

Mindray BS-240 Auto Chemistry Analyzer – PQ Documents

Customer Address: **Mediquest Health care Diagnostic**
Mangalore -575002

Contact person: **Ms.Deeksha**
Telephone: 7760804801

Serial no: **YX-91002366**

QC Running: 06/06/22

Performance Qualification

CALIBRATION:

The Analyser has been calibrated with Mindray Multi Sera calibrator for Calcium, Glucose- G, T.Bilirubin, D.Bilirubin, ALT, AST, GGT, ALP, GGT, TP, TGL, HDL-C, TC, UA, Crea-S.

Calibrator Manufacturer : Mindray

Lipids Calibrator : Mindray

Calibrator name : Multi Sera calibrator

Calibrator Name : LIPID CAL

Lot Number : 150121003

Lot Number : 150421013

Expiry date : 18-10-2022

Expiry Date : 30-11-2022

QUALITY CONTROL CHECK - NORMAL CONTROL

Control manufacturer : RANDOX

QC Name : Randox L2 & L3

Lot Number : 1502UN & 1173UE

Expiry Date : 28-06-2024 & 28-06-2024

Carried out Randox Control found values are within specified range.

REMARKS

The system meets all criteria outlined in this performance qualification documents. All the required parameter have been checked and instrument is ready for regular use:

Performer : **Viswanatha. T**
Designation : Application specialist
Date : 21/06/2022

Reviewer : **Muthu vigneshwar. K.P**
Designation : Application Manager





To Whom It May Concern

For ISO 15189:2012 and ISO 15189:2014 accredited Laboratories — requirements regarding "Calibration & Verification Procedures" [1]

All In vitro Diagnostics Products which are manufactured and distributed by Roche Diagnostics GmbH and for which a Free-Sales-Certificate is issued, are CE-marked.

The In-Vitro-Diagnostics Directive of the European Union [2A.] which is currently switching to IVD Regulation 2017/746/EU (final timeline: May 26, 2022) [2B.] requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the mentioned directive or regulation. This means that all processes in development and manufacturing of Roche Diagnostics GmbH products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 13485:2016 [3] and 21 CFR Part 820 [4].

The mentioned regulations and standards require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated. This status has to be assured by scheduled maintenance and by regular qualification resp. validation reviews and updates.

All physical quantities, calibrators and controls used in Roche Diagnostic systems are fully traceable to certified standards or reference materials. The performance of all In-vitro diagnostics systems of Roche Diagnostics GmbH at the customer site is assured if regular Quality Control measurements, cleaning and maintenance procedures as described in the instructions for use or service documentation are performed. By having controlled internal procedures and by running the tasks required in the respective user documentation, all In-vitro diagnostics systems of Roche Diagnostics GmbH will be performed as specified during their defined lifetime.

Additional calibration or verification procedures are NOT required by the user in order to assure the specified performance of every system of Roche Diagnostics GmbH. Only if a user deviates from these manufacturer's recommendations, the user have to establish site-specific calibration and verification procedures as part of his accreditation process.



- [1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories — Requirements for quality and competence
- [2] A. Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on in vitro diagnostics medical devices;
B. IVD Regulation 2017/746/EU of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- [3] EN ISO 13485:2016 Medical devices — Quality management systems-Requirements for regulatory purposes
- [4] CFR Part 820, Quality System regulations 21 Regulations on medical devices

Mannheim, 10. August 2021

Sincerely,

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa/on behalf of the company

DocuSigned by:

 ECA5294AC4E94AF...

Andrea Weber
 Manager Global Regulatory Affairs
 Centralised and Point of Care Solutions

DocuSigned by:

 A7F0B89FE91A46A...

Ralf Zielenski
 Head Q&R Compliance, PRRC RDG
 Centralised and Point of Care Solutions

Roche Diagnostics GmbH
 Sandhofer Straße 116
 D-68305 Mannheim



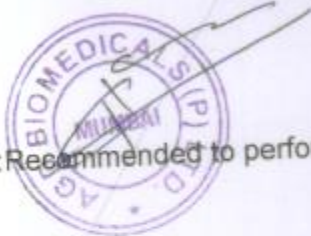
Calibration Certificate

Customer Name : MEDIQUEST HEALTHCARE, MANGLORE
Model Name : EL 120 Electrolyte Analyzer
Serial Number : BC2106009
Calibration Date : 25 May, 2022
Validity of Calibration : 24 November, 2022

Authorized Signatory

AGD Biomedicals (P) Ltd

Note : Recommended to perform calibration every 6 months.



