Installation Qualification for Fully Automatic Hematology Analyser BC-5000 Sr. No:- SS-46000585

Customer Name	: **VEDANTA HOSPITAL**
Address	: Lakshirampur, AZAMGARH – U.P.
Contact Person	: **Mr. SHEKHAR YADAV**
Instrument Model	: **BC- 5000**
Serial No.	: **SS-46000585**
Date Of installation	: 04-08-2014

The instrument was installed And was found to be working satisfactory. Preliminary Customer Training was provided And standardization of the parameters Were done. The results were found to be within the expected range and system found to be working satisfactorily.

For Aspen Diagnostics Pvt Ltd

. Technical Services Department

Customer: Vedanta Hospital, lakshiram azamgarh

Name	**: Priyank Singh**	**Contact Person**	**: Mr. Shekhar Yadav**
Designation	**: Area Manager Sales & Service**	**Designation**	**: Lab Incharge**
Signature	:	**Signature**	:

Area Manager
Aspen Diagnostics Pvt Ltd.
Delhi – 110033

Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)

ISO 9001:2015
CERTIFIED COMPANY

Installation Qualification for Fully Automatic Hematology Analyser BC-5000 Sr. No:- SS-46000585

This is to certify that the instrument BC-5000 Sr. No:- SS-85005597 is successfully installed and comminssioned at Shubham Hospital,Khajuri Varanasi U.P.- and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation : 04-08-2014

For Aspen Diagnostics Pvt Ltd

Technical Services Department

Name : Priyank Singh

Designation : Area Manager Sales & Service

Priyank Singh
04/08/14

Area Manager
Aspen Diagnostics Pvt. Ltd.
Delhi – 110033

B-82, G.T. Karnal Road Industrial Area, Delhi-110 033, Ph.: 45201100, Fax: 91-11-27413437, 45201198
e-mail: drjindal@rdgc.in, www.rapiddiagnostic.in

Installation Qualification for Fully Automatic Hematology Analyser BC-5000 Sr. No:- SS-46000585

Customer Name : **Vedanta Hospital**

Address : Bilariaganj Road Lakshirampur azamgarh – U.P.

Instrument Name : **BC-5000**

Serial No : **SS-46000585**

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:

Found the system to have been delivered in satisfactory condition and no external physical damaged observed on the same,Package was kept in good Condition as per the directional indicators like not tilt, indicating the system has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories as required.

Intallation Procedure And Checklist Attached for the records.

Area Manager
pen Diagnostics Pvt Ltd
Delhi – 110033

External Requirement for Installation:

1. **Input voltage of 220V-240V/50Hz or 60 Hz.**
2. **Recommended operating Temperature is 15-30 degree Celsius, with in Relative Humidity 30-85% and Atmospheric pressure 70-106kPa.**

Installation Qualification for Fully Automatic Hematology Analyser BC-5000 Sr. No:- SS-46000585

Carried out all the installation procedures as per the installation procedure and checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Handover the Instrument for operatos Training And Qualifications

For Aspen Diagnostics Pvt Ltd

Technical Services Department

Name : **Priyank Singh**

Designation : **Area Manager Sales & Service**

Area Manager
Aspen Diagnostics Pvt Ltd
Delhi - 110033

Performance Qualification for Fully Automatic Hematology Analyser BC-5000 , SS-46000585

Calibration Parameters

Checked and found all the control [parameters to be with in the acceptable CV limits and in range.

Checked and found all controls to be within The acceptable SD.

System Certification:

Study data has determined that the system described in this document either meets thenecessary criteria outlined inthis Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The system is ready for Specific Usage.

Protocol Performed By:

Name : PIYUSH SINGH

Designation :Application

PERFORMANCE QUALIFICATION DONE BY

Name : PIYUSH SINGH Designation : Application

Operational Qualification:

System Certfication:

Study data has determeined that the system described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional Conditions, If any Have been Addressed.

The Syatem is ready for specific usage.

