



Calibrator Calibration

Instrument: 5 Part Haematology Analyzer	Model: BC -6000	Serial No.: TU-16001951	Date of Cal. 14.07.2022			
Mode: OV-WB	Calibrator Lot No. PLUS0722			Exp.Date:05.08.2022		
Parameter	WBC	RBC	HGB	MCV	PLT	WBC-D
TARGET	9.05	4.59	13.6	92.5	255	9.05
1.	9.01	4.88	14.5	97.6	246	9.44
2.	9.20	5.00	14.6	97.2	255	9.20
3.	9.04	4.90	14.5	97.5	241	9.27
4.	9.14	4.90	14.4	97.3	258	8.97
5.	9.05	4.93	14.5	97.2	258	9.07
6.	8.84	4.90	14.4	96.7	239	9.14
Mean	9.05	4.92	14.5	97.2	249	9.18
CV(%)	1.366	0.869	0.49	0.34	3.6	1.774
New Cal. Factor (%)	100.04	93.30	93.99	95.12	102.23	
Old Cal. Factors (%)	101.35	89.78	92.73	98.73	92.98	
Old TC1 (%)						99.96
New TC1 (%)						98.54

For Rapid Diagnostic Pvt. Ltd.

G. Nagaraju
Service Engineer

N. Mahender Reddy
Zonal Service Manager



Rapid Diagnostic Pvt. Ltd.



BC-6200 – Hematology Analyzer

**INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION
PERFORMANCE QUALIFICATION
(IQ/OQ/PQ)**

For:

**TDHUB MEDAK
DISTRICT HOSPITAL CAMPUS JAMMIKNTA, MEDAK
PIN- 502110**

Prepared By:

Rapid Diagnostics Private Limited



CERTIFICATE OF INSTALLATION

Customer Name : THUB MEDAK
Instrument Name : BC-6000
Instrument Serial No. : TU-16001951
Address : tdhub medak, pin-502110

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

Engineer Signature:

Engineer Name : N. Ramakrishna Reddy
Designation : Service Engineer

Company : Rapid Diagnostic Pvt. Ltd.

Quality Manager

Signature :

Name : MRS R. PRAGNA

Designation : Lab Manager

Company : TDHUB MEDAK



INSTALLATION REPORT

Customer Name : TDHUB MEDAK
Place : TDHUB MEDAK
Department : Lab-Hematology Laboratory

Contact Person : MRS R. PRAGNA

Instrument Name : BC-6000

Serial Number : TU-16001951

Date of Installation : 20-12-2021

Warranty Expiry : 19-12-2023

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 Rapid Diagnostic Pvt. Ltd.

N. Mahender Reddy
Zonal 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 BC6200 instrument carefully and checked for any physical Damages.

3. ACCESSORIES CHECK-

Check all accessories as per check List

4. SPACE REQUIREMENT –

Checked site for proper space allocation. At least 130CM on each side and enough room on below the countertop to accommodate the reagents & pneumatic unit and waste containers.

<u>Parameter</u>	<u>Analyzer AL</u>
Width mm	826
Depth mm	695
Height mm	672
Weight Kg	87.5

5. POWER REQUIREMENT –

Requirement	Acceptable Range	Observed Ranged
Input Voltage	220 + / - 10 V	220 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C – 30 C	19

REAGENTS , CONTROLS , CALIBRATORS CHECK:

Name	Check	Remark
DS Diluent	Ok	Found as per specifications
LD Lyse	Ok	
LN Lyse	Ok	
LH Lyse	Ok	
FN Dye	Ok	
FD Dye	OK	
Probe Cleaner	Ok	

PRE-INSTALLTION VERIFICATION REPORT :-

S/No.	Parameter	Remark
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 –

S/N	Name	Check	Remark
1	PC set	Installed the PC set	Found everything Ok.
2	Input Power supply	Connect	
3	Printer Connection	operating manual 3.5	
4	External Barcode	Connected & Found working	

2. REAGENT & WASTE CONNECTIONS -

Name	Check	Remark
M-6DS Diluent	Operating Manual 1.23	Found everything Ok.
M-6LH Lyse	Operating Manual 1.23	
M-6LN Lyse	Operating Manual 1.23	
M-6LD Lyse	Operating Manual 1.23	
FD Dye M-6	Operating Manual 1.23	
Waste Connection	Operating Manual 1.23	
Cleanser Connection	Operating Manual 1.23	

