## RANDOX

## CERTIFICATE OF INSTALLATION

INSTRUMENT NAME:

Rx Daytona+

SERIAL NUMBER:

7241-0189

CUSTOMER NAME:

Arpan Diagnostic Centre

ADDRESS:

150 ft Ring Road, Indira Circle, Nr Raj Bank, Rajkot:

360005.

The undersigned performer certifies that the Installation Qualification protocol has been successfully completed for the instrument stated above.

#### **ENGINEER**

Signature

Name:

Jinesh Vadera

Designation:

Customer Support Engineer

Company:

Randox Laboratories India Pvt. Limited

#### LABORATORY INCHARGE:-

Signature (1)

Name: Os. Ann Suvalin.

Designation: puthulo gur

Company Alpan Dinguestie Cente

Randox Laboratories (India) Private Limited

Regd Office: Plot No.191 - 195 & 246 - 250, KIADB Industrial Area. Bommasandra-Jigani Link Road, Bengaluru, India - 560 105 T +91 80 2802 5000 Fax: +91 80 2802 5012 www.randox.com CIN: U24230KA2004PTC070372





## INSTALLATION QUALIFICATION

**FOR** 

Arpan Diagnostic Centre

RANDOX LABORATORIES INDIA PVT. LTD.

Training Report

Customer : Arpan Diagnostic Centre	Product Description : Rx Daytona+	Date: 16th December 2020
	Instrument Serial #: 7241-0189 Installed on: 16th December 2020	Training Period: 21st to 23rd December 2020

Instrument :	Action taken: Rx Daytona+ installed properly with all accessories and validation of instrument done.
Rx Daytona+	
Training provided by:  Jinesh Vadera  Training provided to:  1. Riddhi Pipaliya. 2. Shital Dobariya.	<ol> <li>Check list:         <ol> <li>Explained all major hardware components and their functions</li> <li>Explained in detail the different software aspects and their use</li> <li>Consumable usage and replacement</li> <li>interpretation of calibration and Control results and calibration frequencies</li> <li>Daily, Weekly &amp; Monthly procedures</li> </ol> </li> <li>Follow up: Adequate follow up done</li> <li>Chemistries standardized with good QC Results:         <ol> <li>Glucose, ALT,AST,UREA,Creatinine,Glucose, ALP, Total Protein, TBIL,DBIL, ALB, TG,UA,DHDL,CRP</li> </ol> </li> </ol>
Customer Signature	Trainee Signature:

Make	
Randox	
,	

Rx Daytona+	7241-0189	
Product Name	Serial Number	

This is to certify that this machine has been inspected and calibrated and details given below.

Test Parameters	Measured / Calibrated	Remarks
	230 V AC	O.K
1	900 watts	O.K
	50 Hz	O.K
1	15 – 30 Deg Celsius	O.K
	Test Parameters  Input Voltage  Power Consumption  Input frequency  Operating Temperature	Input Voltage  Power Consumption  Input frequency  230 V AC  900 watts  50 Hz

Name of Engineer Jinesh Vadera Signature

### INSTALLATION REPORT

INSTRUMENT:

Rx Daytona+

INSTRUMENT SERIAL NUMBER:

7241-0189

TELEPHONE:

9825082454/ 9428344158

INSTALLATION DATE:

16th December 2020

#### INSATALLATION COMPLETION STATEMENT

1. INSTALLATION PROCEDURE

Done

OK

2. INSTALLATION CHECK

Done

OK

3. PERFORMANCE CHECK

Done

OK

#### FOR RANDOX LABORATORIES INDIA PVT. LTD.

The Rx Daytona+ bearing Serial Number – 7241-0189 has been successfully installed at Arpan Diagnostic Centre.

Accepted

Date:

16th December 2020

Name:

Jinesh Vadera

Designation: Customer Support Engineer

## INSTALLATION QUALIFICATION

#### Instructions:

- This document is to be completed at the time the system is unpacked and set up for operation
- 2. An authorized Randox representative will check out each module and verify the alignment as outlined in service manual
- 3. All deviations from normal specification to include any problems with installation will be noted in the comments section
- This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by Randox Laboratories India (P) Limited.

## INSTALLATION QUALIFICATION

This Installation Qualification Protocol will be performed on the instrumentation located at Arpan Diagnostic Centre.

This protocol will define the documentation that will be used to evaluate the instrument documented in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrumentation identified has been installed in accordance with intended usage.

Installation checks will be performed to verify that the instrumentation has been installed with proper connections and utilities.

Trained knowledgeable personnel will perform qualification studies as mentioned in Randox Service Manual.

Any exceptional conditions encountered during the Qualification studies will be identified for review.