Protocol Performed by : **For AspenDiagnostics Pvt Ltd**

Name: Priyank Singh

Designation: Area Manager Sales & Service

Customer Authorization : : **Vedanta Hospital**

Bilariaganj Road Lakshirampur azamgarh-u.p.

Name:

Designation:

Priyank Singh

Company Representative Name And Sign

Customer Name And Sign

Date: 04/08/2014

Date:

Area Manager
Aspen Diagnstics Pvt Ltd.
Delhi—110033

Operation Qualification for Fully Automatic Hematology Analyzer BC-5000

1. Verified all the Mechanical Movements : Done
2. Verifeied Hydraulics : Done
3. Verified Electrical Systems : Done
4. Verified the all reagents Systems : Done

For Aspen Diagnostics Pvt Ltd

Technical Services Department

Area Manager
Aspen Diagnostics Pvt. Ltd.
Delhi–110033

Priyank Singh

Name : **PRIYANK SINGH**

Designation : **Area Manager Sales & Service**

Date : 14-08-2014

Instrument Setup

1. Assembled the instrument accessories.
2. Removed the shipping Clamps.
3. Connected the LH LYSE REAGENT .
4. Connected the DILUENT REAGENT.
5. Connected the DIFF LYSE REAGENT
6. Connected the Waste Tubing
7. Connected the Communication Cable.
8. Connected the Power cord and connection cord.
9. Coonected the External Printer.
10. Initialise the machine and follow the installation procedure.

Operational Inspection:

1. Checked and found Mechanical Movements OK.
2. Checked and found Hydraulics OK.
3. Checked and found Electricals OK.
4. Checked with Controls And Samples, Results Are found OK.

For Aspen Diagnostics Pvt Ltd

Technical Services Department

Area Manager
Aspen Diagnostics Pvt. Ltd.
Delhi—110033

Name : **Priyank Singh**

Designation : **Area Manager Sales & Service**

Mindray BC-5000 Hematology Analyzer

Version: 2.11.....	Head of department:Mr. SHEKHAR YADAV
Date effective: 04.12.2020.....	Quality Officer: .....
Copy number:	Director of : .....

Purpose/Definition:

The BC-5000 performs speedy and accurate analysis of 25 parameters in blood (Whole WBC, LYM%, MONO%, BASO%, EOS%, NEUT% , LYM# ,MONO#, BASO#,EOS#, NEUT# , RBC count, Hemoglobin, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, PDW, MPV, P-LCR, PCT, P-LCC)

The BC-5000 employs three detector blocks and two kinds of reagents for blood analysis. The WBC count is measured by the WBC detector block using the Tri-angle laser scatter. The RBC count and platelets are taken by the RBC detector block, also using the DC detection method. The HGB detector block measures the hemoglobin concentration using the non cyanide hemoglobin method.

Responsibilities:

- Hematology department personal are required to be knowledgeable of this procedure.
- New employees are trained and assessed for competence before they can handle patient sample
- The head of the department must resolve any problem with the process and difficulties in using this SOP.

Specimen requirements:

About 2-3 ml of venous blood collected into EDTA tubes.

Specimens should be transported at room temperature 18 - 26°C and can be store in the refrigerator of 2 - 8°C up to 6 hours.. If stored in a refrigerator, samples should be returned to room temperature, for approximately 30 minutes, before analysis.

Specimen reception:

Reception of samples should be recorded, and record time of reception. Pay attention to sample identification and labeling of tubes. **Criteria for rejection hematology specimens**

1. When the identification is missing /inadequate.

Area Manager
Aspen Diagnostics Pvt Ltd.
Delhi–110033

B-82, G.T. Karnal Road Industrial Area, Delhi-110 033, Ph.: 45201100, Fax: 91-11-27413437, 45201198
e-mail: drjindal@rdgc.in, www.rapiddiagnostic.in

2. Insufficient quantity
3. Inappropriate container
4. Inappropriate transport/storage
5. Unknown duration of delay
6. Clotted sample

Equipment & Items required:

Mindray BC -5000 analyzer

Reagent	Storage Conditions
Mindray M-52 Diluent	5 - 30°C
Mindray M-52 LH Lyse	5 - 30°C
Mindray M-52 Diff Lyse	5 - 30°C
Mindray M-52 Probe Cleanser	5 - 30°C

Abbreviations:

CBC: Complete blood count.

