

TRANSASIA®

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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.

Calibration at site performed by
ATHISH M

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

www.transasia.co.in



HO : Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai - 400 072 Tel: +91 22 4030 9000 Fax: +91 22 2857 3030

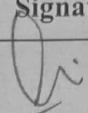
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
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1.0 PRE APPROVAL

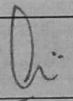
1.1 Prepared By

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

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

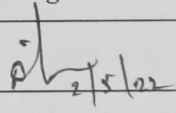
The Scope of this protocol is applicable to EM 200 (Bio-Chemistry Random Analyzer).

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	

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
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

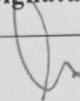
7.0 EXECUTION OF TEST PLAN

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

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

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.

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



CHRONEVA HEALTH LAB

BANGALORE

Test Statistics

Test: GLU
Date From: 02-May-2022
Report Type: Patients
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



CHRONEVA HEALTH LAB

BANGALORE

Test Statistics

Test: CRENZ
Date From: 02-May-2022
Report Type: Patients
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



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