Exceptional conditions will be investigated and appropriate course of action will be determined.

### INSTALLATION QUALIFICATION

#### System Certification

Study data has been determined that the system described in this document either meets all criterial outlines in this Installation Qualification, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any have been addressed.

The system is ready for specified usage.

Protocol performed by:

Randox Laboratories Representative

Name: Jinesh Vadera

Title: Customer Support Engineer

Company: Randox Laboratories India (P) Limited

Customer authorization:

Name: D.s. Anil Savaliza

Title: parhologist

Jinesh Vadera

Engineer Name & Signature

Date: 18-01-2021

Customer Signature

Date: 12-01-2021



## Clinical Chemistry Analyzer

#### **Installation Qualification**

Reference: Service Manual

- 1. Unpacking the Analytical Unit
- 2. Checking inventory
- 3. Placing the Analytical Unit
- 4. Detaching Analytical init protection plates
- Checking & adjusting the surface level where Analytical unit is placed using level sensors
- 6. Connecting the peripherals to the Analytical unit like Waste containers, tubing's
- 7. Filling the System Water and Wash Solutions in the containers
- 8. Installing & interfacing the interface cable & PC to the Analytical Unit
- 9. Connecting the printer
- 10. Seating the circuit boards and checking connections
- 11. Performing Final Visual Inspection
- 12. Applying power to the Analytical Unit
- 13. Installing the software

## OPERATIONAL QUALIFICATION

**FOR** 

Arpan Diagnostic Centre

RANDOX LABORATORIES INDIA (P) LIMITED

## Clinical Chemistry Analyzer

#### OPERATIONAL QUALIFICATION

Reference: Operator and Service manual

- 1. Verifying configuration and alignment
- 2. Priming and filling the system
- 3. Daily maintenance procedure
- 4. Weekly maintenance procedure
- 5. Performing System Check Procedure
- 6. Customer Training Operation and Maintenance

# SYSTEM CHECK PROCEDURE

	ACCEPTABLE RESULTS	OBTAINED RESULTS
SYSTEM CHECK		0.18 - 0.29 for all cuvettes
Cuvette check	< 0.5 Abs for all cuvettes	0.18 - 0.27 101 4
	2.7 Alegat all filters	0.25 - 0.29 at all filters
Photometer check	< 0.5 Abs at all filters	
	37 Deg Centigrade with max	Within acceptable range
Incubator temperature	0.3 Deg variation	
check		Within acceptable range
Reagent compartment cooling check	8 to 15 deg Centigrade	
	0 / 000	Ok for all sensors
Sensor status check	Status On / Off	

The results obtained are as per specifications

Engineer signature

Customer signature

100 A

## PERFORMANCE QUALIFICATION

**FOR** 

Arpan Diagnostic Centre

RANDOX LABORATORIES INDIA (P) LIMITED

## Clinical Chemistry Analyzer

#### PERFORMANCE QUALIFICATION

1. Calibrating Assays and running Controls

Chemistries: ALT, CREATININE, UREA, GLUCOSE, AST, ALB, TBIL, DBIL, ALP, TP, UA, DHDL, TG, CRP.

Calibrator CAL-2 (1320UN), CAL-3 (1086UE)
Calibrator
Q. C. L-2 (1390UN)
Q. C. L-3 (1102UE)

Controls and Calibrators: CAL2 (1320UN) , CAL3 (1086UE) , L2 QC (1390UN) , L3 QC (1102UE)

The chemistry parameters were standardized & controls run for them.

The SD and CV are within acceptable range

## Training Schedule

## (Conduct of Training)

During the course of training the following training requirements have been covered

- 1. System hardware & Software review
- 2. System configuration and supply management
- 3. Sample processing & Test results
- 4. Calibration & Review
- Quality Controls
- 6. Maintenance: Daily & Weekly
- 7. Diagnostics & Trouble shooting

## PERFORMANCE QUALIFICATION

### System Certification

Study data has been determined that the system described in this document either meets all criterial outlines in this Installation Qualification, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any have been addressed.

The system is ready for specified usage.

Protocol performed by:

Randox Laboratories Representative

Name: Jinesh Vadera

Title: Customer Support Engineer

Company: Randox Laboratories India (P) Limited

Customer authorization:

Name: Dr And Savalia.

