

CALIBRATION REPORT

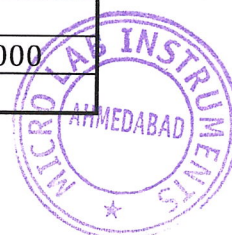
Date: 12.03.2022

1. Instrument: Bio- Chemistry Analyzer
2. Model: RX-50V
3. Sr. No. : 2150146
4. Manufacturing date: 09.03.2022
5. Date of Calibration: 11.03.2022
6. Software version: 4.3.0

TEST PARAMETERS

Test Parameters	Actual Parameters			Ok / Not Ok
Logic Voltage 3.3V	3.3V			Ok
Lamp Voltage (11.8 to 12.2)	11.92V			Ok
SMPS Voltages : 15.31 V	15.31V			Ok
Flow Cell Temperature	25°C 1742	30 °C 1481	37 °C 1185	All Ok
Pump Calibration value	4071			Ok
Incu. SP/ADC (620 - 660)	643			Ok

Sr. No.	Filters	Gain Voltages	Range
1	340nm	1.9748	1.3000-2.1000
2	405nm	2.3270	1.4000-3.0000
3	000nm	-	-
4	505nm	2.5897	1.4000-3.0000
5	546nm	2.5556	1.4000-3.0000
6	578nm	2.7113	1.4000-3.0000
7	630nm	2.6515	1.4000-3.0000
8	000nm	-	-
9	Temp	0.7153	0.6000-1.0000
10	Filter Offset	55	-



Photometric Accuracy :-

The readings of the absorbance are taken of following standard filters at the frequency of 546nm. The results are compared with its range.

Range of the Instrument : Optical Density Linear From 0 to 3.0

Std Absorbance	Measured Absorbance	Range
0.2	0.2054	0.2000-0.2600
0.4	0.4041	0.4000-0.4500
1.0	1.0080	1.0000-1.0900
2.0	2.0037	2.0000-2.0800

Precision Control :-

The absorbance of two standard filters of 0.4 and 2.0 is taken. The 20 replicates of each is made and mentioned as CV (%).

Std Absorbance	CV (%)
0.4	0.02 %
2.0	0.008 %

Clinical chemistry control:-

CHEMISTRY	Level - 1			Level - 2		
	Measured	Mean	Range	Measured	Mean	Range
GLU	92.38	94.0	74.0 - 114	283.88	285	226 - 344
SGPT	30.37	30.0	20.0 - 40.0	98.15	95.0	75.0 - 115
CRTN	2.05	2.10	1.70 - 2.50	4.85	4.80	3.96 - 5.64

Control Date : 11.03.2022

QC Department:



P
ajan.



Date- 11/04/2022

OQ (Operational Qualification)

Equipment is working on PHOTOMETRIC REFLECTION Principle.

Following is a list of tests to be performed and verified:

<u>Test No</u>	<u>Test name</u>	<u>Test Purpose</u>	<u>Verified by and Date</u>
1	Self-checks	Initializing the instrument	Abhijit Jagtap 26/03/2022
2	Mechanism operation Test	To test the mechanism of the instrument	Abhijit Jagtap 26/03/2022
3	Printer	To test the working condition of the printer	Abhijit Jagtap 26/03/2022
4	Calibration	For verification of the factory set calibration	Abhijit Jagtap 26/03/2022
5	Quality control	For verification of calibration and validation of sample analysis	Abhijit Jagtap 26/03/2022

Validation By

Name: Abhijit Jagtap

Designation: Service Engineer

Signature:





Date- 11/04/2022

IQ (Installation Qualification)

<u>Sr No</u>	<u>Utilities to be checked</u>	<u>Observation</u>	<u>Inference</u>	<u>Verified by & Date</u>
1	Environmental condition as per requirement : Ambient Temp Range : <u>05 - 32 °C</u> Humidity Range: <u>Less Than 80 %</u>	Temp : <u>24 °C</u> Humidity : <u>52%</u>	YES / NO	Abhijit Jagtap 26/03/2022
2	Adequate space for installation : Minimum in FT. <u>4(W) X 2.5(D)</u>	OK FT.4.5(W)X2.5(D)	YES / NO	Abhijit Jagtap 26/03/2022
3	Electrical Outlets : Actual voltage on site : <u>140-250 V</u>	236 V AC Regular	YES / NO	Abhijit Jagtap 26/03/2022

