



# EXCEL MEDINET INC.

Deals in All Kind of Medical Equipments, Softwares & Service Support

E-Mail: deepakagarwal\_y@yahoo.com

## Installation Qualification

MODEL: Diachem 240

Sr. No CA24-DC160800020

Version: 1.0.0.6

Date: 30.01.2019

Installation of Diachem 240 (Fully Auto Biochemistry Analyser) at DIAGNOSTIC POINT PATH LAB DILSAD GARDEN DELHI-110095

The installation checklist is as given below:

S.No.	Position	Action	Reference	Status
1	Unpacking	1. Unpack the Complete system	Chapter1	Ok
2	Inventory	2. Check Accessories	As per the list	Ok
3	Installation	3.1 Installation of Cuvettes 3.2 Connection of Pipeline 3.3 Connection of the Equipment 3.4 Installation of Software	Chapter 2.1-2.3 Chapter 2.4 Chapter 2.1-2.3 Chapter 2.9	Ok
4	Service	4.1 Action/Hardware Test 4.2 Prime 4.3 Check Blank/Optics/Cuvettes 4.4 Parameter Program	Chapter 4.9.1 Chapter 4.9.1 Chapter 4.9.1 Chapter 4.6.1	Ok
5	User	5.1 Start Work Procedure 5.2 Check Reagent & DDW 5.3 Blank Test 5.4 Run QC 5.5 Run Samples/Check Reproducibility 5.6 Stop Work Procedure	Chapter 4.1.1 Chapter 4.4.2 Chapter 5.1.13 Chapter 5.1.15 Chapter 5.1.16 Chapter 5.3.14	Ok

Tested By:



Checked By:

2977A, Street No. 3, Shalimar Park Ext., Bhola Nath Nagar, Shahdara, Delhi -110032 Contact : +91-9650598248



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## Operational Qualification

MODEL: Diachem 240

Sr. No CA24-DC160800020

Version: 1.0.0.6

Date: 30.01.2019

### Operational Qualification Protocol:

S.No.	Description	Status
1	Blank/Optics	Passed
2	Assays(Parameter) Calibration	Passed
3	Assay(Parameter) Control	Passed
4	Assay(Parameter) Samples/Patient	Passed

Imparted Operator's Training & Maintenance Completed

I confirm that the above specified analyzer Diachem 240(Fully automated Biochemistry Analyser) is installed properly and its performance is within the specifications.

Tested By:



Checked By:



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## Performance Qualification

MODEL: Diachem 240 PLUS

Sr. No CA24-DC160800020

Version: 1.0.0.6

Date: 30.01.2019

PQ is performed

According to the assay results that are comprised in this document the Diachem 240 system can be approved for the routine operation.

System released for routine operation.

PERFORMANCE CALIBRATION DONE BY CALIBRATOR							
LOT No: 280035			Exp Date:				
TEST	TARGET	RANGE	RESULT	SD	CV (%)	FACTOR	
GLU (End Point)	291	261-321	291	2.085	0.71	1.00	
			295				
			293				
UREA (Fixed Time)	99	93-105	103	3.606	3.61	1.00	
			101				
			96				
CRE (Fixed Time)	4.9	4.4-5.4	4.71	0.111	2.37	1.00	
			4.83				
			4.62				
URIC ACID (End Point)	9.7	9.0-10.4	9.1	0.115	1.25	1.00	
			9.3				
			9.2				
TGL (End Point)	84.2	76.5-91.5	83	2.682	3.24	1.00	
			85				
			80				
CHO (End Point)	95.7	88-102	95	2.00	2.06	1.00	
			99				
			97				



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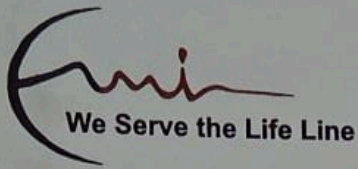


## Diagnostic Point Path Lab

VERIFICATION FORMAT- LINEARITY CHECK

S.NO	TEST PARAMETER	UNDILUTED SAMPLE	DILUTIONS											
			1:2 OBSERVED ACTUAL	1:4 OBSERVED ACTUAL	1:8 OBSERVED ACTUAL	1:16 OBSERVED ACTUAL	1:32 OBSERVED ACTUAL							
1	GLU	290.0	145.0	72.5	36.3	18.1	9.1	10.0	151.0	72.5	36.3	18.1	9.1	10.0
2	URE	113.0	56.5	28.3	14.1	7.1	3.5	4.0	60.0	28.3	14.1	7.1	3.5	4.0
3	CRE	5.66	2.83	1.42	0.71	0.35	0.18	0.25	2.86	1.42	0.71	0.35	0.18	0.25
4	UA	9.40	4.70	2.35	1.18	0.59	0.29	0.30	5.20	2.35	1.18	0.59	0.29	0.30
5	CAL	12.30	6.15	3.08	1.54	0.77	0.38	0.30	6.80	3.08	1.54	0.77	0.38	0.30
6	PHOS	7.40	3.70	1.85	0.93	0.46	0.23	0.20	3.80	1.85	0.93	0.46	0.23	0.20
7	BILT	4.62	2.31	1.16	0.58	0.29	0.14	0.47	2.53	1.16	0.58	0.29	0.14	0.47
8	SGOT	216.0	108.0	54.0	27.0	13.5	6.8	10.0	113.0	54.0	27.0	13.5	6.8	10.0
9	SGPT	109.0	54.5	27.3	13.6	6.8	3.4	4.0	56.0	27.3	13.6	6.8	3.4	4.0
10	ALP	376.0	188.0	94.0	47.0	23.5	11.8	12.0	169.0	94.0	47.0	23.5	11.8	12.0
11	CHOL	252.0	126.0	63.0	31.5	15.8	7.9	2.0	140.0	63.0	31.5	15.8	7.9	2.0
12	TG	211.0	105.5	52.8	26.4	13.2	6.6	6.0	117.0	52.8	26.4	13.2	6.6	6.0
13	HDL	82.0	41.0	20.5	10.3	5.1	2.6	3.0	43.0	20.5	10.3	5.1	2.6	3.0
14	TP	6.9	3.45	1.73	0.86	0.43	0.22	0.30	3.70	1.73	0.86	0.43	0.22	0.30
15	ALB	4.1	2.05	1.03	0.51	0.26	0.13	0.20	2.40	1.03	0.51	0.26	0.13	0.20

*1.0/1.0*



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## Calibration Certificate

Calibration of Diachem 240 )Fully automated Biochemistry analyserhas been carried out as per the recommendations of principal company.

Customer Name: Diagnostic Point Path Lab

Date of Installation: 30-01-2019

Calibration Date: 02-01-2021

Model : Diachem 240

Sr. No.: CA24-DC160800020

Version: 1.0.13(128)

Date:02.01.2021

### Hardware Calibration

ARM	Home Position		Sample Position		Reagent Position		Reaction Position	
	Horizontal	Vertical	Horizontal	Vertical	Horizontal	Vertical	Horizontal	Vertical
Reagent 1	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed
Reagent2	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed
Mixer	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed

Wash arm			
Reaction Vertical Position	Home Position	Water In time	Waste Out Time
Passed	Passed	Passed	Passed

Temperature	
37° C	Passed

AD Value		
Blank Voltage	32000-62000	Passed
Optics(DDW)	0.0001	Passed

OD Linear Range is 0 to 3.0A.

Next Calibration due on: January 2022

Tested By:

Checked By:

2977 A, Ground Floor, Shalimar Park Ext, Bholanath Nagar, Shahdra, Delhi-110032.