

ASPEN

mindray  
BC-5000

Menu Sample Analysis Table Review QC Reagent Setup Diluent Print

Sample ID: 118992 Name: \_\_\_\_\_  
Time: 10-11-2024 02:15 Age: \_\_\_\_\_  
Mode: WB-CBC+DIFF Gender: \_\_\_\_\_

| Parameter | Result  | Unit               | Parameter | Result  | Unit                |
|-----------|---------|--------------------|-----------|---------|---------------------|
| WBC       | H 14.37 | 10 <sup>9</sup> /L | RBC       | H 6.02  | 10 <sup>12</sup> /L |
| Neu#      | H 9.44  | 10 <sup>9</sup> /L | HGB       | 12.6    | g/dL                |
| Lym#      | H 4.63  | 10 <sup>9</sup> /L | HCT       | 39.4    | %                   |
| Mon#      | 0.30    | 10 <sup>9</sup> /L | MCV       | L 65.5  | fL                  |
| Eos#      | L 0.00  | 10 <sup>9</sup> /L | MCH       | L 21.0  | pg                  |
| Bas#      | 0.00    | 10 <sup>9</sup> /L | MCHC      | 321     | g/dL                |
| Neu%      | 65.7    | %                  | RDW-CV    | H 17.2  | %                   |
| Lym%      | 32.2    | %                  | RDW-SD    | 43.3    | fL                  |
| Mon%      | L 2.1   | %                  | PLT       | 369     | 10 <sup>9</sup> /L  |
| Eos%      | L 0.0   | %                  | MPV       | 8.7     | fL                  |
| Bas%      | 0.0     | %                  | PDW       | 15.7    | %                   |
|           |         |                    | PCT       | H 0.321 | %                   |
|           |         |                    | P-LCC     | 76      | 10 <sup>9</sup> /L  |
|           |         |                    | P-LCR     | 20.7    | %                   |

WBC Message: Lymphocytosis  
RBC Message: RBC Distribution Abnormal, Microcytosis  
PLT Message: \_\_\_\_\_

LAS DIFF WBC  
RBC PLT

Next Sample Mode Validate RUO Screen Scattergram

Standby: Press the aspirate key to exit Administrator: Admin 10-11-2024 11:03

Cute 5 Part



INSTRUMENT DETAILS



Micropath Laboratory  
Om Plaza, Konda Lane,  
Laxminagar, Kolhapur, 416002

|                             |                           |
|-----------------------------|---------------------------|
| INSTRUMENT NAME             | Mindray BC-5000           |
| INSTRUMENT NUMBER           | BML/INST-03               |
| SERIAL NUMBER               | SS-22009018               |
| MODEL NUMBER                | BC-5000                   |
| MANUFACTURER'S NAME         | Mindray                   |
| VENDOR NAME                 | Aspen Diagnostic Pvt Ltd. |
| INSTALLATION DATE           | 15/05/2024                |
| DATE ENTERING IN TO SERVICE | 15/05/2024                |
| LOCATION                    | Kolhapur                  |

Admin



**Aspen Diagnostics Pvt. Ltd.**



ISO 9001:2015  
CERTIFIED COMPANY

Mindray BC-5000 Hematology Analyzer

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

**MICROPATH LABORATORY**

**Kolhapur**

***BY - Aspen Diagnostic Pvt Ltd.***



**Aspen Diagnostics Pvt. Ltd.**



**CERTIFICATE OF INSTALLATION**

**INSTRUMENT NAME: BC-5000**

**SERIAL NUMBER : SS-21008967**

**CUSTOMER NAME : MICROPATH LABORATORY**

**ADDRESS : Om Plaza, Konda Lane, Laxmipuri,  
Kolhapur**

**Date of Installation : 15 May 2024**

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

**Area Service Manager**

**Signature :**



**Name :**

**Prasad Jadhav**

**Company :**

**Aspen Diagnostic Pvt.Ltd.**



**INSTALLATION REPORT**

**Customer Name** : Micropath Laboratory  
**Place** : Om Plaza, Konda Lane, Laxmipuri,  
Kohapur  
**Department** : Hematology Laboratory  
**Contact Person** : Dr. Vijay Kulkarni  
(Lab Director & Head Pathologist)  
**Instrument Name** : BC-5000  
**Serial Number** : SS-22009018  
**Date of Installation** : 15.05.2024

*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



Area Service Manager



## INSTALLATION QUALIFICATION

### IO 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 verification.*

#### 1. SYSTEM UNPACKING

#### 2. SYSTEM CHECKING

Unpack the instrument carefully and check 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 100 CM on each side and enough room on below the countertop to accommodate the reagents and waste containers.