AGD Biomedicals (P) Ltd.
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Mumbai - 400 099 INDIA

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+91-22-28257999
E : sales@agdbio.com
W : www.agdbio.com

ISO : 9001 : 2015
ISO : 13485 : 2016

MINDRAY BC-5130 CALIBRATION CERTIFICATE

Customer Name	Mediquest Health Care Diagnostics (Mangalore)					
Department	Department of Pathology-Laboratory Services					
Address	Mahim complex, Pumpwell old Road, Near cochin bakery, Kankanady, Mangalore – 575002.					
				Date of Calibration	24-06-2022	
Instrument	BC-5130 Auto Haematology Analyzer			Next Calibration Date	23-06-2023	
Serial No	SR-68001484			Calibrator Lot Number	PLUS0622	
				Calibrator Expiry date	05-07-2022	
<u>Calibration Values</u>	<u>Parameter</u>	<u>Target</u>	<u>Range</u>	<u>Mean of Measured Values</u>	<u>New Factor</u>	<u>Old Factor</u>
	WBC x 10 ⁹ /L	9.02	9.08-9.48	9.08	99.45%	100.01%
	RBC x 10 ¹² /L	4.53	4.45-4.61	4.56	110.53%	110.06%
	HGB g/dL	13.3	13.1-13.5	13.4	102.94%	101.00%
	MCV fl	88.2	86.2-90.2	88.4	103.40%	104.96%
	PLT x 10 ⁹ /L	254	242-266	251	117.31%	110.92%
This is to certify that the Mindray BC - 5130 Hematology Analyzer with Serial No: SR-68001484, installed at Mediquest Health Care Diagnostics has been calibrated using the standard reference material PLUS0622 Calibrator.						

Runned By :

[Signature]

Date: 25/06/2022

Application Specialist-IVD
Golden Harvest Industries.

Reviewed By :

[Signature]

Date: 25/06/2022

Manager – Application
Golden Harvest Industries.





ARK *Diagnosics Bangalore Pvt. Ltd.*

CERTIFICATE of CALIBRATION

Manufacturer : Ark Diagnostics Bangalore Pvt Ltd

Instrument : HPLC Analyser - CKK -A1C.

Serial Number : 123-027

Customer : **Mediquest Health Care.**

Ark Diagnostics Bangalore Pvt. Ltd., certifies that the above listed instrument was calibrated on date noted at. Mediquest healthcare, Mahim complex, Pumpwell, old kankanady road, near fether muller circle, kankanady, Mangalore-575002, in accordance with the specifications set forth by the manufacturer using the certified control material as per the provided assay values and expected ranges from the manufacturer.

Calibration Date:-19th January 2022

Calibrated by: - Mr. Vineeth.

Calibration Due:-18th January 2023.

For ark Diagnostics Bangalore Pvt. Ltd.,

Authorized signature





L-95, 5th Cross, 1st Main, Kirloskar Colony 3rd Stage,
Water Tank Road, Basaveshwaranagar, Bangalore-560079.
+91 080-2322 3936, 96633 04352
calibration@sarvashree.com
www.sarvashree.com



Cert No. : CC-2291

NABL Accredited Calibration Services as per ISO/IEC 17025:2017

CALIBRATION CERTIFICATE

SS/FF-20/v1

Page 1 of 2

Name and Address of Customer : M/s. MEDIQUEST HEALTHCARE.,
Mahim Complex, Pumpwell Old Road,
Near Cochin Bakery, Kankanady, Mangalore -575002.

Customer Reference

2.1 SRF No : 6220
2.2 Certification No. : SS/22/6220-01
2.3 Date of Calibration : 25 June 2022
2.4 Next Calibration Due : 24 June 2023

Dated : 25 June 2022
ULR No. : CC229122000007886F

Details Of Unit Under Calibration(UUC).

3.1 Nomenclature : Centrifuge
3.2 Make : Remi Model : R-8C-Plus
3.3 Sl.No : ZGBN-05284 ID. No. : --
3.4 No. of Pages : 2 Location: --
3.5 Calibration Procedure No. : SOP-MSC-07
3.6 DUC Condition : Satisfactory
3.7 Calibration done at : Onsite

Environmental Condition

4.1 Temperature : 25 ± 5 °C Humidity : 40 to 60 %Rh

Standards Used for calibration


Sl. No.	Nomenclature	Make & Model	Sl. No	Traceable Cert. No.	Validity
1	Tachometer	Lutron	Q652908	TVCSPL 22/01/155-01	30-Jan-23

Standard followed -SANAS TR 45-01

Note:

- 6.1. Measurement uncertainty reported is at approx 95% confidence level with coverage factor k=2
- 6.2. Kindly refer Note(s) Section mentioned over leaf.

