



Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



ISO 9001:2015
CERTIFIED COMPANY


Calibration Certificate

Customer Name	M/s Sanjeevani Laboratory
Address	C/o Shinde Hospital, Nizampur Road, Mangaon, Raigad, Maharashtra- 402104.
Contact Person	Mr. Sagar Sawant
Contact No.	+918605337888
Instrument	Mindray Hematology Cell Counter
Model	BC-5000
Serial No.	SS-65002711
Instrument Status	Out of Warranty (Service against Chargeable Call)
Calibration Done On	16.11.2022
Next Calibration Due On	15.11.2023

for Aspen Diagnostic Pvt. Ltd.

Arvind Singh
Service Engineer
(Mumbai)




Rajaram Krishnamurthy
National Service Manager



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CALIBRATOR DATA

Instrument : 5 Part Hematology Analyzer		Model : BC- 5000		Serial No. SS-65002711		Date Of cal. 16.11.2022	
Mode: OV-WB		Calibrator Lot No.PLUS1122				Exp.Date: 05.12.2022	
Parameter	WBC	RBC	HGB	MCV	PLT		
Target	9.06	4.54	13.2	88.1	249		
1	8.01	3.85	10.9	84.2	229		
2	8.32	3.89	11.0	83.7	238		
3	8.15	3.89	10.9	83.9	222		
4	8.37	3.90	10.9	83.3	225		
5	8.27	3.87	10.9	83.4	230		
6	8.27	3.93	10.9	83.3	228		
7	8.52	4.10	12.2	82.0	245		
8	8.42	4.12	12.1	82.1	236		
9	8.48	4.10	12.2	82.1	239		
10	8.45	4.12	12.1	81.6	241		
11	8.67	4.09	12.2	81.9	245		
12	8.37	4.10	12.1	81.8	229		
CBC Mean	8.23	3.89	10.9	83.6	229		
CBC-CV%	1.6	0.7	0.4	0.5	2.3		
Diff- Mean	8.49	4.10	12.2	81.9	24.2		
Diff-CV%	1.2	0.3	0.4	0.3	1.4		
New Factor (%)	110.06	116.74	120.94	105.34	108.82		
Transfer Factors	97.00	94.77	89.75	102.06	94.72		

for Aspen Diagnostic Pvt. Ltd.

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**BC-5000 Mindray Hematology Analyzer
(5-Part Differential Fully Automated Cell Counter)**

**Installation Qualification
Operational Qualification
Performance Qualification
(IQ/OQ/PQ)**

(M/s Sanjeevani Laboratory.)

**Address: C/o Shinde Hospital, Nizampur Road,
Mangaon, Raigad, Maharashtra- 402104.**

**By: M/s. Aspen Diagnostics Pvt. Ltd.
Mumbai.**





CERTIFICATE OF INSTALLATION

Instrument Name : BC-5000 Mindray Hematology Cell Counter
Serial Number : SS-65002711
Customer Name : M/s. Sanjeevani Laboratory.
Address : C/o Shinde Hospital, Nizampur Road, Mangaon, Raigad
Maharashtra. Pin: 402104

The undersigned performers certify that the Installation Qualification Protocol has been successfully completed for the instrument stated above.

Service & Application Engineer:-

Signature :

Name : Mr. Nitin Hanchate
Designation : Senior Service & Application Engineer
Company : M/s. Aspen Diagnostics Pvt. Ltd.
Place : Navi Mumbai

Quality Manager

Signature :

Name : Mr. Sagar Sawant
Designation : Laboratory Incharge
Institution : M/s. Sanjeevani Laboratory
Place : Mangaon

Lab Incharge : Mr. Sagar Sawant

Sanjeevani Laboratory
Nizampur Road
Mangaon Raigad
Phone:02140-262199



INSTALLATION REPORT

Customer Name : M/s. Sanjeevani Laboratory
Address : C/o Shinde Hospital, Nizampur Road, Mangaon, Raigad
Maharashtra. Pin: 402104
Department : Pathology Laboratory
Contact Person : Mr. Sagar Sawant - Lab Incharge
Instrument Name : BC-5000 Mindray Hematology Analyzer
Serial Number : SS-65002711

(The Analyzer was installed along with the necessary standard accessories. All basic requirements and adjustments were checked and are found to be satisfactory. The preliminary standardization of the analyzer and the training were provided to the complete satisfaction of the customer. The analyzer is found to be working satisfactorily.)

For Aspen Diagnostics Pvt. Ltd.

For Sanjeevani Laboratory

Mr. Nitin Hanchate
Sr. Service & Application Eng.
Mobile: 9920057820
E-mail id: nitin@rdgc.in
Place: Navi Mumbai

Mr. Sagar Sawant.
Lab Incharge
Mob: 8605337888
E-mail id: sanjeevanipathlab@gmail.com
Place: Mangaon



Sanjeevani Laboratory
Nizampur Road
Mangaon Raigad
Phone: 02140-262199



INSTALLATION QUALIFICATION

IQ PROTOCOL

1. System Unpacking
2. System Checking For any Damages
3. All accessories as per check List verification
4. Space Requirement
5. Power Requirement
6. Reagents, Control, Calibrators verification.