#### 5. POWER REQUIREMENT –

| <i>Requirement</i>  | <i>Acceptable Range</i> | <i>Observed Ranged</i> |
|---------------------|-------------------------|------------------------|
| Input Voltage       | 220 + / - 10 V          | 225 V                  |
| Line Frequency      | 50 HZ                   | 50 HZ                  |
| Ambient Temperature | 15 C – 30 C             | 23                     |



## 6. Reagents, Control, Calibrators Check-

| NAME           | CHECK | Remark |
|----------------|-------|--------|
| DILUENT M-52   | OK    | OK     |
| Diff Lyse M-52 | OK    | OK     |
| LH Lyse M-52   | OK    | OK     |
| Probe Cleanser | OK    | OK     |

## PRE-INSTALLTION VERIFICATION REPORT:-

| PRE-INSTALLATION VERIFICATION REPORT |                             |        |
|--------------------------------------|-----------------------------|--------|
| S/N                                  | 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.

## OO 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                  | Printer Connection | operating manual | Ok     |

## 2. 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 | Operating Manual 5.3.2 | Ok     |

## 3. SYSTEM BOOTING, INITIALIZATION & Check -

Power ON System and check instrument Initialization successfully.



## 4. MAINTENANCE PROCEDURES:-

| MAINTENANCE |                            |                 |        |
|-------------|----------------------------|-----------------|--------|
| S/N         | Parameters                 | Check           | Remark |
| 1           | Using Maintenance Menu     | Operator Manual | Ok     |
| 2           | Replacing Priming Reagents | Operator Manual | Ok     |
| 3           | Cleaning                   | Operator Manual | Ok     |
| 4           | Maintenance                | Operator Manual | Ok     |
| 5           | Overall Maintenance        | Operator Manual | Ok     |
| 6           | Version Information        | Operator Manual | Ok     |
| 7           | Temperature & Pressure     | Operator Manual | Ok     |
| 8           | Touch Screen Calibration   | Operator Manual | Ok     |
|             |                            |                 |        |

| ADJUSTMENT |                                  |                 |        |
|------------|----------------------------------|-----------------|--------|
| S/N        | Parameters                       | Check           | Remark |
| 1          | Vacuum , Pressure & HB Voltage   | Operator Manual | Ok     |
| 2          | Error Messages & Recommendations | Operator Manual | Ok     |
|            |                                  |                 |        |

For Aspen Diagnostics



Area Service Manager





**PERFORMANCE QUALIFICATION-**

- |                         |        |
|-------------------------|--------|
| 1) BACKGROUND CHECK     | - DONE |
| 2) START UP PROCEDURE   | - DONE |
| 3) SAMPLE PROCESSING    | - DONE |
| 4) QC SET UP AND QC RUN | - DONE |
| 5) SHUT DOWN PROCEDURE  | - DONE |
| 6) MAINTENANCE SCHEDULE | - DONE |

For Aspen Diagnostics



Area Service Manager

| Reproducibility |             | Date/Time | Operator         | WBC  | RBC  | HGB  | MCV  | PLT  | Neu% | Lym% | Mon% | Eos% | Bas% | MPV  |
|-----------------|-------------|-----------|------------------|------|------|------|------|------|------|------|------|------|------|------|
| Mode:           | WB-CBC      | CV %      |                  | 1.1  | 0.8  | 0.8  | 0.3  | 2.2  | 0.0  | 0.0  | 0.0  | 0.0  | 0.0  | 1.5  |
| Material:       | BC-5D       |           |                  | 2.5  | 1.5  | 1.5  | 1.0  | 4.0  |      |      |      |      |      | 4.0  |
| Lot No.:        | BC2311BN    |           |                  | Pass | Pass | Pass | Pass | Pass | Fail | Fail | Fail | Fail | Fail | Pass |
| No.             | 10          | 1         | 15-05-2024 14:33 | 7.80 | 4.06 | 12.0 | 96.8 | 266  |      |      |      | 11.6 |      |      |
| Analyzer SN:    | SS-22009018 |           |                  |      |      |      |      |      |      |      |      |      |      |      |

