Transasia Bio-Medicals Ltd., No. 43, Castle Street, Richmond Road, Opp. Empire Suitess, Asholnagar Bengaluru - 560025
Tel: 080 4430 9000 / 2556 8044 **Email** : sz2@transasia.co.in **CIN** : U33110MH1985PLC036198

TRANSASIA®

TRANSASIA
Proud to be Indian
UNMATCHED SERVICE
SINCE 1979...

Date: 26-10-2023
Effective Date: 26-10-2023

CERTIFICATE OF CALIBRATION

Customer Name : CHRONEVA HEALTH LAB PRIVATE LIMITED

MODEL : Automated Biochemistry Analyzer EM360

Serial N : 601057

Date of Calibration : 26-10-2023

Next Calibration Due : 25-10-2024

This is to certify that the above mentioned product has been verified of calibration according to the industry standard procedures.

Bio-Medicals Pvt. Ltd.

Calibration at site performed by
ATHISH M

Technical Service Department
Transasia Bio-Medicals Ltd.,
Mumbai.

Scanned with ACE Scanner

TABLE OF CONTENTS

S. No	Title	Page No.
1.0	Pre approval	02
2.0	Objective	03
3.0	Scope	03
4.0	Pre- Requisites	03
5.0	Execution Team	03
6.0	Test Plan	04
7.0	Execution of Test Plan	05
8.0	Deficiencies / Deviations	05
9.0	Summary and Evaluation	06
10.0	Abbreviations	06
11.0	Post Approval	07

Scanned with OKEN Scanner

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Mr. Yogesh Vanmali	Application Manager		02/05/2022

1.2 Checked By

Name	Designation	Signature	Date
Ms. Dinakaran	Lab Manager		02/05/22

1.3 Approved By

Name	Designation	Signature	Date
Mr. Yogesh Vanmali	Application Manager		02/05/22

Scanned with OKEN Scanner

2.0 OBJECTIVE

The objective of this protocol is to establish documented evidence for the Performance Qualification of EM 200 (Bio-Chemistry Random Analyzer) and to ensure that the results obtained are within the pre-determined Acceptance Criteria.

3.0 SCOPE

The Scope of this protocol is applicable to EM 200 (Bio-Chemistry Random Analyzer).

4.0 PRE-REQUISITES:

Following Pre-requisites are required before the execution of Performance Qualification.

- Completion of Installation Qualification prior to PQ.
- Completion of Operational Qualification prior to PQ.

5.0 EXECUTION TEAM

Name	Department	Designation	Signature
Mr. Dinakaran	Biochemistry	Lab Manager	2/5/22

Scanned with OKEN Scanner

6.0 TEST PLAN

The following tests precision shall be performed and check the CV% during the Performance Qualification of EM 360 (Fully Automated Bio-chemistry Analyzer).

6.1 Precision Data:

	GLU		CRENZ	
01	90.2	239.3	1.74	4.73
02	91.3	240.1	1.75	4.69
03	90.1	239.9	1.76	4.71
04	89.3	238.2	1.73	4.70
05	91.0	238.8	1.74	4.72
06	88.9	240.8	1.75	4.72
07	90.9	241.7	1.78	4.71
08	92.3	240.2	1.76	4.69
09	91.8	239.5	1.73	4.68
10	90.0	239.9	1.74	4.81
Mean	90.6	239.8	1.75	4.72
S.D	1.08	0.99	0.02	0.04
CV%	1.19	0.41	0.89	0.78
Acceptable Range (%)	< 5	< 5	< 5	< 5
Remarks	**Pass**	**Pass**	**Pass**	**Pass**

Scanned with OKEN Scanner

7.0 EXECUTION OF TEST PLAN

Reviewed by:

Name	Signature	Date
Yogesh Vanmali		02/05/2022

8.0 DEFICIENCIES / DEVIATIONS: Not Observed

Reviewed by:

Name	Signature	Date
Yogesh Vanmali		02/05/2022

Scanned with OKEN Scanner

9.0 SUMMARY AND EVALUATION:

Reviewed by:

Name	Signature	Date
Yogesh Vanmali		02/05/2022

10.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification

Scanned with OKEN Scanner

11.0 POST APPROVAL

11.1 Checked by

Name	Designation	Signature	Date
Mr. Dinakaran	Lab Manager		02/05/2022

11.2 Approved by

Name	Designation	Signature	Date
Yogesh Vanmali	Asst. Manager		02/05/2022

Note: This report is effective from the date of approval.

Scanned with OKEN Scanner

CHRONEVA HEALTH LAB

BANGALORE

Test Statistics

Test	GLU	*Report Type*	*Patients*
Date From	02-May-2022	Date To	02-May-2022

Sample ID EP PRECISION Patient Name - Age -

Sr#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	239.3	mg/dl	H	02-May-2022 12:09:27	9272	22-Dec-2021 17:09:09
2	240.1	mg/dl	H	02-May-2022 12:09:17	9271	22-Dec-2021 17:09:09
3	239.9	mg/dl	H	02-May-2022 12:09:08	9270	22-Dec-2021 17:09:09
4	238.2	mg/dl	H	02-May-2022 12:08:58	9269	22-Dec-2021 17:09:09
5	238.8	mg/dl	H	02-May-2022 12:08:48	9268	22-Dec-2021 17:09:09
6	240.8	mg/dl	H	02-May-2022 12:08:38	9267	22-Dec-2021 17:09:09
7	241.7	mg/dl	H	02-May-2022 12:08:28	9266	22-Dec-2021 17:09:09
8	240.2	mg/dl	H	02-May-2022 12:08:19	9265	22-Dec-2021 17:09:09
9	239.5	mg/dl	H	02-May-2022 12:08:09	9264	22-Dec-2021 17:09:09
10	239.9	mg/dl	H	02-May-2022 12:07:59	9263	22-Dec-2021 17:09:09

