



## Calibration Certificate

Date – 20<sup>th</sup>OCT, 2023

Name & Address of the customer	Shiv Diagnostics at Near Spectrum Mall Court Road, Kashipur, Uttarakhand-244713.
Make	Mindray
Product Name	BC-5130 – Auto Hematology Analyzer
Serial No.	TR-81000446

This is to certify that the cell counter installed at the above mentioned customer site has been calibrated with SC-CAL Plus Calibrator 3 MI (Lot No.: PLUS0923 & Expiry date: 2023-12-11)

Sr. No.	Procedures	Parameter	Remarks
1	Startup	WBC/ RBC/ HGB/ PLT	PASS
2	Reproducibility	WBC/ RBC/ HGB/ MCV/ PLT/ MPV	PASS
3	QC Trilevel	WBC/ RBC/ HGB/ MCV/ PLT/ MPV	PASS
4	Calibration	WBC/ RBC/ HGB/ MCV/ PLT/ MPV	PASS

Date of Calibration : 20-OCT-23	Next Calibration due on : 19-OCT-24
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**Certificate of Quality Control**

Instrument Name: BC5130  
Serial Number: TR-81000446  
Customer Name: Shiv Diagnostics  
Address: near spectrum mall court road kashipur-244713

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE INSTALLATION QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

**ENGINEER**

Signature :  
Name : Vishnu Sharma  
Designation : Sr. Service Engineer  
Company : Star Biomed Private Limited

**LABORATORY**

Signature :  
Name : Dr. Bharat Bhushan  
Designation : Director  
Organization : Shiv Diagnostics





***STAR BIOMED PVT. LTD.***

**BC-5130 Hematology Analyzer  
(5part Differential Fully Automated Analyzer)**

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

**Shiv Diagnostics.**

**By: Star Biomed Pvt. Ltd.**

**CERTIFICATE OF INSTALLATION**

**Instrument Name : BC-5130**

**Serial Number : TR-81000446**

**Customer Name : Shiv Diagnostics**

**Address : near spectrum mall court road kashipur-  
244713**





## ***STAR BIOMED PVT. LTD.***

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

### **Service Engineer**

Signature :  
Name : Vishnu Sharma  
Company : Star Biomed Pvt. Ltd.

### **Quality Manager**

Signature:  
Name : Mr. Manoj Shroff  
Designation : Senior Service Manager  
Institution : Star Biomed Pvt. Ltd.







**INSTALLATION REPORT**

**Customer Name** : Star Biomed Pvt. Ltd.  
**Place** : Kashipur ,Uttarakhand  
**Department** : Hospital  
**Contact Person** : Dr. Bharat Bhushan  
**Instrument Name** : BC-5130  
**Serial Number** : TR-81000446  
**Date of Installation** : 19/10/2023

(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 Star Biomed Pvt. Ltd.**

Service Manager





## **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.





<b>DIMENSIONS</b>	
<b>Parameter</b>	<b>Analyzer OV</b>
Width mm	320
Depth mm	400
Height mm	410
Weight Kg	24

**5. POWER REQUIREMENT –**

<b>Requirement</b>	<b>Acceptable Range</b>	<b>Observed Ranged</b>
Input Voltage	220 + / - 10 V	223 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C – 30 C	23 C

**6. REAGENTS , CONTROLS , CALIBRATOR CHECK-**

<b>Name</b>	<b>Check</b>	<b>Remark</b>
Diluent BC5130	Ok	-
Diff. Lyse BC5130	Ok	-
LH Lyse BC5130	Ok	-
Probe Cleanser	Ok	-







**PRE-INSTALLTION VERIFICATION REPORT :-**

<b>PRE-INSTALLATION VERIFICATION REPORT</b>		
<b>S/N</b>	<b>Parameters</b>	<b>Remarks</b>
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**







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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

## 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.**

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

**05. MAINTENANCE PROCEDURES:-**

<b>MAINTENANCE</b>
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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







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## PERFORMANCE QUALIFICATION-

Test Item	Result	Unit	Ref.Range
WBC	11.67	10 <sup>9</sup> /L	17.17+/-2.50

Neu#	7.94	10 <sup>9</sup> /L	10.44+/-2.06
Lym#	2.85	10 <sup>9</sup> /L	3.14+/-1.21
Mon#	0.87	10 <sup>9</sup> /L	1.56+/-1.56
Eos#	0.01	10 <sup>9</sup> /L	1.70+/-1.70
Bas#	0.00	10 <sup>9</sup> /L	0.31+/-0.31
Neu%	0.651	%	60.9+/-12.0
Lym%	0.244	%	18.3+/-7.0
Mon%	0.074	%	9.1+/-9.1
Eos%	0.001	%	9.9+/-9.9
Bas%	0.000	%	1.8+/-1.8

### NORMAL BACKGROUND CHECK

S/No.	Parameter	Actual	Remark	Remark
1	WBC	0.1	<.20	Ok
2	RBC	0.00	<.02	Ok
3	HGB	0.00	<1	Ok
4	PLT	0.0	<10	Ok







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<b>REPRODUCIBILITY CHECK</b>				
<b>S/N</b>	<b>Parameter</b>	<b>Actual</b>	<b>Range CV%</b>	<b>Remark</b>
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

**For Star Biomed Pvt. Ltd.**

Service Manager