| Reproducibility |             | Date/Time | Operator         | WBC  | RBC  | HGB  | MCV  | PLT  | Neu% | Lym% | Mon% | Eos% | Bas% | MPV  |
|-----------------|-------------|-----------|------------------|------|------|------|------|------|------|------|------|------|------|------|
| Mode:           | WB-CBC      | CV %      |                  | 1.1  | 0.8  | 0.8  | 0.3  | 2.2  | 0.0  | 0.0  | 0.0  | 0.0  | 0.0  | 1.5  |
| Material:       | BC-5D       |           |                  | 2.5  | 1.5  | 1.5  | 1.0  | 4.0  |      |      |      |      |      | 4.0  |
| Lot No.:        | BC2311BN    |           |                  | Pass | Pass | Pass | Pass | Pass | Fail | Fail | Fail | Fail | Fail | Pass |
| No.             | 10          | 10        | 15-05-2024 14:47 | 7.73 | 3.99 | 12.0 | 96.6 | 265  |      |      |      | 11.5 |      |      |
| Analyzer SN:    | SS-22009018 | 9         | 15-05-2024 14:46 | 7.85 | 4.06 | 12.3 | 96.9 | 274  |      |      |      | 11.6 |      |      |
|                 |             | 8         | 15-05-2024 14:44 | 7.74 | 4.00 | 12.1 | 96.9 | 269  |      |      |      | 11.6 |      |      |
|                 |             | 7         | 15-05-2024 14:43 | 7.67 | 3.98 | 12.0 | 96.9 | 256  |      |      |      | 11.6 |      |      |
|                 |             | 6         | 15-05-2024 14:41 | 7.58 | 3.98 | 12.0 | 96.3 | 273  |      |      |      | 11.3 |      |      |
|                 |             | 5         | 15-05-2024 14:40 | 7.74 | 4.02 | 12.1 | 97.1 | 272  |      |      |      | 11.3 |      |      |
|                 |             | 4         | 15-05-2024 14:38 | 7.60 | 3.99 | 12.2 | 97.1 | 269  |      |      |      | 11.6 |      |      |
|                 |             | 3         | 15-05-2024 14:36 | 7.68 | 4.00 | 12.1 | 97.1 | 264  |      |      |      | 11.6 |      |      |
|                 |             | 2         | 15-05-2024 14:35 | 7.71 | 4.05 | 12.1 | 96.8 | 258  |      |      |      | 11.9 |      |      |

Mode: WB

Carryover

| Date/Time         | Operator | WBC   | RBC  | HGB  | HCT  | PLT  |
|-------------------|----------|-------|------|------|------|------|
| 15-05-2024 15:22  | service  | 17.72 | 4.86 | 16.1 | 51.4 | 518  |
| 15-05-2024 15:24  | service  | 17.89 | 4.88 | 16.0 | 51.6 | 528  |
| 15-05-2024 15:25  | service  | 18.19 | 4.94 | 15.9 | 52.2 | 531  |
| 15-05-2024 15:40  | service  | 0.06  | 0.01 | 0.0  | 0.0  | 5    |
| 15-05-2024 15:42  | service  | 0.01  | 0.00 | 0.0  | 0.0  | 1    |
| 15-05-2024 15:43  | service  | 0.00  | 0.00 | 0.0  | 0.0  | 0    |
| Carryover% Limit% |          | 0.3%  | 0.2% | 0.0% | 0.0% | 0.9% |
|                   |          | 0.5%  | 0.5% | 0.6% | 0.5% | 1.0% |

Background

| Mode         | WB          | Limit  | Select | Date/Time        | Operator | WBC  | RBC  | HGB  | HCT  | PLT  |
|--------------|-------------|--------|--------|------------------|----------|------|------|------|------|------|
| No           | 1           | Result |        |                  |          | Pass | Pass | Pass | Pass | Pass |
| Analyzer SN: | SS-22009018 | 2      | Yes    | 15-05-2024 14:24 | service  | 0.01 | 0.00 | 0.0  | 0.0  | 0    |
|              |             | 1      | No     | 15-05-2024 14:00 | service  | 0.01 | 0.00 | 0.0  | 0.0  | 1    |

Manual

WB Calibration Factor

| Parameter | Calibration Factor (%) | Date       |
|-----------|------------------------|------------|
| WBC       | 99.87                  | 15-05-2024 |
| RBC       | 103.12                 | 15-05-2024 |
| HGB       | 100.55                 | 15-05-2024 |
| MCV       | 98.81                  | 15-05-2024 |
| PLT       | 104.44                 | 15-05-2024 |

PD Calibration Factor

| Parameter | Calibration Factor (%) | Date       |
|-----------|------------------------|------------|
| WBC       | 100.00                 | 05-03-2022 |
| RBC       | 100.00                 | 05-03-2022 |
| HGB       | 100.00                 | 05-03-2022 |
| MCV       | 100.00                 | 05-03-2022 |
| PLT       | 100.00                 | 05-03-2022 |

