

**CERTIFICATE OF CALIBRATION**

**Customer Name** : Likhitha's Diagnostics - Speciality Lab

**Address of the customer** : 101, 1st Floor, Stellar Enclave, Aundh

**Date of Calibration** : 20/09/2022

**Calibration Due on** : 19/03/2023

**Instrument Model** : BC 3000 Plus – 3 Part Hematology Analyzer

**Serial No.** : RJ-19132044

**Date of Installation** : 23/02/2022

This is to certify that the above mentioned product has been calibrated for CBC parameters (WBC, RBC, HGB, MCV, PLT) according to the standard operating procedure given by the MINDRAY

The reference instruments used for value assignment are managed by the traceability system in Shenzhen Mindray Bio – Medical Electronics Co., Ltd, and these are traceable to the International Standards such as ICSH/WHO, NCCLS.

For AGAPPE DIAGNOSTICS LTD.



*Hitendra Mahajan*

Authorized Signatory

**Name : Hitendra Mahajan**  
**Designation : Regional Service Manager**

**AGAPPE DIAGNOSTICS LTD.** ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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Lot No.: PLUS1022

Exp. Date: 05-11-2022

| Para | Mean | 1    | 2    | 3    | 4    | 5    | CV%  | Factor(%) |
|------|------|------|------|------|------|------|------|-----------|
| WBC  | 10.0 | 10.3 | 10.4 | 10.4 | 10.4 | 10.5 | 0.68 | 96.2      |
| RBC  | 4.66 | 4.67 | 4.58 | 4.59 | 4.66 | 4.60 | 0.91 | 100.9     |
| HGB  | 13.6 | 14.2 | 14.0 | 14.0 | 14.1 | 14.1 | 0.59 | 96.6      |
| MCV  | 87.3 | 86.3 | 87.2 | 87.7 | 87.4 | 87.3 | 0.60 | 100.1     |
| PLT  | 251  | 243  | 228  | 242  | 244  | 237  | 2.77 | 105.1     |



| Para | Factor  | Time       |
|------|---------|------------|
| WBC  | 96.2 %  | 20-09-2022 |
| RBC  | 100.9 % | 20-09-2022 |
| HGB  | 96.6 %  | 20-09-2022 |
| MCV  | 100.1 % | 20-09-2022 |
| PLT  | 105.1 % | 20-09-2022 |

DETAILS OF CONTROL RUN

Instrument Model : BC 3000 PLUS - 3 Part Hematology Analyzer  
 Serial No : RJ-19132044  
 Date of Control Run : 20-09-2022  
 Control Used : LOW  
 Lot No : 0822  
 Expiry : 5 - 11 - 2022

The results of repeatability test are summarized in the following table. Refer the attached control sheets for details

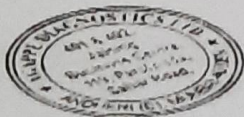
| Sample No       | WBC K/ $\mu$ L | RBC M/ $\mu$ L | HGB g/dL | MCV fL | PLT K/ $\mu$ L |
|-----------------|----------------|----------------|----------|--------|----------------|
| 1               | 2.5            | 2.33           | 6.5      | 83.1   | 83             |
| 2               | 2.5            | 2.25           | 6.2      | 82.8   | 81             |
| 3               | 2.4            | 2.28           | 6.3      | 82.8   | 88             |
| 4               | 2.5            | 2.25           | 6.4      | 83.0   | 91             |
| Instrument Mean | 2.2            | 2.29           | 5.8      | 76.8   | 73             |
| CV %            | 2.27           | 1.07           | 2.23     | 0.18   | 5.33           |
| Factor          | 96.2           | 100.9          | 96.6     | 100.1  | 105.1          |

This is to certify that the above mentioned product has been calibrated for CBC parameters (WBC, RBC, HGB, MCV, PLT) according to the standard operating procedure given by the Mindray

The control run after calibration shows good repeatability and precision

Next Calibration due on **19/03/2023**

For AGAPPE DIAGNOSTICS LTD.