<u>Verified By</u>	<u>Date</u>
Abhijit Jagtap	26/03/2022
Abhijit Jagtap	26/03/2022
Abhijit Jagtap	26/03/2022
Abhijit Jagtap	26/03/2022
Abhijit Jagtap	26/03/2022

The instrument has been verified for the following:

<u>Sr No.</u>	<u>Verification</u>		<u>Verified by & Date</u>
1	Equipment is identified	YES	Abhijit Jagtap 26/03/2022
2	Manufacturer's specifications are included	YES	Abhijit Jagtap 26/03/2022
3	Accessories / consumables are listed	YES	Abhijit Jagtap 26/03/2022





CALIBRATION REPORT

To,
Villo Poonawala Memorial Hospital,
Pune.

Date- 20/06/2022

Dear sir/Madam,
As desired by you please find enclosed herewith the report.

Name of System	<i>Rx50 V</i>
Sr. No.	2150146
Calibration done on	20 th June 2022
Next calibration Due on	19 th June 2023
Calibrated By	Mr. Abhijit Jagtap

Instrument calibration Values,

Quality Control Level 3:-

Assay Parameter	Tg	Glucose	Creatinine
Results	271.01	304	3.77
Range	225-309	234-318	3.38-5.04

All value is within range.
Checked instrument all found ok.

With Regards



Crystal Diagnosis
Service Engineer.





CALIBRATION REPORT

To,
Villo Poonawala Memorial Hospital,
Pune.

Date- 20/06/2022

Dear sir/Madam,

As desired by you please find enclosed herewith the report.

Name of System	Rx50 V
Sr. No	2150146
Calibration done on	20 th June 2022
Next calibration Due on	19 ^h June 2023
Calibrated By	Mr. Abhijit Jagtap

Instrument calibration Values,

Quality Control Level 2:-

Assay Parameter	Tg	Glucose	Creatinine
Results	92.35	115.2	1.59
Range	81.2-112	94.4-128	1.16-1.76

All value is within range.

Checked instrument all found ok.

With Regards



Crystal Diagnostics
Service Engineer.