1. SYSTEM UNPACKING&2. SYSTEM CHECKING

Unpacked the instrument carefully and checked for any physical Damages. It was found to be perfectly OK.

3. ACCESSORIES CHECK-

Checked all accessories as per check List

4. SPACE REQUIREMENT-

Checked site for proper space allocation. At least 100 CM on each side and enough room on below the countertop to accommodate the reagents & pneumatic unit and waste containers.





DIMENSIONS	
Parameter	Analyzer OV
Width mm	320
Depth mm	400
Height mm	410
Weight Kg	24

5. POWER REQUIREMENT –

Requirement	Acceptable Range	Observed Ranged
Input Voltage	220 + / - 10 V	226 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C – 30 C	24.0 C

6. REAGENTS, CONTROLS, CALIBRATOR CHECK-

Name	Check	Remark
Diluent BC5000	Pass	Ok
Diff. Lyse BC5000	Pass	Ok
LH Lyse BC5000	Pass	Ok
Probe Cleanser	Pass	Ok

PRE-INSTALLTION VERIFICATION REPORT:-

PRE-INSTALLATION VERIFICATION REPORT		
S/N	Parameters	Remarks
1	Unpacking Instrument	Ok
2	System Checking for damages	Ok
3	Accessories check	Ok
4	Space Check	Ok
5	Power Check	Ok
6	Reagents Check	Ok



OPERATIONAL QUALIFICATION

The Operational Qualification procedure specifies the methodology for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

OQ PROTOCOL

1. System Connections
2. Reagent & Waste Connections
3. Customizing the Analyzer Software
4. System Booting , Initialization & Check
5. Maintenance procedures.
6. Customer Training – Operation & Maintenance.

1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/N.	Name	Check	Remark
1	Input Power supply	Connect	Ok
2.	PC & Peripherals	Installed	Ok
3.	Printer Connection	Installed	Ok
4.	Barcode Scanner	Installed	Ok

2. REAGENT & WASTE CONNECTIONS:

Installed the reagent & waste connections as mentioned in the manual and colour coding available on instrument's rear panel.



3. CUSTOMIZING ANALYZER SOFTWARE –

Customizing Analyzer Software			
S/N	Parameters	Check	Remark
1	Date & Time	Operating Manual 5.2.1	Ok
2	Reagents	Operating Manual 5.2.1	Ok
3	Reference Ranges	Operating Manual 5.3.1	Ok
4	Reference Units	Operating Manual 5.3.1	Ok
5	Printing format	Operating Manual 5.3.1	Ok
6	Creating New User Accounts	Operating Manual 5.3.2	Ok

4. SYSTEM BOOTING, INITIALIZATION & Check -

Power ON System and check instrument Initialization successfully.

Checked the following Parameters.

TEMPERATURES & PRESSURES				
S/N	Parameters	Actual	Range	Remark
1	Preheat Bath	40.5	30 to 50	Pass Ok
2	Reaction Bath	36.9	30 to 45	Pass Ok
3	Ambience	25.4	15 to 35	Pass Ok
4	Laser Diode	35.9	15 to 45	Pass Ok



05. MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Operator Manual 10.2	Ok
2	Replacing Priming Reagents	Operator Manual 10.2.1	Ok
3	Cleaning	Operator Manual 10.2.2	Ok
4	Maintenance	Operator Manual 10.2.3	Ok
5	Overall Maintenance	Operator Manual 10.2.4	Ok
6	Version Information	Operator Manual 10.3.1	Ok
7	Temperature & Pressure	Operator Manual 10.3.2	Ok
8	Touch Screen Calibration	Operator Manual 10.4.4	Ok

For Aspen Diagnostics Pvt. Ltd.

For Sanjeevani Laboratory

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Place: Mangaon



PERFORMANCE QUALIFICATION

1. Normal Level Control

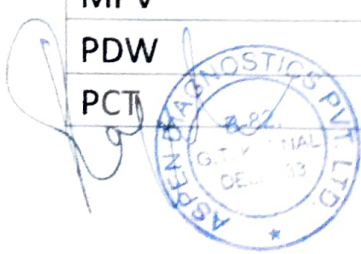
Normal Control	Lot No.BC2211BN	Exp.2023-01-10	Mode-OV/WB
Test Item	Result	Unit	Ref.Range
WBC	8.09	10 ⁹ /L	7.42-8.42
Neutrophils #	4.41	10 ⁹ /L	4.41-5.21
Lymphocyte #	2.27	10 ⁹ /L	1.73-2.33
Monocyte #	0.66	10 ⁹ /L	0.19-0.67
Eosinophil #	0.61	10 ⁹ /L	0.39-0.71
Basophil #	0.12	10 ⁹ /L	0.07-0.13
Neutrophils %	54.5	%	48.8-72.8
Lymphocyte %	28.1	%	16.6-34.6
Monocyte %	8.4	%	-2-12.8
Eosinophil %	7.5	%	2.1-11.9
Basophil %	1.5	%	0.2-2.2
RBC	4.34	10 ¹² /L	4.03-4.39
Hemoglobin	12.8	g/dL	12-12.8
HCT	40.2	%	37.4-40.4
MCV	92.8	fL	87.3-97.3
MCH	31.9	pg	27-32
MCHC	32	g/dL	31.6-32.2
RDW CV	16	%	14.4-20.4
RDW SD	54.2	fL	50.4-66.4
Platelet	260	10 ⁹ /L	229-269
MPV	11.4	fL	8.3-14.3
PDW	16.1		13.5-19.5
PCT	0.296	%	0.231-0.331