Authorized Signatory

*Hitendra Mahajan*

Name : Hitendra Mahajan

Designation : Regional Service Manager

**AGAPPE DIAGNOSTICS LTD.**

ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | ION U24239MH1998PLC115413

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 Email: bangalore@agappe.in

# SC-CAL PLUS

## HEMATOLOGY CALIBRATOR

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| <b>CALIBRATOR</b> |
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|------------|-----------------|
| <b>LOT</b> | <b>PLUS1022</b> |
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| <b>2022-11-05</b> |
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| Instrument  | Parameter   | Calibration Values                          | Acceptable Range   |
|---|---|---|--|
| BC-6800, BC-6600  | WBC x 10 <sup>9</sup> /L<br>RBCx 10 <sup>12</sup> /L<br>HGB g/L<br>MCV fL<br>PLT x 10 <sup>9</sup> /L             | 9.03<br>4.54<br>133<br>91.1<br>249          | 8.83 - 9.23<br>4.46 - 4.62<br>131 - 135<br>89.1 - 93.1<br>237 - 261  |
| BC-6800Plus<br>BC-6700Plus<br>BC-6600Plus   | WBC x 10 <sup>9</sup> /L<br>RBCx 10 <sup>12</sup> /L<br>HGB g/L<br>MCV fL<br>PLT x 10 <sup>9</sup> /L             | 9.10<br>4.55<br>134<br>91.4<br>244          | 8.90 - 9.30<br>4.47 - 4.63<br>132 - 136<br>89.4 - 93.4<br>232 - 256  |
| BC-6200<br>BC-6100Plus, BC-6100<br>BC-6000Plus, BC-6000   | WBC x 10 <sup>9</sup> /L<br>RBCx 10 <sup>12</sup> /L<br>HGB g/L<br>MCV fL<br>PLT x 10 <sup>9</sup> /L             | 9.34<br>4.58<br>135<br>91.7<br>244          | 9.14 - 9.54<br>4.50 - 4.66<br>133 - 137<br>89.7 - 93.7<br>232 - 256  |
| BC-5800, BC-5600  | WBC x 10 <sup>9</sup> /L<br>RBCx 10 <sup>12</sup> /L<br>HGB g/L<br>MCV fL<br>PLT x 10 <sup>9</sup> /L             | 9.55<br>4.63<br>135<br>86.4<br>263          | 9.35 - 9.75<br>4.55 - 4.71<br>133 - 137<br>84.4 - 88.4<br>251 - 275  |
| BC-5390   | WBC x 10 <sup>9</sup> /L<br>RBCx 10 <sup>12</sup> /L<br>HGB g/L<br>MCV fL<br>PLT x 10 <sup>9</sup> /L             | 9.80<br>4.59<br>135<br>84.5<br>253          | 9.60 - 10.00<br>4.51 - 4.67<br>133 - 137<br>82.5 - 86.5<br>241 - 265 |
| BC-5390CRP, BC-5180CRP<br>BC-5310CRP<br>BC-5100CRP  | WBC x 10 <sup>9</sup> /L<br>RBCx 10 <sup>12</sup> /L<br>HGB g/L<br>MCV fL<br>PLT x 10 <sup>9</sup> /L             | 9.78<br>4.53<br>135<br>84.8<br>248          | 9.58 - 9.98<br>4.45 - 4.61<br>133 - 137<br>82.8 - 86.8<br>236 - 260  |
| BC-5380, BC-5180<br>BC-5300, BC-5300Vet<br>BC-5100, BC-5100Vet<br>(Software version lower<br>than 1.24.00.16860)                  | WBC x 10 <sup>9</sup> /L<br>RBCx 10 <sup>12</sup> /L<br>HGB g/L<br>MCV fL<br>PLT x 10 <sup>9</sup> /L             | 9.45<br>4.54<br>135<br>88.8<br>256          | 9.25 - 9.65<br>4.46 - 4.62<br>133 - 137<br>86.8 - 90.8<br>244 - 268  |
| BC-5380, BC-5180<br>BC-5300, BC-5100<br>(Software version<br>1.24.00.16860 or higher)   | WBC x 10 <sup>9</sup> /L<br>RBCx 10 <sup>12</sup> /L<br>HGB g/L<br>MCV fL<br>PLT x 10 <sup>9</sup> /L             | 9.72<br>4.54<br>136<br>86.9<br>256          | 9.52 - 9.92<br>4.46 - 4.62<br>134 - 138<br>84.9 - 88.9<br>244 - 268  |
| BC-5000, BC-5000Vet<br>BC-5150, BC-5140<br>BC-5130, BC-5120   | WBC x 10 <sup>9</sup> /L<br>RBCx 10 <sup>12</sup> /L<br>HGB g/L<br>MCV fL<br>PLT x 10 <sup>9</sup> /L             | 9.35<br>4.59<br>134<br>87.9<br>254          | 9.15 - 9.55<br>4.51 - 4.67<br>132 - 136<br>85.9 - 89.9<br>242 - 266  |
| BC-700[B], BC-700[R], BC-720[R],<br>BC-760[B], BC-760[R], BC-780[R],<br>BC-700[B] CS, BC-760[B] CS,<br>BC-700[R] CS, BC-760[R] CS | WBC x 10 <sup>9</sup> /L<br>RBCx 10 <sup>12</sup> /L<br>HGB g/L<br>MCV fL<br>PLT x 10 <sup>9</sup> /L<br>ESR mm/h | 9.55<br>4.60<br>134<br>91.6<br>252<br>14.63 | 9.35 - 9.75<br>4.52 - 4.68<br>132 - 136<br>89.6 - 93.6<br>240 - 264  |
| BC-7500[B] CRP,<br>BC-7500[R] CRP,<br>BC-7500[N] CRP,<br>BC-7500[NR] CRP  | WBC x 10 <sup>9</sup> /L<br>RBCx 10 <sup>12</sup> /L<br>HGB g/L<br>MCV fL<br>PLT x 10 <sup>9</sup> /L             | 9.32<br>4.61<br>135<br>91.2<br>248          | 9.12 - 9.52<br>4.53 - 4.69<br>133 - 137<br>89.2 - 93.2<br>236 - 260  |

Before using, refer to the instruction sheet for mixing directions.