TEST :GLU

Factor : 372.52
Calibrated on:20/06/22
20/06/22 04:23:59 PM

Pid ABS ms/dL Fla

TEST :GLU

5
0.3547 132.1 N

TEST :GLU

6
0.3635 135.4 N

TEST :GLU

7
0.8165 304.1 H

TEST :GLU

8
0.3913 145.7 H

TEST :TRIG

Factor : 864.79
Calibrated on:11/06/22
20/06/22 12:11:02 PM

Pid ABS ms/dL Fla

BLK 0.0304 ---
STD 0.2300 200.00 ---
Factor = 869.61

New Factor : 869.61

TEST :TRIG

1
0.2336 203.18 H

TEST :TRIG

2
0.1588 130.05 N

TEST :TRIG

3
0.1119 97.29 N

TEST :TRIG

4
0.2974 258.59 H

TEST :TRIG

Factor : 869.61
Calibrated on:20/06/22
20/06/22 03:53:44 PM

Pid ABS ms/dL Fla

TEST :TRIG

5
0.1062 92.35 N

TEST :TRIG

6
0.3126 271.81 H

TEST :CRTN

FACTOR : 28.59
Calibrated on:12/06/22
20/06/22 03:29:57 PM

Pid ABS ms/dL Fla

INITAL ABS: 0.2111
STD 0.0661 2.00 ---
Factor = 30.26

New Factor : 30.26

TEST :CRTN

FACTOR : 30.26

Calibrated on:20/06/22
20/06/22 03:39:56 PM

TEST :CRTN

Pid ABS ms/dL Fla

INITAL ABS: 0.3089
14
0.0526 1.59 H

TEST :CRTN

FACTOR : 30.26

Calibrated on:20/06/22
20/06/22 03:47:35 PM

TEST :CRTN

Pid ABS ms/dL Fla

INITAL ABS: 0.7546
15
0.1247 3.77 H

TEST :CRTN

FACTOR : 28.59
Calibrated on:12/06/22
19/06/22 12:49:26 PM

TEST :CRTN

Pid ABS ms/dL Fla

INITAL ABS: 0.3080
127
0.0584 1.67 H

TEST :CRTN

INITAL ABS: 0.6363
128
0.1448 4.14 H

TEST :CRTN

TEST :GLU

Factor : 289.56
Calibrated on:09/06/22
19/06/22 12:55:28 PM

Pid ABS ms/dL Fla

TEST :GLU

29
0.6810 197.1 H

TEST :GLU

30
0.3382 97.9 N

TEST :GLU

31
0.0954 259.2 H

TEST :GLU

Slope ?
32
-0.0207 -5.9 L

TEST :TRIG

Factor : 864.79
Calibrated on:11/06/22
19/06/22 12:57:50 PM

Pid ABS ms/dL Fla

TEST :TRIG

29
0.1057 91.36 N

TEST :TRIG

30
0.3016 260.80 H

TEST :GLU

Factor : 200.50



Equipment Description:

<u>Instrument Identification</u>		<u>Verified By</u>	<u>Date</u>
Equipment Name	Semiautomatic biochemistry analyzer	Abhijit Jagtap	26/03/2022
Model	RX50V	Abhijit Jagtap	26/03/2022
Manufacturer	MICROLAB INSTRUMENTS	Abhijit Jagtap	26/03/2022
Marketed By	CRYSTAL DIAGNOVISION	Abhijit Jagtap	26/03/2022
Serial Number	2150146	Abhijit Jagtap	26/03/2022
SUPPLY	AC-220 V 50Hz POWER- 80VA	Abhijit Jagtap	26/03/2022

Validation By :

Name: Abhijit Jagtap

Designation: Service Engineer

Signature:



