

TRANSASIA[®]

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CIN : U33110MH1985PLC036198



EM-200
AUTOMATED BIOCHEMISTRY ANALYZER

PERFORMANCE
QUALIFICATION

For

“GOODDAYS DIAGNOSTIC”
CHINSURAH

Marketed by:
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Transasia House,
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TRANSASIA BIOMEDICALS LIMITED
PERFORMANCE QUALIFICATION



Instrument Name EM-200 Instrument Serial Number V200262

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TRANSASIA BIOMEDICALS LIMITED


PERFORMANCE QUALIFICATION

TRANSASIA
BIOMEDICALS

Instrument Name: EQV-200 Instrument Serial Number: N200262

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
SUDIPTAJANA	APPLICATION MANAGER		



1.2 Checked By

Name	Designation	Signature	Date

1.3 Approved By

Name	Designation	Signature	Date

TRANSASA BIOMEDICALS LIMITED
 PERFORMANCE QUALIFICATION



Instrument Name EM-200 Instrument Serial Number V200262

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
Uma Bhattacharya	Biochemistry	St. Lab Tech.	
Dolon Malo	Microbiology	Lab Tech	Dolon Malo
Ahmedjit Das	Haematology & Biochemistry	St. Lab Tech.	

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Instrument Name	EM-200	Instrument Serial Number	V200262
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7.0 EXECUTION OF TEST PLAN

- A. PRECISION CHECK FOR GLUCOSE & UREA → REPORT ATTACHED
- B. CARRYOVER TEST FOR GLUCOSE & UREA → REPORT ATTACHED
- C. LINEARITY TEST FOR GLUCOSE & UREA → REPORT ATTACHED
- D. QC DATA FOR ALL PARAMETERS → REPORT ATTACHED

Reviewed by:

Name	Signature	Date

TRANSASIA BIOMEDICALS LIMITED
PERFORMANCE QUALIFICATION

TRANSASIA
Bio-Medicals Ltd

Instrument Name EM-200 Instrument Serial Number V200262

11.0 POST APPROVAL

11.1 Checked by

Name	Designation	Signature	Date
Wan Pinelchany	Gr. Lab Tech		
Dolon Male	Lab Tech	- Dolon Male	
Mohrajit D.	Sr. Lab Tech		

11.2 Approved by

Name	Designation	Signature	Date

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

GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Test Statistics

Test	GLU	Report Type	Patients
Date From	12-Oct-2023	Date To	12-Oct-2023

Sample ID	PRECISION	Patient Name	Age		
Sr#	Result Unit	Flag	Result Date	Curve #	Used Calibration
1	76.4 mg/dL	-	12-Oct-2023 13:52:07	34575	06-Oct-2023 13:44:06
2	76.7 mg/dL	-	12-Oct-2023 13:51:49	34574	06-Oct-2023 13:44:06
3	75.7 mg/dL	-	12-Oct-2023 13:51:30	34573	06-Oct-2023 13:44:06
4	76.5 mg/dL	-	12-Oct-2023 13:51:12	34572	06-Oct-2023 13:44:06
5	75.9 mg/dL	-	12-Oct-2023 13:50:54	34571	06-Oct-2023 13:44:06
6	74.7 mg/dL	-	12-Oct-2023 13:50:36	34570	06-Oct-2023 13:44:06
7	75.5 mg/dL	-	12-Oct-2023 13:50:18	34569	06-Oct-2023 13:44:06
8	76.4 mg/dL	-	12-Oct-2023 13:50:00	34568	06-Oct-2023 13:44:06
9	76.1 mg/dL	-	12-Oct-2023 13:49:42	34567	06-Oct-2023 13:44:06
10	76.3 mg/dL	-	12-Oct-2023 13:49:24	34566	06-Oct-2023 13:44:06
11	76.8 mg/dL	-	12-Oct-2023 13:49:06	34565	06-Oct-2023 13:44:06
12	76.2 mg/dL	-	12-Oct-2023 13:48:48	34564	06-Oct-2023 13:44:06
13	76.7 mg/dL	-	12-Oct-2023 13:48:30	34563	06-Oct-2023 13:44:06
14	76.1 mg/dL	-	12-Oct-2023 13:48:12	34562	06-Oct-2023 13:44:06
15	76.1 mg/dL	-	12-Oct-2023 13:47:54	34561	06-Oct-2023 13:44:06
16	76.0 mg/dL	-	12-Oct-2023 13:47:36	34560	06-Oct-2023 13:44:06
17	75.9 mg/dL	-	12-Oct-2023 13:47:18	34559	06-Oct-2023 13:44:06
18	75.7 mg/dL	-	12-Oct-2023 13:47:00	34558	06-Oct-2023 13:44:06
19	76.7 mg/dL	-	12-Oct-2023 13:46:42	34557	06-Oct-2023 13:44:06
20	76.0 mg/dL	-	12-Oct-2023 13:46:23	34556	06-Oct-2023 13:44:06