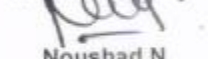
Calibrated By


Rakesh J

(Calibration Engineer)



Authorised By


Noushad N
(Lab In-Charge)

CAL CERT. NO.

SS/22/6220-01

ULR No. : CC22912200007886F

Page No: 2 of 2

Results :

Range : 6000 RPM

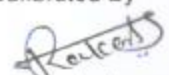
L.C 10 RPM

Sl No.	DUC Set	DUC Reading	Standard Readings	Deviation Observed	Expanded Uncertainty Ue
	in RPM	in RPM	in RPM	in RPM	in \pm RPM%
1	500	500	500.5	-0.5	0.90
2	1000	1000	1002	-2	
3	1500	1500	1503	-3	
4	3000	3000	3004	-4	
5	5000	5000	5007	-7	
5	6000	6000	6008	-8	

Conclusion Remarks

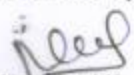
- 1) Calibration done without any adjustments.
- 2) DUC indicates Device Under Calibration

Calibrated By


Rakesh J
(Calibration Engineer)



Authorised By


Noushad N
(Lab In-Charge)



L-95, 5th Cross, 1st Main, Kirloskar Colony 3rd Stage,
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www.sarvashree.com



Cert No. : CC-2291

NABL Accredited Calibration Services as per ISO/IEC 17025:2017

CALIBRATION CERTIFICATE

SS/ FF-20/THM-07

Page 1 of 2

1 Name and Address of Customer: M/s. MEDIQUEST HEALTHCARE.,
Mahim Complex, Pumpwell Old Road,
Near Cochin Bakery, Kankanady, Mangalore -575002.

2 Customer Reference

2.1 SRF No : 6220 Dated : 25 June 2022
2.2 Certificate No. : SS/22/6220-03 ULR No. : CC229122000007888F
2.3 Date of Calibration : 25 June 2022
2.4 Next Calibration Due : 24 June 2023

3 Details Of Device Under Calibration(DUC).

3.1 Nomenclature : Refrigerator Model : CRAR2523
3.2 Make : Croma ID. No. : SFSL/884/DNA/I-51
3.3 SI.No : CRAR25310190045 Location : DNA
3.4 No. of Pages : 2
3.5 Calibration Procedure No. : SOP-THM-07
3.6 DUC Condition : Satisfactory
3.7 Calibration done at : Onsite

4 Environmental Condition

Temperature 25 ± 4 °C Humidity 30 to 75 %RH

5 Standards Used for calibration

Sl. No.	Nomenclature	Make & Model	Sl. No	Traceable Cert. No.	Validity
1	RTD Sensors With Data Logger	Brainchild/Tempsens & Simplex / PR20	410199 / 18B290020	TSC/21-22/17892-02	12-Mar-23

6 Note:

- 6.1. Measurement uncertainty reported is at approx 95% confidence level with coverage factor k=2.
- 6.2. Kindly refer Note(s) Section mentioned over leaf.

Calibrated By

Rakesh J

(Calibration Engineer)



Authorized By

Neushad N

(Lab In-Charge)

Certificate No. SS/22/6220-03

ULR No.: CC229122000007888F

Page No. : 2 of 2

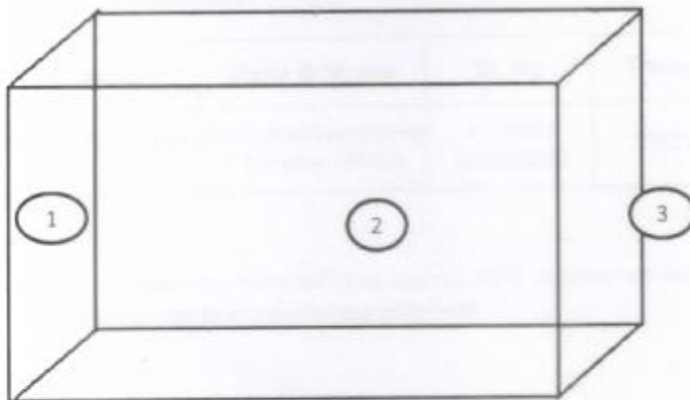
Results :-

Range : -25°C to 8°C

L.C: 0.1°C

Sl. No.	DUC Setting @ (°C)		DUC Reading in °C	Standard Readings in °C			Uniformity in °C
				1	2	3	
1	Top	low	-15.2	-15.3	-15.5	-15.2	0.3
2		high	-13.1	-13.4	-13.5	-13.1	0.4
3	Bottom	1	10.1	10.2	10.6	10.3	0.4
4		2	11.3	11.2	11.4	11.7	0.5
5		3	12.4	12.5	12.2	12.8	0.6
6		4	13.8	13.8	13.1	13.7	0.7
7		5	14.6	14.4	14.0	14.8	0.8