FACTOR : 28.59
Calibrated on:12/06/22
16/06/22 07:29:49 PM

TEST :CRTN

Pid ABS mg/dL Flag

INITAL ABS: -0.0026

94 0.0011 0.03 L

TEST :CRTN

INITAL ABS: 1.3675

95 0.0710 2.03 H

TEST :CRTN

INITAL ABS: 0.6015

96 0.2521 7.20 H

TEST :CRTN

INITAL ABS: 0.3139

97 0.0656 1.87 H

TEST :CRTN

INITAL ABS: 0.6294

98 0.1507 4.30 H

TEST :GLU

Factor : 289.56

Calibrated on:09/06/22
16/06/22 07:50:22 PM

Pid ABS mg/dL Flag

TEST :GLU

19 0.4490 130.0 N

TEST :GLU

20 0.4433 128.3 N

TEST :GLU

21 0.3356 97.1 N

TEST :GLU

22 0.9302 269.3 H

TEST :TRIG

Factor : 864.79

Calibrated on:11/06/22
16/06/22 07:53:25 PM

Pid ABS mg/dL Flag

TEST :TRIG

19 0.1317 113.85 N

TEST :TRIG

20 0.0967 83.61 N

TEST :TRIG

21 0.0987 85.35 N

TEST :TRIG

22 0.2582 223.27 H

TEST :TRIG

TEST :CRTN

FACTOR : 28.59

Calibrated on:12/06/22
17/06/22 10:07:24 AM

TEST :CRTN

Pid ABS mg/dL Flag

INITAL ABS: 0.2933

104 0.0562 1.60 H

TEST :CRTN

INITAL ABS: 0.5924

105 0.1384 3.95 H

TEST :CRTN

INITAL ABS: 0.2919

106 0.0938 2.68 H

TEST :TRIG

Factor : 864.79

Calibrated on:11/06/22
17/06/22 10:18:09 AM

Pid ABS mg/dL Flag

TEST :TRIG

23 0.1289 111.48 N

TEST :TRIG

24 0.3426 296.27 H

TEST :GLU

Factor : 289.56

Calibrated on:09/06/22
17/06/22 10:29:34 AM

Pid ABS mg/dL Flag

TEST :GLU

23 0.3922 113.5 N

TEST :GLU

24 1.0732 310.7 H

15/06/22 05:34:16 PM

TEST :GLU

Factor : 289.56

Calibrated on:09/06/22
15/06/22 06:06:00 PM

Pid ABS mg/dL Flag

TEST :GLU

17 0.3503 101.4 N

TEST :GLU

18 0.9392 271.9 H

TEST :TRIG

Factor : 864.79

Calibrated on:11/06/22
15/06/22 06:08:12 PM

Pid ABS mg/dL Flag

TEST :TRIG

17 0.1033 89.31 N

TEST :TRIG

18 0.2862 247.50 H

TEST :CRTN

FACTOR : 28.59

Calibrated on:12/06/22
15/06/22 06:19:32

TEST :CRTN

Pid ABS mg/dL Flag

INITAL ABS: 0.3157

80 0.0643 1.83 H

TEST :CRTN

FACTOR : 28.59

Calibrated on:12/06/22
15/06/22 06:16:52 PM

TEST :CRTN

Pid ABS mg/dL Flag

INITAL ABS: 0.6180

81 0.1540 4.40 H

TEST :GLU

Factor : 289.56

Calibrated on:09/06/22
15/06/22 06:26:05 PM

FACTOR : 20.07
Calibrated on:12/06/22
16/06/22 07:29:49 PM

TEST :CRTN

Pid ABS mg/dL Fla

INITAL ABS: -0.0026

94
0.0011 0.03 L

TEST :CRTN

INITAL ABS: 1.3675

95
0.0710 2.03 H

TEST :CRTN

INITAL ABS: 0.6015

96
0.2521 7.20 H

TEST :CRTN

INITAL ABS: 0.3139

97
0.0656 1.87 H

TEST :CRTN

INITAL ABS: 0.6294

90
0.1507 4.30 H

TEST :GLU

Factor : 289.56

Calibrated on:09/06/22
16/06/22 07:50:22 PM

Pid ABS mg/dL Fla

TEST :GLU

19
0.4490 130.0 N

TEST :GLU

20
0.4433 128.3 N

TEST :GLU

21
0.3356 97.1 N

TEST :GLU

22
0.9302 269.3 H

TEST :TRIG

Factor : 864.79

Calibrated on:11/06/22
16/06/22 07:53:25 PM

Pid ABS mg/dL Fla

TEST :TRIG

19
0.1317 113.85 N

TEST :TRIG

20
0.0967 83.61 N

TEST :TRIG

21
0.0987 85.35 N

TEST :TRIG

22
0.2582 223.27 H

TEST :TRIG

TEST :CRTN

FACTOR : 28.59

Calibrated on:12/06/22
17/06/22 10:07:24 AM

