10^9/L$	9.26	± 0.20
	RBC	$\times 10^{12}/L$	4.62	± 0.08
	HGB	g/L	134	± 2
	MCV	fL	93.7	± 2.0
	PLT	$\times 10^9/L$	256	± 12
DH36X (Technical File Version A1.0 or higher)	WBC	$\times 10^9/L$	9.37	± 0.20
	RBC	$\times 10^{12}/L$	4.65	± 0.08
	HGB	g/L	133	± 2
	MCV	fL	88.3	± 2.0
	PLT	$\times 10^9/L$	250	± 12

【NOTE】

1. The calibrator should be stored in refrigerator (2°C~8°C). After opening, it will keep stable for 7 days when it is stored airtight at 2°C~8°C.
2. Before mixing and running the calibrator after take it out from the refrigerator, please keep it at least 15 minutes until reaching room temperature(15°C~30°C).
3. Calibrator must be well mixed before using. Please mix gently, to avoid cells rupture and/or generating bubbles.
4. After using, put the calibrator back into the refrigerator to prevent contamination and evaporation.

CBC-3D

HEMATOLOGY CONTROL

Assay values and ranges provided by DYMIND

CONTROL

LOT B0821

2021-07-09

2021-11-05

Instrument	Parameter	Unit	Low		Normal		High	
DYMIND DH31 DH33 DH36 (Technical File Version A5.0 or higher) DH36Vet Technical File Version A1.0 to A4.0)	WBC	×10 ⁹ /L	2.12	±0.60	7.97	±1.00	21.20	±2.50
	Lym%	%	59.4	±9.0	31.9	±8.0	14.8	±8.0
	Gran%	%	29.0	±9.0	61.9	±8.0	82.1	±8.0
	Mid%	%	11.6	±10.0	6.2	±6.0	3.1	±3.1
	Lym#	×10 ⁹ /L	1.26	±0.30	2.54	±0.70	3.14	±2.00
	Gran#	×10 ⁹ /L	0.62	±0.30	4.93	±0.70	17.40	±2.00
	Mid#	×10 ⁹ /L	0.25	±0.20	0.49	±0.49	0.66	±0.50
	RBC	×10 ¹² /L	2.42	±0.24	4.89	±0.24	6.13	±0.30
	HGB	g/L	58	±6	137	±6	192	±8
	HCT	%	18.6	±2.0	43.5	±3.0	59.7	±4.0
	MCV	fL	76.7	±5.0	88.8	±5.0	97.4	±5.0
	MCH	pg	23.8	±2.5	28.0	±2.5	31.3	±2.5
	MCHC	g/L	310	±30	315	±30	322	±30
	RDW-CV	%	15.2	±3.0	14.7	±3.0	13.9	±3.0
	RDW-SD	fL	47.0	±8.0	52.6	±8.0	54.6	±8.0
	PLT	×10 ⁹ /L	71	±20	268	±40	524	±60
	MPV	fL	9.1	±3.0	9.4	±3.0	9.4	±3.0
	PDW	/	16.0	±3.0	16.2	±3.0	16.4	±3.0
	PDW	fL	11.5	±3.0	12.0	±3.0	12.3	±3.0
	PCT	%	0.066	±0.066	0.255	±0.200	0.505	±0.200
P-LCR	%	21.9	±10.0	23.1	±10.0	24.1	±10.0	
P-LCC	×10 ⁹ /L	16	±15	63	±25	129	±30	

【NOTE】

1. The controls should be stored in refrigerator (2~8℃). After opening, it will keep stable for 14 days when it is stored airtight at 2~8℃.
2. Before mixing and running the control after take it out from the refrigerator, please keep it at least 15 minutes until reaching room temperature(15~30℃).
3. Controls must be well mixed before using. Please mix gently, to avoid cells rupture and/or generating bubbles.
4. After using, put the controls back into the refrigerator to prevent contamination and evaporation.

