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CALIBRATION CERTIFICATE

Customer Name	***Shree Raksha Labs pvt ltd-Bangalore***		
Department	Department of Haematology-Laboratory Medicine		
Address	No:#46,17th cross ,Malleshwaram,Bangalore-560055		
		Date of Calibration	27.07.2022
Instrument	*Mindray BC-5130 ANALYZER*	**Next Calibration Date**	26.07.2023
Serial No	TR-21006640	**Calibrator Lot Number**	PLUS0722
		Calibrator Expiry date	05.08.2022

	Parameter	***Target***	***Range***	***Mean of Measured Values***	***New Factor***	***Old Factor***
Calibration Values	**WBC x 10^3/L**	9.04	8.84-9.24	8.84	102.23	100.00
	RBC x10^{12}/L	4.57	4.49-4.65	4.39	104.08	100.00
	HGB g/L	13.5	13.3-13.7	13.3	101.45	100.00
	MCV fl	89.4	87.4-91.4	90.3	99.03	100.00
	PLT x 10^3/L	254	242-266	244	104.04	100.00

This is to certify that the Mindray BC 5130 Hematology Analayzer Sr.No: TR-21006640system, installed at Shree Raksha Labs Pvt Ltd , Bangalore has been calibrated using the standard reference material SC CAL PLUS-0522 Calibrator. Traceablity of SC CAL PLUS Calibrator material from the manufacturer is attached along with this certificate.

Application Specialist-IVD Date:27.07.2022
Mindray Medical India Pvt.Ltd

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Address	No:#46,17th cross ,Malleshwaram,Bangalore-560055		
		Date of Calibration	27.07.2022
Instrument	*Mindray BC-5130 ANALYZER*	**Next Calibration Date**	26.07.2023
Serial No	TR-21006640	**Calibrator Lot Number**	PLUS0722
		Calibrator Expiry date	05.08.2022

	Parameter	***Target***	***Range***	***Mean of Measured Values***	***New Factor***	***Old Factor***
Calibration Values	**WBC x 10^9/L**	9.04	8.84-9.24	8.84	102.23	100.00
	RBC x10^{12}/L	4.57	4.49-4.65	4.39	104.08	100.00
	HGB g/L	13.5	13.3-13.7	13.3	101.45	100.00
	MCV fl	89.4	87.4-91.4	90.3	99.03	100.00
	PLT x 10^9/L	254	242-266	244	104.04	100.00

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Application Specialist-IVD Date:27.07.2022
Mindray Medical India Pvt.Ltd

PERFORMANCE QUALIFICATION

BC 5130

AUTOMATED HAEMATOLOGY

ANALYSER

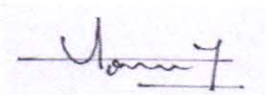
INSTALLED AT SHREE RAKSHA LABS PVT LTD
No:#46,17th Cross, Malleswaram, Bangalore, Karnataka- 560055

Type of Instrument:	
Module.	**Serial No**
BC-5130	TR-21006640

PERFORMANCE QUALIFICATION VERIFICATION REPORT

This is to certify that the following checks mentioned in the performance verification protocol have been performed and found to be satisfactory.

PERFORMANCE VERIFICATION		
1	BACKGROUND	**PASS**
2	PRECISION (REPRODUCIBILITY) CHECK	**PASS**
3	CARRY OVER	**PASS**
4	CALIBRATION	**PASS**



Representative Signature

Date:14.09.2022

Customer Signature

Date:

Performance Specifications

The following performance specifications apply to systems that have been installed and maintained according to the guidelines in this manual and are operated with the recommended reagents and supplies. Specifications listed apply to all modes and test selections. System performance is expected to meet or exceed the specifications listed.

Checking before Calibration

Background

Background concentrations represent apparent sample-related constituents that actually originate from blood-free reagents and/or electronic "noise." The background concentrations are used to confirm the System's baseline performance, where no actual sample is aspirated. The following table lists acceptable background concentration limits that must be met before using the instrument.

Before calibration, make sure the background (blank count) results, repeatability results and carryover results are all within the specified ranges.

Background/blank count requirements for blood samples

Parameters	**Acceptable range**
WBC	$\leq 0.2 \quad 10^9$ / L
RBC	$\leq 0.02\ 10^{12}$ / L
HGB	≤ 1 g / L
PLT	$\leq 10 \quad 10^9$ / L

Precision (Reproducibility)

Precision refers to the closeness of two or more measurements to each other.

Imprecision is the standard deviation (SD) or coefficient of variation (%CV) of analytic results in a set of replicate measurements. Fresh whole blood specimens used to verify imprecision specifications should have mean values that fall within the range tested in the following table and should not display any Suspect Parameter flags for the measurand (parameter) studied.

Whole blood sample repeatability requirements (calibration parameters)

Parameters	**Measuring range Whole Blood**	**Repeatability CV%**
WBC	$\geq 4.0 \times 10^9$/L	≤2.5%
RBC	$\geq 3.5 \times 10^{12}$/L	≤1.5%
HGB	(110-180)g/L	≤1.5%
MCV	(70-120)fL	\≤1.0%
PLT	$\geq 150 \times 10^9$/L	≤4.0%

Carryover

"Carryover" in laboratory testing, is defined as "the contamination of a specimen by the previous one". Carryover testing is performed to help to prove or disprove carryover from the sample probe in clinical laboratory testing.

Carryover requirements for blood sample analysis

Measurement Parameters	**Carryover**
WBC	≤0.5
RBC	≤0.5
HGB	≤0.6%
HCT	≤0.5%
PLT	≤1.0%

****Appendix*

Performance Verification results

PERFORMANCE QUALIFICATION

SYSTEM CERTIFICATION

Study data has determined that the system described in this document meets all criteria outlined in this Performance Qualification protocol. All exceptional conditions if any have been addressed. The system is ready for specified usage.

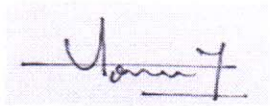
Protocol performed by: **Mindray Representative**

Name: ARUNKUMAR PJ
Title: ASST APPLICATION MANAGER

Customer Authorization:

Name: .....

Title: .....



Representative Signature

Date:14.09.2022

Customer Signature

Date:

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CALIBRATION DATA BC 5130 TR-21006640

Lot No.	PLUS0722		Exp. Date	05/08/2022			
Operator	Admin		Completion time of calibration	27/07/2022			
	Select	WBC	RBC	HGB	MCV	PLT	
		10^3/uL	10^6/uL	g/dL	fL	10^3/uL	
Target		9.04	4.57	13.5	89.4	254	
1	Yes	8.94	4.43	13.3	90.4	254	
2	No	8.75	4.39	13.3	90.3	244	
3	Yes	8.79	4.33	13.3	90.5	242	
4	Yes	8.89	4.4	13.3	90.1	246	
5	Yes	8.96	4.42	13.4	90.0	246	
6	Yes	8.78	4.38	13.3	90.0	244	
7	Yes	8.8	4.43	13.4	90.1	237	
8	No	8.94	4.4	13.3	90.2	247	
9	Yes	8.85	4.4	13.3	90.6	235	
10	Yes	8.73	4.34	13.1	90.6	247	
Mean		8.84	4.39	13.3	90.3	244	
CV (%)		1	0.8	0.6	0.3	2.2	
New Factor (%)		102.23	104.08	101.45	99.03	104.04	
Old Factor (%)		100.00	100.00	100.00	100.00	100.00	