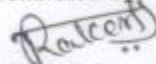
Pictorial Representation of Insertion of Sensors in Refrigerator



Conclusion / Remarks :-

- 1 Measurement Uncertainty ± 2.1
- 2 DUC Indicates Device Under Calibration. Calibration Points given as per customer request.
- 3 DUC Condition : OK

Calibrated By

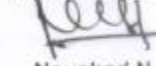


Rakesh J

(Calibration Engineer)



Authorized By



Noushad N

(Lab In-Charge)



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CALIBRATION CERTIFICATE

SS/ FF-20/THM-07

Page 1 of 2

1 Name and Address of Customer: M/s. MEDIQUEST HEALTHCARE.,
Mahim Complex, Pumpwell Old Road,
Near Cochin Bakery, Kankanady, Mangalore -575002.

2 Customer Reference

2.1 SRF No : 6220 Dated : 25 June 2022
2.2 Certificate No. : SS/22/6220-02 ULR No. : CC229122000007887F
2.3 Date of Calibration : 25 June 2022
2.4 Next Calibration Due : 24 June 2023

3 Details Of Device Under Calibration(DUC).

3.1 Nomenclature : Refrigerator Model : CRAR2403
3.2 Make : Croma ID. No. : --
3.3 SI.No : 8901876004791 Location : --
3.4 No.of Pages : 2
3.5 Calibration Procedure No. : SOP-THM-07
3.6 DUC Condition : Satisfactory
3.7 Calibration done at : Onsite

4 Environmental Condition

Temperature : 25 ± 4 °C Humidity : 30 to 75 %RH

5 Standards Used for calibration

Sl. No.	Nomenclature	Make & Model	Sl. No	Traceable Cert. No.	Validity
1	RTD Sensors With Data Logger	Brainchild/Tempsens & Simplex / PR20	410199 / 18B290020	TSC/21-22/17892-02	12-Mar-23

6 Note:

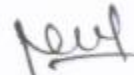
- 6.1. Measurement uncertainty reported is at approx 95% confidence level with coverage factor k=2.
6.2. Kindly refer Note(s) Section mentioned over leaf.

Calibrated By


Rakesh J
(Calibration Engineer)



Authorized By


Noushad N
(Lab In-Charge)

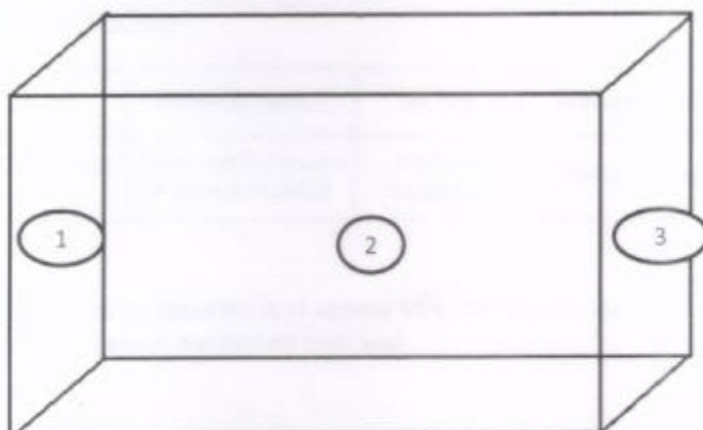
Certificate No. SS/22/6220-02 ULR No. : CC229122000007887F Page No. : 2 of 2

Results :-

Range : -25°C to 8°C L.C: 0.1

Sl. No.	DUC Setting @ (°C)		DUC Reading in °C	Standard Readings in °C			Uniformity in °C
				1	2	3	
1	Top	Min	-4.5	-4.6	-4.6	-4.4	0.2
2		Mid	-8.6	-8.3	-8.6	-8.5	0.3
3		Max	-9.8	-9.4	-9.7	-9.6	0.3
4	Bottom	1	3.5	3.2	3.4	3.6	0.4
5		2	4.2	4.5	4.6	4.1	0.5
6		3	4.8	4.7	4.3	4.9	0.6
7		5	5.1	5.4	5.3	5.9	0.6
8		7	6.4	6.1	6.5	6.9	0.8

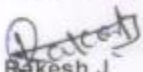
Pictorial Representation of Insertion of Sensors in Refrigerator



Conclusion / Remarks :-

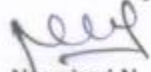
- 1 Measurement Uncertainty ± 2.1
- 2 DUC Indicates Device Under Calibration. Calibration Points given as per customer request.
- 3 DUC Condition : OK

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