TEST :CRTN

Pid ABS mg/dL Fla

INITAL ABS: 0.2933

104
0.0562 1.60 H

TEST :CRTN

INITAL ABS: 0.5924

105
0.1384 3.95 H

TEST :CRTN

INITAL ABS: 0.2919

106
0.0938 2.68 H

TEST :TRIG

Factor : 864.79

Calibrated on:11/06/22
17/06/22 10:18:09 AM

Pid ABS mg/dL Fla

TEST :TRIG

23
0.1289 111.48 N

TEST :TRIG

24
0.3426 296.27 H

TEST :GLU

Factor : 289.56

Calibrated on:09/06/22
17/06/22 10:29:34 AM

Pid ABS mg/dL Fla

TEST :GLU

23
0.3922 113.5 N

TEST :GLU

24
1.0732 310.7 H

15/06/22 06:04:10 PM

TEST :GLU

Factor : 289.56

Calibrated on:09/06/22
15/06/22 06:06:00 PM

Pid ABS mg/dL Fla

TEST :GLU

17
0.3503 101.4 N

TEST :GLU

18
0.9392 271.9 H

TEST :TRIG

Factor : 864.79

Calibrated on:11/06/22
15/06/22 06:08:12 PM

Pid ABS mg/dL Fla

TEST :TRIG

17
0.1033 89.31 N

TEST :TRIG

18
0.2862 247.50 H

TEST :CRTN

FACTOR : 28.59

Calibrated on:12/06/22
15/06/22 08:10:37 PM

TEST :CRTN

Pid ABS mg/dL Fla

INITAL ABS: 0.3157

80
0.0643 1.83 H

TEST :CRTN

FACTOR : 28.59

Calibrated on:12/06/22
15/06/22 08:10:52 PM

TEST :CRTN

Pid ABS mg/dL Fla

INITAL ABS: 0.6180

81
0.1540 4.40 H

TEST :GLU

Factor : 289.56

Calibrated on:09/06/22
15/06/22 06:26:05 PM

TEST :GLU

Factor : 372.52
Calibrated on:20/06/22
20/06/22 04:23:59 PM

Pid ABS mg/dL Fla

TEST :GLU

5
0.3547 132.1 N

TEST :GLU

6
0.3635 135.4 N

TEST :GLU

7
0.8165 304.1 H

TEST :GLU

8
0.3913 145.7 H

TEST :TRIG

Factor : 864.79
Calibrated on:11/06/22
20/06/22 12:11:02 PM

Pid ABS mg/dL Fla

BLK 0.0304 ---
STD 0.2300 200.00 ---
Factor = 869.61

New Factor : 869.61

TEST :TRIG

1
0.2336 203.18 H

TEST :TRIG

2
0.1500 130.05 N

TEST :TRIG

3
0.1119 97.29 N

TEST :TRIG

4
0.2974 258.59 H

TEST :TRIG

Factor : 869.61
Calibrated on:20/06/22
20/06/22 03:53:44 PM

Pid ABS mg/dL Fla

TEST :TRIG

5
0.1062 92.35 N

TEST :TRIG

6
0.3126 271.01 H

TEST :CRTN

FACTOR : 28.59
Calibrated on:12/06/22
20/06/22 03:29:57 PM

Pid ABS mg/dL Fla

INITIAL ABS: 0.2111
STD 0.0661 2.00 ---
Factor = 30.26

New Factor : 30.26

TEST :CRTN

FACTOR : 30.26
Calibrated on:20/06/22
20/06/22 03:39:56 PM

TEST :CRTN

Pid ABS mg/dL Fla

INITIAL ABS: 0.3089
14
0.0526 1.59 H

TEST :CRTN

FACTOR : 30.26
Calibrated on:20/06/22
20/06/22 03:47:35 PM

TEST :CRTN

Pid ABS mg/dL Fla

INITIAL ABS: 0.7546
15
0.1247 3.77 H

TEST :CRTN

FACTOR : 28.59
Calibrated on:12/06/22
19/06/22 12:49:26 PM

TEST :CRTN

Pid ABS mg/dL Fla

INITIAL ABS: 0.3080
127
0.0584 1.67 H

TEST :CRTN

INITIAL ABS: 0.6363
128
0.1448 4.14 H

TEST :CRTN

TEST :GLU

Factor : 289.56
Calibrated on:09/06/22
19/06/22 12:55:28 PM

Pid ABS mg/dL Fla

TEST :GLU

29
0.6810 197.1 H

TEST :GLU

30
0.3382 97.9 N

TEST :GLU

31
0.8954 259.2 H

TEST :GLU

Slope ?
32
-0.0207 -5.9 L

TEST :TRIG

Factor : 864.79
Calibrated on:11/06/22
19/06/22 12:57:50 PM

Pid ABS mg/dL Fla

TEST :TRIG

29
0.1057 91.36 N

TEST :TRIG

30
0.3016 260.00 H

TEST :GLU

Factor : 200.50