EDTA: Ethylene diamine tetra acetic acid

WBC: White Blood Cells

LYM%: Lymphocyte percentage

LYM#: Lymphocyte absolute value

MON%: Monocyte percentage

MON#: Monocyte absolute value

BASO%: Basophil percentage

BASO#: Basophil absolute value

EOS%: Eosinophil percentage

EOS#: Eosinophil absolute value

NEU%: Neutrophil percentage

NEU#: Neutrophil absolute value

RBC: Red Blood Cells

HGB: Hemoglobin

HCT: Hematocrit

MCV: Mean Corpuscular Volume

MCH: Mean Corpuscular Hemoglobin

MCHC: Mean Corpuscular Hemoglobin Concentration

RDW-CV: Red cell Distribution Width Coefficient Variation

RDW-SD: Red cell Distribution Width Standard Deviation

PLT: Platelets

MPV: Mean Platelet Volume

PDW*: Platelet Distribution Width

PCT*: Plateletcrit

P-LCR: Platelet larger cell ratio

P-LCC : Platelet larger cell count

Procedures:

1. Check to see that the reagents needed for the number of the samples to be processed for the day are available.
2. Turn ON the power switch on the right side of the unit. Self-check, auto rinse, and background check will be automatically performed, and the "Green Light" (ready for analysis) will appear.

Permissible Background	
WBC	$< 0.20 \times 10^9$/L
RBC	$< 0.02 \times 10^{12}$/L
HGB	< 0.10 x g/dl
HCT	< 0.50 %
PLT	$< 10 \times 10^9$/L

3. When auto rinse and background check are normally completed, "Green Light" is displayed.
4. Perform quality control analysis on 3 levels of control blood material (low, normal and high) to verify that the instrument is performing within the specified ranges of the quality control material.
5. If the result of quality control in acceptable range input your blood samples.
6. Input from the Touch Screen.
7. Press [Next Sample] key in the Ready status.
8. Entering patient ID, sample ID, Patient name, etc

9. Press [OK] key, This will fix the sample No. and the status becomes ready for analysis.
10. Mix the sample sufficiently before analysis.
11. Remove the plug while taking care not to allow blood scatter.
12. Set the tube to the sample probe, and in that condition, press the start switch.
13. when the BEEP comes remove the tube.
14. After that, the unit executes automatic analysis and displays the result on the LCD screen.
15. Then the unit turns to the ready status, becoming ready for analysis of the next samples.

Quality control procedures:

1. At the beginning of each work shift, all parameters are tested with blood control.
2. The 3 levels include: Abnormal Low, Normal, Abnormal High
3. Controls are stored at 2-8°C and brought to room temperature before use .
4. Controls are gently inverted eight times according to the manufacturer's instruction before use.
5. From the LCD screen, press [QC].
6. Select the appropriate QC file (i.e., low, normal or high) input QC SETUP , save them . Run the QC SAMPLE in correct file .

9. Control values must be within three standard deviations, otherwise the measurement has to be repeated, if the control still out of range:

   a. Check operation of the machine, ensuring it is clean and that all required supplies are present in sufficient quantities.
   b. Check reagents for expiration dates and lot numbers. Ensure that all machine lines are in appropriate receptacle where applicable, If this does not solve the problem:

- ✓ Prepare new control(s) and try again.
- ✓ If the controls are still out, inform your supervisor to check the operator's manual, or recalibrate instrument and If controls are still out,. Contact Medical Maintenance where applicable, or servicing engineer.

7. All control data are managed using software that provides graphical reports (Levey Jennings graphs,).
8. Dilute the sample if White blood cell counts ≥500,000 /mm3 and platelet counts ≥5,000,000 /mm3 are outside the linearity specifications of the instrument.