WB Factory Cal. Factor

| Parameter | Factory Cal. Factor (%) | Date       |
|-----------|-------------------------|------------|
| WBC       | 106.89                  | 05-03-2022 |
| RBC       | 98.96                   | 05-03-2022 |
| HGB       | 104.45                  | 05-03-2022 |
| MCV       | 104.38                  | 05-03-2022 |
| PLT       | 96.22                   | 05-03-2022 |

PD Factory Cal. Factor

| Parameter | Factory Cal. Factor (%) | Date       |
|-----------|-------------------------|------------|
| WBC       | 105.78                  | 05-03-2022 |
| RBC       | 94.53                   | 05-03-2022 |
| HGB       | 101.28                  | 05-03-2022 |
| MCV       | 104.84                  | 05-03-2022 |
| PLT       | 90.53                   | 05-03-2022 |

WB Factory Transfer Factor

| Parameter | Transfer Factor (%) | Date       |
|-----------|---------------------|------------|
| WBC       | 96.62               | 05-03-2022 |
| RBC       | 97.01               | 05-03-2022 |
| HGB       | 88.72               | 05-03-2022 |
| MCV       | 98.97               | 05-03-2022 |
| PLT       | 98.26               | 05-03-2022 |

PD Factory Transfer Factor

| Parameter | Transfer Factor (%) | Date       |
|-----------|---------------------|------------|
| WBC       | 100.27              | 05-03-2022 |
| RBC       | 103.59              | 05-03-2022 |
| HGB       | 89.14               | 05-03-2022 |
| MCV       | 99.01               | 05-03-2022 |
| PLT       | 103.83              | 05-03-2022 |

| Mode         | WB Select | Date/Time        | Operator | WBC  | RBC  | HGB  | HCT  | PLT  |
|--------------|-----------|------------------|----------|------|------|------|------|------|
| 2            | Yes       | 15-05-2024 14.24 | service  | 0.01 | 0    | 0    | 0    | 0    |
| 1            | No        | 15-05-2024 14.00 | service  | 0.01 | 0    | 0    | 0    | 1    |
|              |           |                  |          | 0.2  | 0.02 | 0.1  | 0.5  | 10   |
| Limit Result |           |                  |          | Pass | Pass | Pass | Pass | Pass |
| Number of    |           | 1                |          |      |      |      |      |      |

| Mode       | WB               |          |       |       |       |       |       |  |
|------------|------------------|----------|-------|-------|-------|-------|-------|--|
|            | Date/Time        | Operator | WBC   | RBC   | HGB   | HCT   | PLT   |  |
| High-Level | 15-05-2024 15.22 | service  | 17.72 | 4.86  | 16.1  | 51.4  | 518   |  |
| High-Level | 15-05-2024 15.24 | service  | 17.89 | 4.88  | 16    | 51.6  | 528   |  |
| High-Level | 15-05-2024 15.25 | service  | 18.19 | 4.94  | 15.9  | 52.2  | 531   |  |
| Low-Level  | 15-05-2024 15.40 | service  | 0.06  | 0.01  | 0     | 0     | 5     |  |
| Low-Level  | 15-05-2024 15.42 | service  | 0.01  | 0     | 0     | 0     | 1     |  |
| Low-Level  | 15-05-2024 15.43 | service  | 0     | 0     | 0     | 0     | 0     |  |
| Carryover% |                  |          | 0.30% | 0.20% | 0.00% | 0.00% | 0.90% |  |
| Limit%     |                  |          | 0.50% | 0.50% | 0.60% | 0.50% | 1.00% |  |