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Test Statistics

Test	GLU	Report Type	Patients
Date From	12-Oct-2023	Date To	12-Oct-2023

Computed Ranges And Statistical Values

Reference Range	21
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	21

Sr# From - To -

N	20
Mean	76.1
SD	0.60
%CV	0.65
Range	2.1



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Test Statistics

Test	UREA	Report Type	Patients
Date From	12-Oct-2023	Date To	12-Oct-2023

Sample ID	PRECISION1	Patient Name	Age	Curve #	Used Calibration
Sid	Result Unit	Flag	Result Date		
1	88.6 mg/dL	H	12-Oct-2023 13:58:25	34596	11-Oct-2023 13:02:46
2	87.7 mg/dL	H	12-Oct-2023 13:58:07	34595	11-Oct-2023 13:02:46
3	87.5 mg/dL	H	12-Oct-2023 13:57:50	34594	11-Oct-2023 13:02:46
4	89.0 mg/dL	H	12-Oct-2023 13:57:31	34593	11-Oct-2023 13:02:46
5	88.0 mg/dL	H	12-Oct-2023 13:57:13	34592	11-Oct-2023 13:02:46
6	87.8 mg/dL	H	12-Oct-2023 13:56:55	34591	11-Oct-2023 13:02:46
7	86.3 mg/dL	H	12-Oct-2023 13:56:37	34590	11-Oct-2023 13:02:46
8	87.7 mg/dL	H	12-Oct-2023 13:56:19	34589	11-Oct-2023 13:02:46
9	86.7 mg/dL	H	12-Oct-2023 13:56:01	34588	11-Oct-2023 13:02:46
10	89.5 mg/dL	H	12-Oct-2023 13:55:43	34587	11-Oct-2023 13:02:46
11	86.4 mg/dL	H	12-Oct-2023 13:55:25	34586	11-Oct-2023 13:02:46
12	86.2 mg/dL	H	12-Oct-2023 13:55:07	34585	11-Oct-2023 13:02:46
13	86.3 mg/dL	H	12-Oct-2023 13:54:49	34584	11-Oct-2023 13:02:46
14	86.0 mg/dL	H	12-Oct-2023 13:54:31	34583	11-Oct-2023 13:02:46
15	87.0 mg/dL	H	12-Oct-2023 13:54:13	34582	11-Oct-2023 13:02:46
16	86.6 mg/dL	H	12-Oct-2023 13:53:55	34581	11-Oct-2023 13:02:46
17	87.6 mg/dL	H	12-Oct-2023 13:53:37	34580	11-Oct-2023 13:02:46
18	87.4 mg/dL	H	12-Oct-2023 13:53:19	34579	11-Oct-2023 13:02:46
19	86.7 mg/dL	H	12-Oct-2023 13:53:01	34578	11-Oct-2023 13:02:46
20	87.1 mg/dL	H	12-Oct-2023 13:52:43	34577	11-Oct-2023 13:02:46



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Test Statistics

Test	UREA	Report Type	Patients
Date From	12-Oct-2023	Date To	12-Oct-2023

Computed Ranges And Statistical Values

Reference Range	0
Above Reference Range	21
Below Reference Range	0
Default Range	0
Total Test(s)	21

Stat From - To -

N	20
Mean	97.8
SD	0.86
%CV	0.88
Range	3.2



GOODDAYS DIAGNOSTIC

Carryover worksheet.