Linearity:

Parameter	Linearity Range Low	Linearity Range High	Deviation Range
WBC	< 0.00 x 10^9/L	< 500.00 x 10^9/L	10.0%
RBC	< 0.00 x 10^{12}/L	< 8.00 x 10^{12}/L	< 5.0%
HGB	< 0.00 x g/dl	< 25.00 x g/dl	2.0%
PLT	< 0.0 x 10^9/L	< 5000.00 x 10^9/L	8.0 %

Limitations/ Interfering substance:

The following is a list of possible substances that may interfere with the listed parameters.

1. WBC: platelet aggregation, giant platelets, nucleated RBCs, cryoglobulins, lyseresistant RBCs in patients with haemoglobinopathies, severe liver disease or neonates.
2. RBC: Cold agglutinins, severe micryocytosis, fragmented RBCs, large numbers of giant platelets, in vitro haemolysis.
3. HGB: Lipemia, abnormal proteins in blood plasma, severe leukocytes (above 100,000/µl). The effect of abnormal proteins and Lipemia may be removed by plasma replacement or plasma blank procedures.
4. HCT: Cold agglutinins, leukocytosis (above 100,000/µl), abnormal red cell fragility.
5. PLT: Pseudothrombocytopenia, platelet aggregation, increased micrcrocytosis, megalocyttic platelets
6. Low sample volume of <1 mL may dilute patient samples with EDTA in the collection tube giving falsely low results. If a low sample volume is expected, use a pediatric EDTA tube; fill to the second line and mix well.
7. Dilute the sample if White blood cell counts ≥500,000 /mm3 and platelet counts ≥5,000,000 /mm3 are outside the linearity specifications of the instrument

Expected values:

Age	HGB (g/dL)	HCT (%)	RBC (x106/µL)	MCV (fl)	MCH (pg)	MCHC (%)	RDW (%)	PLT (x103/µL)	WBC (X103/µL)	Neutro %	Lympho%	Eosino %	Baso %	Mono %
0 - 3 Day	14.5 - 22.5	45 - 67	4.00 – 6.60	95 - 121	31 - 37	29 - 37	12.0 – 18.0	150 – 450	9.0 – 30.0	32 – 62	19 – 29	0 – 2	0 - 1	5 – 7
4 - 9 Day	13.5 – 19.5	42 - 66	3.90 – 6.30	88 - 125	28 - 40	28 - 38	13.0 – 18.0	150 – 450	5.0 – 21.0	19 – 49	26 – 36	0 – 2	0 – 1	5 – 7
10 - 14 Day	12.5 – 20.5	39 – 63	3.60 – 6.20	86 - 124	28 - 40	28 – 38	13.0 – 18.0	150 – 450	5.0 – 20.0	14 – 34	36 – 45	0 – 2	0 – 1	6 – 10
15 - 30 Day	10.0 – 18.0	31 - 55	3.00 – 5.40	85 - 123	28 - 40	29 - 37	11.5 – 16.0	150 – 450	5.0 –19.5	15 – 35	43 – 53	0 – 2	0 – 1	7 – 11
2 – 6 Month	9.5 – 13.6	29 - 41	3.10 – 4.50	74 - 108	25 - 35	30 -36	11.5 – 16.0	150 – 450	6.0 – 17.5	13 – 33	41 – 71	0 – 3	0 – 1	4 – 7
7-24 month	10.5 – 13.5	33 - 49	3.70 – 5.30	70 - 86	23 - 31	30 - 36	11.5 – 16.0	150 – 450	6.0 – 17.0	15 - 35	45 – 76	0 – 3	0 – 1	3 – 6
2 – 6 Years	11.5 – 15.5	34 - 40	3.90 – 5.30	75 - 87	24 - 30	32 - 36	11.5 – 15.0	150 – 450	5.5 – 15.5	23 - 45	35 – 65	0 – 3	0 – 1	3 – 6
6 – 12 Years	11.5 – 15.5	35 - 45	4.00 – 5.20	77 - 95	25 - 33	32 - 36	11.5 – 15.0	150 – 450	4.5 – 13.5	33 – 61	28 – 48	0 – 3	0 – 1	3 – 6
12 – 18 Years (Male)	13.0 – 16.0	36 - 51	4.50 – 5.30	78 - 98	25 - 35	32 - 36	11.5 – 14.0	150 – 450	4.5 – 13.0	34 – 64	25 – 45	0 – 3	0 – 1	3 – 6
12 – 18 Years (Female)	12.0 – 16.0	33 - 51	4.10 – 5.10	78 - 102	25 - 35	32 - 36	11.5 – 14.0	150 – 450	4.5 – 13.0	34 – 64	25 – 45	0 – 3	0 – 1	3 – 6
>18 Years (Male)	13.5 – 17.5	37 - 53	4.50 – 5.90	80 – 100	26 – 34	32 - 36	11.5 – 13.1	150 – 450	4.5 – 11.0	36 – 66	24 – 44	0 – 3	0 – 1	3 – 6
>18 Years (Female)	12.0 – 16.0	33 - 51	4.00 – 5.20	80 - 100	26 - 34	32 - 36	11.5 – 13.1	150 – 450	4.5 – 11.0	35 – 66	24 – 44	0 – 3	0 – 1	3 – 6