Computed Ranges And Statistical Values

Reference Range	0
Above Reference Range	10
Below Reference Range	0
Default Range	0
Total Test(s)	10

Sr# From 1 To 10

N	10
Mean	239.8
SD	0.99
%CV	0.41
Range	3.5

Scanned with OKEN Scanner

CHRONEVA HEALTH LAB

BANGALORE

Test Statistics

Test	GLU	*Report Type*	*Patients*
Date From	02-May-2022	Date To	02-May-2022

Sample ID EN PRECISION Patient Name - Age -

Sr#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	90.2	mg/dl	-	02-May-2022 12:06:11	9252	22-Dec-2021 17:09:09
2	91.3	mg/dl	-	02-May-2022 12:06:01	9251	22-Dec-2021 17:09:09
3	90.1	mg/dl	-	02-May-2022 12:05:52	9250	22-Dec-2021 17:09:09
4	89.3	mg/dl	-	02-May-2022 12:05:42	9249	22-Dec-2021 17:09:09
5	91.0	mg/dl	-	02-May-2022 12:05:32	9248	22-Dec-2021 17:09:09
6	88.9	mg/dl	-	02-May-2022 12:05:22	9247	22-Dec-2021 17:09:09
7	90.9	mg/dl	-	02-May-2022 12:05:12	9246	22-Dec-2021 17:09:09
8	92.3	mg/dl	-	02-May-2022 12:05:03	9245	22-Dec-2021 17:09:09
9	91.8	mg/dl	-	02-May-2022 12:04:53	9244	22-Dec-2021 17:09:09
10	90.0	mg/dl	-	02-May-2022 12:04:43	9243	22-Dec-2021 17:09:09

Computed Ranges And Statistical Values

Reference Range	10
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	10

Sr# From 1 To 10

N	10
Mean	90.6
SD	1.08
%CV	1.19
Range	3.4

Scanned with OKEN Scanner

CHRONEVA HEALTH LAB

BANGALORE

Test Statistics

Test	CRENZ	*Report Type*	*Patients*
Date From	02-May-2022	Date To	02-May-2022

Sample ID EP PRECISION Patient Name - Age -

Sr#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	4.73	mg/dl	H	02-May-2022 12:07:49	9262	20-Apr-2022 12:03:10
2	4.69	mg/dl	H	02-May-2022 12:07:39	9261	20-Apr-2022 12:03:10
3	4.71	mg/dl	H	02-May-2022 12:07:30	9260	20-Apr-2022 12:03:10
4	4.70	mg/dl	H	02-May-2022 12:07:20	9259	20-Apr-2022 12:03:10
5	4.72	mg/dl	H	02-May-2022 12:07:10	9258	20-Apr-2022 12:03:10
6	4.72	mg/dl	H	02-May-2022 12:07:00	9257	20-Apr-2022 12:03:10
7	4.71	mg/dl	H	02-May-2022 12:06:50	9256	20-Apr-2022 12:03:10
8	4.69	mg/dl	H	02-May-2022 12:06:41	9255	20-Apr-2022 12:03:10
9	4.68	mg/dl	H	02-May-2022 12:06:31	9254	20-Apr-2022 12:03:10
10	4.81	mg/dl	H	02-May-2022 12:06:21	9253	20-Apr-2022 12:03:10

Computed Ranges And Statistical Values

Reference Range	0
Above Reference Range	10
Below Reference Range	0
Default Range	0
Total Test(s)	10

Sr# From 1 To 10

N	10
Mean	4.72
SD	0.04
%CV	0.78
Range	0.13

Scanned with OKEN Scanner

CHRONEVA HEALTH LAB

BANGALORE

Test Statistics

Test	CRENZ	*Report Type*	*Patients*
Date From	02-May-2022	Date To	02-May-2022

Sample ID EN PRECISION Patient Name - Age -

Sr#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	1.74	mg/dl	H	02-May-2022 12:04:33	9242	20-Apr-2022 12:03:10
2	1.75	mg/dl	H	02-May-2022 12:04:23	9241	20-Apr-2022 12:03:10
3	1.76	mg/dl	H	02-May-2022 12:04:14	9240	20-Apr-2022 12:03:10
4	1.73	mg/dl	H	02-May-2022 12:04:04	9239	20-Apr-2022 12:03:10
5	1.74	mg/dl	H	02-May-2022 12:03:54	9238	20-Apr-2022 12:03:10
6	1.75	mg/dl	H	02-May-2022 12:03:44	9237	20-Apr-2022 12:03:10
7	1.78	mg/dl	H	02-May-2022 12:03:34	9236	20-Apr-2022 12:03:10
8	1.76	mg/dl	H	02-May-2022 12:03:25	9235	20-Apr-2022 12:03:10
9	1.73	mg/dl	H	02-May-2022 12:03:15	9234	20-Apr-2022 12:03:10
10	1.74	mg/dl	H	02-May-2022 12:03:05	9233	20-Apr-2022 12:03:10

Computed Ranges And Statistical Values

Reference Range	0
Above Reference Range	10
Below Reference Range	0
Default Range	0
Total Test(s)	10

Sr# From 1 To 10

N	10
Mean	1.75
SD	0.02
%CV	0.89
Range	0.05

Scanned with OKEN Scanner