2. High Level Control

High Control	Lot No. BC2211BH	Exp. 10/01/2023	Mode-OV/WB
Test Item	Result	Unit	Ref. Range
WBC	17.68	10 ⁹ /L	14.32-19.32
Neutrophils #	10.88	10 ⁹ /L	9-13.04
Lymphocyte #	3.2	10 ⁹ /L	1.68-4.04
Monocyte #	1.62	10 ⁹ /L	0-1.98
Eosinophil #	1.69	10 ⁹ /L	0-3.3
Basophil #	0.29	10 ⁹ /L	0-0.6
Neutrophils %	61.5	%	53.5-77.5
Lymphocyte %	18.1	%	10-24
Monocyte %	9.2	%	0-11.8
Eosinophil %	9.6	%	0-19.6
Basophil %	1.6	%	0-3.6
RBC	5.17	10 ¹² /L	4.63-5.23
Hemoglobin	16.5	g/dL	15.4-17
HCT	51.9	%	48.2-53
MCV	100.1	fL	97.6-107.6
MCH	31.8	pg	30.4-35.4
MCHC	32	g/dL	31.7-32.3
RDW CV	15.5	%	12.9-18.9
RDW SD	57.1	fL	51.6-67.6
Platelet	530	10 ⁹ /L	443-563
MPV	11.3	fL	8.1-14.1
PDW	16.5		13.3-19.3
PCT	0.599	%	0.358-0.758





3. Low Level Control

Low Control	Lot No. BC2211BL	Exp. 10/01/2023	Mode-OV/WB
Test Item	Result	Unit	Ref. Range
WBC	3.56	10 ⁹ /L	2.77-3.77
Neutrophils #	1.9	10 ⁹ /L	1.33-2.13
Lymphocyte #	1.25	10 ⁹ /L	0.81-1.41
Monocyte #	0.28	10 ⁹ /L	0-0.48
Eosinophil #	0.11	10 ⁹ /L	0-0.32
Basophil #	0.02	10 ⁹ /L	0-0.06
Neutrophils %	53.3	%	40.9-64.9
Lymphocyte %	34.9	%	24.8-42.8
Monocyte %	8.1	%	0-14.8
Eosinophil %	3.2	%	0-9.8
Basophil %	0.5	%	0-2
RBC	2.16	10 ¹² /L	1.8-2.16
Hemoglobin	5.4	g/dL	4.9-5.7
HCT	17.6	%	15-18
MCV	84.6	fL	78.3-88.3
MCH	29	pg	24.3-29.3
MCHC	35	g/dL	29.1-35.1
RDW CV	19.8	%	15.7-21.7
RDW SD	56.2	fL	48-64
Platelet	41	10 ⁹ /L	28-68
MPV	10.9	fL	7.4-13.4
PDW	15.2		12.5-18.5
PCT	0.045	%	0-0.1





NORMAL BACKGROUND CHECK

S/No.	Parameter	Actual	Remark	Remark
1	WBC	0.02	<.20	Ok
2	RBC	0.00	<.02	Ok
3	HGB	0.00	<1	Ok
4	PLT	0.0	<10	Ok

REPRODUCIBILITY CHECK

S/N	Parameter	Actual	Range CV%	Remark
1	WBC	2.12	2.5	Pass
2	RBC	0.77	1.5	Pass
3	HGB	0.47	1.5	Pass
4	MCV	0.18	1	Pass
5	PLT	3.32	6	Pass





CARRYOVER CHECK

Parameter	WBC	RBC	HGB	HCT	PLT
High Level-1	17.62	4.93	16	50.1	510
High Level-2	17.48	4.92	16	50.1	500
High Level-3	17.49	4.92	15.8	50.1	505
Low Level-1	3.53	1.9	5.2	16.8	59
Low Level-2	3.6	1.94	5.3	17.2	62
Low Level-3	3.58	1.95	5.3	17.3	62
Carryover %	-0.40%	-1.70%	-1.00%	-1.50%	-0.70%
Limit %	≤0.5%	≤0.5%	≤0.6%	≤1%	≤1.0%

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