3. CUSTOMIZING ANALYZER SOFTWARE -

CUSTOMIZING ANALYZER SOFTWARE			
S/N	Parameters	Check	Remark
1	Date & Time	Operating Manual 6.3.3	Done
2	Reagents	Operating Manual 12.3.1	Done
3	Reference Ranges	Operating Manual 6.3.9	Done
4	Reference Units	Operating Manual 6.3.9	Done
5	Printing format	Operating Manual 6.3.16	Done
6	Creating New User	Operating Manual 6.3.5	Done

4. SYSTEM BOOTING, INITIALIZATION & CHECK -

Power ON System and check instrument Initialization successfully.
 Check following Parameters.

CURRENT TEMPERATURES And PRESSURE		
CURRENT TEMPERATURES (°C)		
Parameters	Actual	Range
Optical System	32.6	31.0 -38.0
SPMT	33.0	31.0-38.0
WBC Reaction Bath	41.9	40.0-43.3
Preheating Bath	32.1	29.0-34.0
RBC Diluent	29.8	12.0-36.0
Analyzer Temp.	31.0	12.0-36.0
CPU	48.0	0.0-100.0
PRESSURE (kPa)		
	Actual	Range
+120kPa	115.0	110.0-125.0
120 kPa Detect	100.4	0.0-170.0
+90 kPa	91.5	85.0-95.0
+50 kPa	51.5	45.0-55.0
-30 kPa	-30.5	-35.0-25.0
-40 kPa	-40.4	-45.0-35.0
Liquid Pressure	94.7	50.0-120.0

5. MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Operator Manual 12.4	Demonstrated
2	Replacing Priming Reagents	Operator Manual 12.3.3	Demonstrated
3	Cleaning	Operator Manual 12.4.1	Demonstrated
4	Maintenance	Operator Manual 12.4.2	Demonstrated
5	Overall Maintenance	Operator Manual 12.5	Demonstrated
6	Version Information	Operator Manual 10.4.1	Demonstrated
7	Temperature & Pressure	Operator Manual 10.4.1	Demonstrated

6. CUSTOMER TRAINING – OPERATION & MAINTENANCE-

Training for technical staff has been done for operating procedure & maintenance procedure also demonstration has been done for the same.

PERFORMANCE QUALIFICATION

NORMAL BACKGROUND CHECK				
S/No.	Parameter	Actual	Remark	Remark
1	WBC	0.1	<.1	Ok
2	RBC	0.02	<.03	Ok
3	HGB	0.1	<.1	Ok
4	PLT	5	<10	Ok

REPRODUCIBILITY CHECK				
S/N	Parameter	Actual	Range CV%	Remark
1	WBC	1.4	2.5	Pass
2	RBC	1.4	1.5	Pass
3	HGB	0.6	1	Pass
4	MCV	0.3	1	Pass
5	PLT	3	4	Pass



BLANK CHECK					
No. Of Year	WBC	RBC	HBG	PLT	WBC-D
5	0	0	0	0	0
4	0	0	0	0	0
3	0	0	0	0	0
2	0	0	0	0	0
1	0	0	0	0	0
Limit	0.1	0.02	0.1	5	0.2
Result	Pass	Pass	Pass	Pass	Pass

CARRYOVER CHECK						
(HIGH/LOW LEVEL QC)						
Parameter	WBC	RBC	HBG	HCT	PLT	WBC-D
High Level-1	20.63	5.64	17.8	56.1	418	20.93
High Level-2	20.59	5.74	17.8	57.2	405	20.73
High Level-3	20.83	5.75	17.8	57.1	400	20.77
Low Level-1	3.62	2.46	6	19.7	56	3.68
Low Level-2	3.56	2.49	6	19.9	61	3.63
Low Level-3	3.67	2.49	6.1	20	58	3.74
Carryover %	-0.30%	-0.90%	-0.90%	-0.80%	-0.60%	-0.40%
Limit %	≤1.0%	≤1.0%	≤1.0%	≤1.0%	≤1.0%	≤1.5%