



ADL/DO/SER/0023/23-24

CERTIFICATE OF CALIBRATION

Customer Name : Shifa Hospital

Address of the customer : C/o Simple Medical Solutions, 59,
Pattukkottai Road, Adirampattinam,
Thanjavur, Tamil Nadu, Adirampattinam,
Adirampattinam, Tamil Nadu-614701, India

Date of Calibration : 29/03/2023

Calibration Due on : 28/Sept/2023

Instrument Model : BC 3000 Plus – 3 Part Hematology Analyzer

Serial No. : RJ-8C127453

Date of Installation : 29-03-2019

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 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.

 

Authorized Signatory

Name : H.Sriram

Designation : Asst. Manager - Customer service

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

CORPORATE OFFICE / REAGENT PLANT
Agappe Hills, Pattinattom (PO), Dist. Ernakulam, Kerala - 683 562, India.
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EQUIPMENT PLANT
X/588-CB, Block No. 32, KINFRA Small Industrial Park,
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KOLKATA OFFICE
406, Merin Matrix, Plot No-10, Block-DN, Sector V,
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401 & 402, 4th Floor, Jaisingh Business Centre, 119,
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BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No-26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in

DETAILS OF CONTROL RUN

Instrument Model : BC 3000 PLUS - 3 Part Hematology Analyzer
 Serial No : RJ-8C127453
 Date of Control Run : 29/03/2023
 Control Used : Hematology control (crit level) - Normal control
 Lot No : 32805033
 Expiry : 05/09/2023

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

Sample No	WBC K/ μ L	RBC M/ μ L	HGB g/dL	MCV fL	PLT K/ μ L
1	7.8	4.29	12.9	79.6	244
2	8.0	4.30	12.8	79.6	245
3	7.9	4.27	12.8	79.6	246
4	8.1	4.39	13.3	79.9	244
Instrument Mean	7.95	4.31	12.95	79.6	246
CV %	0.016	0.014	0.018	0.012	0.013
Factor	92.2	92.9	83.7	91.6	83.1

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 **28/Sept/2023**

For **AGAPPE DIAGNOSTICS LTD.**

Authorized Signatory

Name : H.Sriram

Designation : Asst. Manager - Customer service

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