# SC-CAL PLUS

## HEMATOLOGY CALIBRATOR

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|-------------------|
| <b>CALIBRATOR</b> |
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| <b>LOT</b> | <b>PLUS1022</b> |
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| <b>2022-11-05</b> |
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| Instrument   | Parameter                | Calibration Values | Acceptable Range |
|--|--------------------------|--------------------|------------------|
| BC-3600, BC-3300   | WBC x 10 <sup>9</sup> /L | 9.7                | 9.5 - 9.9        |
|  | RBCx 10 <sup>12</sup> /L | 4.65               | 4.57 - 4.73      |
|  | HGB g/L                  | 136                | 134 - 138        |
|  | MCV fL                   | 85.6               | 83.6 - 87.6      |
|  | PLT x 10 <sup>9</sup> /L | 252                | 240 - 264        |
| BC-3200, BC-3000 CT                                      | WBC x 10 <sup>9</sup> /L | 10.0               | 9.8 - 10.2       |
|  | RBCx 10 <sup>12</sup> /L | 4.66               | 4.58 - 4.74      |
|  | HGB g/L                  | 136                | 134 - 138        |
|  | MCV fL                   | 87.3               | 85.3 - 89.3      |
|  | PLT x 10 <sup>9</sup> /L | 251                | 239 - 263        |
| BC-3000 Plus, BC-2900<br>BC-1800                         | WBC x 10 <sup>9</sup> /L | 10.0               | 9.8 - 10.2       |
|  | RBCx 10 <sup>12</sup> /L | 4.71               | 4.63 - 4.79      |
|  | HGB g/L                  | 138                | 136 - 140        |
|  | MCV fL                   | 86.0               | 84.0 - 88.0      |
|  | PLT x 10 <sup>9</sup> /L | 257                | 245 - 269        |
| BC-2800, BC-2600<br>BC-2800Vet, BC-2600Vet               | WBC x 10 <sup>9</sup> /L | 9.5                | 9.3 - 9.7        |
|  | RBCx 10 <sup>12</sup> /L | 4.62               | 4.54 - 4.70      |
|  | HGB g/L                  | 137                | 135 - 139        |
|  | MCV fL                   | 87.7               | 85.7 - 89.7      |
|  | PLT x 10 <sup>9</sup> /L | 248                | 236 - 260        |
| BC-2300, BC-2100   | WBC x 10 <sup>9</sup> /L | 9.6                | 9.4 - 9.8        |
|  | RBCx 10 <sup>12</sup> /L | 4.47               | 4.37 - 4.57      |
|  | HGB g/L                  | 135                | 133 - 137        |
|  | MCV fL                   | 86.2               | 84.2 - 88.2      |
|  | PLT x 10 <sup>9</sup> /L | 247                | 232 - 262        |
| BC-20s, BC-21s<br>BC-30, BC-30s, BC-30e<br>BC-31, BC-31s | WBC x 10 <sup>9</sup> /L | 9.6                | 9.4 - 9.8        |
|  | RBCx 10 <sup>12</sup> /L | 4.48               | 4.38 - 4.58      |
|  | HGB g/L                  | 138                | 136 - 140        |
|  | MCV fL                   | 88.6               | 86.6 - 90.6      |
|  | PLT x 10 <sup>9</sup> /L | 247                | 232 - 262        |
| BC-10, BC-10e, BC-11<br>BC-20, BC-21                     | WBC x 10 <sup>9</sup> /L | 9.4                | 9.2 - 9.6        |
|  | RBCx 10 <sup>12</sup> /L | 4.52               | 4.42 - 4.62      |
|  | HGB g/L                  | 136                | 134 - 138        |
|  | MCV fL                   | 88.4               | 86.4 - 90.4      |
|  | PLT x 10 <sup>9</sup> /L | 243                | 228 - 258        |

Before using, refer to the instruction sheet for mixing directions.



**Mindray**

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| <b>EC</b> | <b>REP</b> |
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TO WHOM SOEVER IT MAY CONCERN

Certificate of Traceability

Mindray SC-CAL Plus Hematology Calibrator, manufactured by R&D Systems , is used for the calibration of Mindray BC 3000 Plus and which is traceable to standard reference methods.

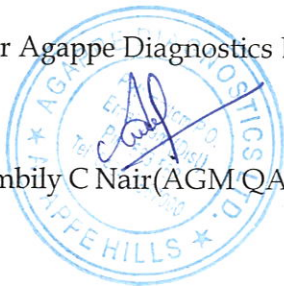
The **White Blood Cell (WBC)** and **Red Blood Cell (RBC)** are analyzed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

**Hemoglobin** is measured using the Clinical Laboratory Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method <sup>(1)</sup>. Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations <sup>(1)</sup>.

The **hematocrit** (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H7-A3 document <sup>(2)</sup>. No correction is made for trapped plasma.

**Platelets** are assayed using a hemocytometer and phase contrast optics.

For Agappe Diagnostics Ltd.



Ambily C Nair (AGM QA/QC)