Interpretation of the results:

Certain disease states are defined by an absolute increase or decrease in the number of a particular type of cell in the bloodstream and many types of anemia.

Reporting result:

According to lab policy.(automated printing or computerized)

Performance Qualification:-

Instrument Name - **BC-5000**

Serial No- **SS-46000585**

1- **Precision Test:-** Precision is checked running blood samples in 5 replicates & getting CV% in within acceptance..

Parameters	Acceptable Range	Observed Value	Comments
WBC 10^9/L	< 2.5% (>4.00 10^9/L)	1.30	PASSED
RBC 10^12/L	< 1.5 % (>3.5 10^12/L)	0.4	PASSED
HGB g/dl	< 1.0% (11.0-18.0 g/dl)	0.26	PASSED
HCT %	< 1.5 % (30%-50%)	0.9	PASSED
PLT 10^3	< 4.0 % (>100 10^9/L)	1.62	PASSED

Checked By:-

Area Manager
Aspen Diagnostics Pvt Ltd
Delhi–110033

Verified By:-

Sigma Medicals And Diagnostic Services

Calibration Certificate, Automated Hematology Analyzer

Name	BC – 5000 (5 PART HEMATOLOGY ANALYZER)
Hospital	VEDANTA HOSPITAL AZAMGARH – (U.P.)
Date	21 December 2021

This is certify that BC-5000 (5-Part Hematology Analyzer) have calibrated dated ..

Calibrator Details:-

- **SC – CAL PLUS**
- **LOT NO- PLUS1221**
- **Exp – 05-01-2022**

Instrument identification				QC Passed	
Serial no.	SS-46000585	Date of Calibration	21.12.2021	Yes	Yes
Model	BC 5000	Due Date of Calibration	20.12.2022	Yes	Yes

After calibration Q.C. Test for all level passed successfully.

Test results is coming ok	✓	*Remarks*	Done

SIGMA MEDICALS AND DIAGNOSTIC SERVICES

Service Engineer

Araji No. 528, G.S.S. Enclave, Tarna, Ganeshpur, Shivpur, Varanasi - 221003
Cell No.: 9454104886, 9794845476 • E-mail : sigmamedicalvns@gmail.com

Performance Qualification:-

Instrument Name - **BC-5000**

Serial No- **SS-46000585**

ATTACHMENT:-

Attachment No	Documents Title	Page No	Checked By
1	Start Up Result	1	PASSED
2	Q.C. Report	1 NO EACH	PASSED
3	Sample Repeatability Report	5 NO	PASSED

Checked By:- Priyanka Sonu

Area Manager
Aspen Diagnostics Pvt. Ltd.
Delhi—110033

Verified By:-