Analyzer SI SS-22009018  
Lot No. PLUS0524  
Operator Admin

Calibrator type  
Exp. Date 05-06-2024  
Completior 15-05-2024

| Select         | WBC<br>10 <sup>9</sup> /L | RBC<br>10 <sup>12</sup> /L | HGB<br>g/dL | MCV<br>fL | PLT<br>10 <sup>9</sup> /L |
|----------------|---------------------------|----------------------------|-------------|-----------|---------------------------|
| Target         | 9.14                      | 4.53                       | 13.3        | 88.3      | 248                       |
| 1 Yes          | 8.93                      | 4.36                       | 13.1        | 89.5      | 229                       |
| 2 Yes          | 9.09                      | 4.4                        | 13.3        | 89.4      | 240                       |
| 3 Yes          | 8.94                      | 4.41                       | 13.3        | 89.5      | 241                       |
| 4 Yes          | 9.34                      | 4.41                       | 13.2        | 89.3      | 241                       |
| 5 Yes          | 9.15                      | 4.39                       | 13.2        | 89.3      | 231                       |
| 6 Yes          | 9.14                      | 4.38                       | 13.2        | 89.2      | 236                       |
| 7 Yes          | 9.36                      | 4.36                       | 13.2        | 89.2      | 244                       |
| 8 Yes          | 9                         | 4.41                       | 13.3        | 89.3      | 235                       |
| 9 Yes          | 9.39                      | 4.37                       | 13.3        | 89.4      | 235                       |
| 10 Yes         | 9.18                      | 4.44                       | 13.2        | 89.5      | 243                       |
| Mean           | 9.15                      | 4.39                       | 13.2        | 89.4      | 237                       |
| CV (%)         | 1.8                       | 0.6                        | 0.5         | 0.1       | 2.2                       |
| New Factor (%) | 99.87                     | 103.12                     | 100.55      | 98.81     | 104.44                    |
| Old Factor (%) | 100                       | 100                        | 100         | 100       | 100                       |

Mode WB-CBC  
 Substan BC-5D  
 Number 10  
 Lot No. BC2311BN

| Select   | Date/Time        | Operator | WBC   | RBC   | HGB  | MCV  | PLT  |
|----------|------------------|----------|-------|-------|------|------|------|
| 10 Yes   | 15-05-2024 14.47 | service  | 7.73  | 3.99  | 12   | 96.6 | 265  |
| 9 Yes    | 15-05-2024 14.46 | service  | 7.85  | 4.06  | 12.3 | 96.9 | 274  |
| 8 Yes    | 15-05-2024 14.44 | service  | 7.74  | 4     | 12.1 | 96.9 | 269  |
| 7 Yes    | 15-05-2024 14.43 | service  | 7.67  | 3.98  | 12   | 96.9 | 256  |
| 6 Yes    | 15-05-2024 14.41 | service  | 7.58  | 3.98  | 12   | 96.3 | 273  |
| 5 Yes    | 15-05-2024 14.40 | service  | 7.74  | 4.02  | 12.1 | 97.1 | 272  |
| 4 Yes    | 15-05-2024 14.38 | service  | 7.6   | 3.99  | 12.2 | 97.1 | 269  |
| 3 Yes    | 15-05-2024 14.36 | service  | 7.68  | 4     | 12.1 | 97.1 | 264  |
| 2 Yes    | 15-05-2024 14.35 | service  | 7.71  | 4.05  | 12.1 | 96.8 | 258  |
| 1 Yes    | 15-05-2024 14.33 | service  | 7.8   | 4.06  | 12   | 96.8 | 266  |
| Mean     |                  |          | 7.71  | 4.01  | 12.1 | 96.8 | 266  |
| SD       |                  |          | 0.084 | 0.033 | 0.1  | 0.25 | 5.9  |
| Min      |                  |          | 7.58  | 3.98  | 12   | 96.3 | 256  |
| Max      |                  |          | 7.85  | 4.06  | 12.3 | 97.1 | 274  |
| R        |                  |          | 0.27  | 0.08  | 0.3  | 0.8  | 18   |
| d(Min)   |                  |          | 0     | 0.01  | 0    | 0    | 1    |
| d(Max)   |                  |          | 0.14  | 0.05  | 0.2  | 0.5  | 10   |
| CV %     |                  |          | 1.1   | 0.8   | 0.8  | 0.3  | 2.2  |
| Limit(%) |                  |          | 2.5   | 1.5   | 1.5  | 1    | 4    |
| Result   |                  |          | Pass  | Pass  | Pass | Pass | Pass |



**TRAINING CERTIFICATE**

**To whome so ever it may Concern**

This is to certify that the below mentioned lab personnel of

**MICROPATH LABORATORY**

**KOLHAPUR**

Has undergone Operator Training course On

**BC-5000 ( Hematology Analyzer ) On 15.05.2024**

And is qualified to operate the system.

- 1) Miss. Shusma Kolekar
- 2) Miss. Sujata Biranje
- 3) Miss. Madhuri Savekar
- 4) Mr. Avadhoot Ghatage
- 5) Miss. Madhavi Pandhav
- 6) Mr. Pratik Nalawade

The training included the below mentioned aspects-

- The method principle & instrument Operation,
- Basic instrument & Maintenance, Running
- interpreting quality Control and instrument troubleshooting The training was conducted by our company representative

For Aspen Diagnostic Pvt. Ltd

  
Area Service Manager

**Prasad Jadhav**