Instrument ID: EM 200 SN= V200262

Date performed: 10/12/2023

Carryover calculation:

$$\text{Carryover \%} = (L1-L3) / (H3-L3) * 100.$$

Interpretation of results. :

1) If (L1-L3) is equal to a negative number or zero then stop as there is no evidence of carryover.

Instrument	Analytes	
	GLUCOSE	UREA
H1	284.5	99.4
H2	288.4	97.3
H3	288.5	97.5
L1	17.7	13.1
L2	17.9	13.1
L3	17.8	12.8
% age Carryover	-0.04	0.35
Acceptble Range	1.0	1.0
Status	PASS	PASS



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Result Reprint

Report Type	Patients	Test UREA				
Sr #	Sample ID	Test	Result Unit	Flag	Curve #	Result Date
1	H/G1	UREA	88.4 mg/dL	H	34633	12-Oct-2023 16:27:50
2	H/G1	UREA	87.3 mg/dL	H	34634	12-Oct-2023 16:28:08
3	H/G1	UREA	87.5 mg/dL	H	34635	12-Oct-2023 16:28:26
4	L/O1 -	UREA	13.1 mg/dL	L	34636	12-Oct-2023 16:28:44
5	L/O1 -	UREA	13.1 mg/dL	L	34637	12-Oct-2023 16:29:02
6	L/O1 -	UREA	12.8 mg/dL	L	34638	12-Oct-2023 16:29:20



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Result Reprint

Report Type	Patients	Test	GLU			
Sr #	Sample ID	Test	Result Unit	Flag	Curve #	Result Date
1	HIGH	GLU	284.5 mg/dL	H	34626	12-Oct-2023 15:23:55
2	HIGH	GLU	288.4 mg/dL	H	34627	12-Oct-2023 15:24:13
3	HIGH	GLU	288.5 mg/dL	H	34628	12-Oct-2023 15:24:31
4	LOW	GLU	17.7 mg/dL	L	34629	12-Oct-2023 15:24:49
5	LOW	GLU	17.9 mg/dL	L	34630	12-Oct-2023 15:25:07
6	LOW	GLU	17.8 mg/dL	L	34631	12-Oct-2023 15:25:25



GOODDAYS DIAGNOSTIC

Instrument Id:

Date performed:

12-Oct-23

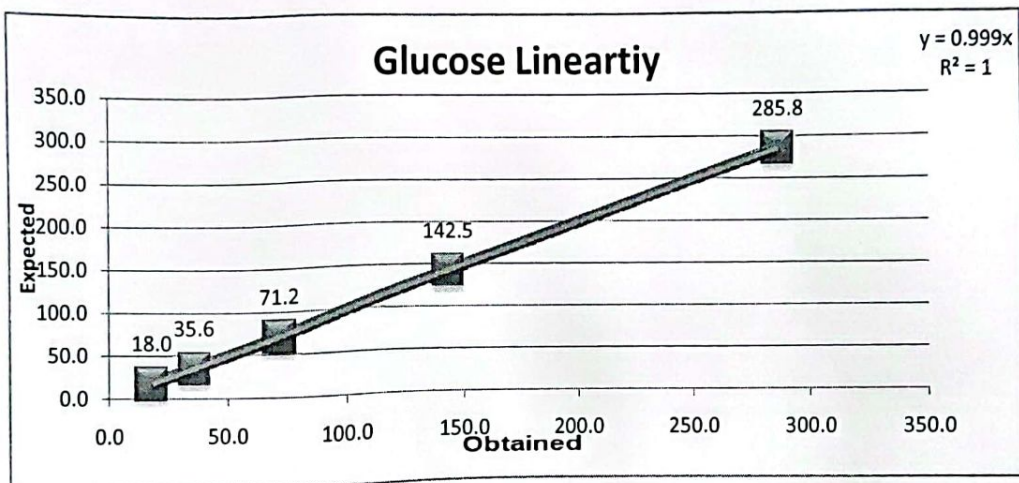
Linearity Parameter:

Glucose

Instrument Name:

EM 200, SN:V200262

GLUCOSE	Expected	Obtained
Neat	285.8	285.8
1:2	142.9	142.5
1:4	71.5	71.2
1:8	35.7	35.6
1:16	17.9	18.0



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Result Reprint

Report Type	Patients	Test: GLU					
Sr #	Sample ID	Test	Result	Unit	Flag	Curve #	Result Date
1	NEAT	GLU	255.8	mg/dL	H	34507	12-Oct-2023 15:05:52
2	1-2	GLU	142.5	mg/dL	H	34511	12-Oct-2023 15:07:04
3	1-4	GLU	71.2	mg/dL	L	34516	12-Oct-2023 15:08:34
4	1-8	GLU	35.6	mg/dL	L	34520	12-Oct-2023 15:09:47
5	1-15	GLU	18.0	mg/dL	L	34521	12-Oct-2023 15:10:05



GOODDAYS DIAGNOSTIC

Instrument Id:

Date performed:

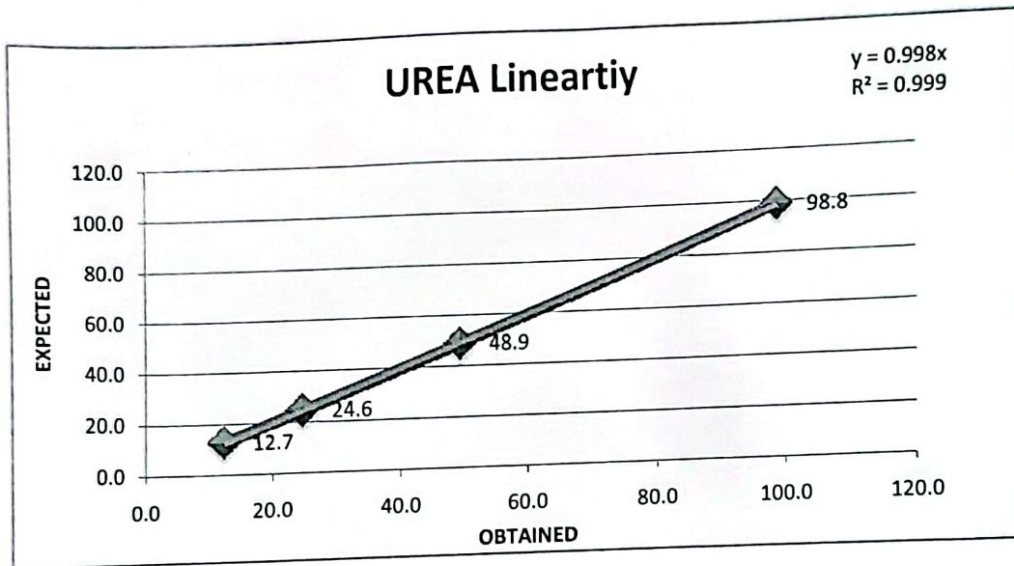
12-Oct-23

Linearity Parameter:

UREA

EM 200, SN:V200262

Instrument Name:		Expected	Obtained
UREA		98.8	98.8
Neat		49.4	48.9
1:2		24.7	24.6
1:4		12.4	12.7
1:8			



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Result Reprint

Report Type : Patients Test UREA

Sr #	Sample ID	Test	Result	Unit	Flag	Curve #	Result Date
1	NEAT	UREA	98.8	mg/dL	H	34605	12-Oct-2023 15:05:16
2	1-2	UREA	48.9	mg/dL		34610	12-Oct-2023 15:06:46
3	1-4	UREA	24.6	mg/dL		34613	12-Oct-2023 15:07:40
4	1-8	UREA	12.7	mg/dL	L	34618	12-Oct-2023 15:09:10