Title: parhologis

Jinesh Vadera Engineer Name & Signature

Date: 18-01-2021

Customer Signature Date 18-1-2021



## Calibration Certificate Rx Daytona+

Instrument	Rx Daytona+ Clinical Chemistry Analyser
Serial No	7201-0189
Account Name	Arpan Diagnostic Centre, Rajkot
Installation Date	16/12/2020
Calibration Date	16/07/2021
Next Calibration Due	16/01/2022

This is to certify that this analyser has been inspected and calibrated for following parameters:

Test Parameter	Target Value	Obtained Value
Input Voltage	230 -240 V AC	231 V AC
	< 0.50 Abs for all cuvettes	< 0.18 Abs for all cuvettes
Cuvette Check		Between 1 to 104 for all
Photometer Gain Check	< 127 for all wavelengths	wavelengths.
Gain Voltage for all wavelengths	> 8.5 V DC	Between 8.6 to 9.13 V DC
Absorbance for all wavelengths	50 - 150 Abs	65 - 105 Abs
Check Lamp voltage	< 8.3 V DC	8.3 V DC
Incubator Temperature	37° C ± 0.3 max	37.0° C
Reagent Tray Temperature	8- 15 ° C	7.84° C
12V Lamp Supply	$12 \pm 0.3 \text{ volts}$	12.06 volts
5V Supply	5 ± 0.3 volts	5.04 volts
24V Supply	24 ± 0.3 volts	24.05 volts

The results obtained are as per specifications & tolerance ranges. The above calibration was done with an M/s. Mastech Digital Multimeter. (Model no. MAS830L). (Calibration certificate is enclosed herewith).

Thank You

Shyam Kale

Customer Support Engineer, Mumbai.

Randox Laboratories (India) Private Limited

Regd Office: Plot No.191 - 195 & 246 - 250, KIADB Industrial Area Bommasandra-Jigani Link Road, Bengaluru, India - 560 105 T +91 80 2802 5000 Fax +91 80 2802 5012 www.randox.com CIN: U24230KA2004PTC070372









## Calibration Certificate Rx Daytona+

Instrument	Rx Daytona+ Clinical Chemistry Analyser
Serial No	7201-0189
Account Name	Arpan Diagnostic Centre, Rajkot
Installation Date	16/12/2020
Calibration Date	02/02/2022
Next Calibration Due	02/08/2022

This is to certify that this analyser has been inspected and calibrated for following parameters:

Test Parameter	Target Value	Obtained Value
Input Voltage	230 -240 V AC	231 V AC
Cuvette Check	< 0.50 Abs for all cuvettes	< 0.18 Abs for all cuvettes
Photometer Gain Check	< 127 for all wavelengths	Between 1 to 104 for all wavelengths.
Gain Voltage for all wavelengths	> 8.5 V DC	Between 8.6 to 9.13 V DC
Absorbance for all wavelengths	50 - 150 Abs	65 - 105 Abs
Check Lamp voltage	< 8.3 V DC	8.3 V DC
Incubator Temperature	37° C ± 0.3 max	37.0° C
Reagent Tray Temperature	8- 15 ° C	7.84° €
12V Lamp Supply	12 ± 0.3 volts	12.06 volts
5V Supply	$5 \pm 0.3$ volts	5.04 volts
24V Supply	24 ± 0.3 volts	24.05 volts

The results obtained are as per specifications & tolerance ranges. The above calibration was done with an M/s. Mastech Digital Multimeter. (Model no. MAS830L). (Calibration certificate is enclosed herewith).

Thank You

Shyam Kale

Customer Support Engineer, Mumbai.

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T +91 80 2802 5000 Fax +91 80 2802 5012 www.randox.com CIN: U24230KA2004PTC070372









# Vaidyanatheshwara Instruments

### CERTIFICATE OF CALIBRATION





No. 301/A, 9th Main Road, 3rd Cross, Rajiv Gandhi Nagar, J.B. Kaval, Nandhini Layout Post, Bangalore - 560 096.

Contact: 080-23377266, Mob: 9986586789 / 9448080177 / 9964308118 | Email: info@viplgroup.com Web: www.viplgroup.com

NABL Accredited Calibration Lab as per ISO/IEC 17025 : 2017 With vide Certificate No: CC-2473

Certificate No.

VI/21-22/0105-07

Page No: 3 of 3

#### Results Continued....

SI. No.	Parameter	Range	STD	DUC Reading	Error Claimed (±)	Error Observed	Measurement Uncertainty (±)	Factor
31			20 μΑ	20.1 μΑ	0.5 μΑ	0.1 μΑ	0.0054 μΑ	2.0
32		200 μΑ	100	100.4	1.3	0.4	0.0270	2.0
33			180	180.5	2.1	0.5	0.0486	2.0
34			0.2 mA	0.201 mA	0.005 mA	0.001 mA	0.00003 mA	2.0
35		2 mA	1	1.003	0.013	0.003	0.00016	2.0
36			1.8	1.805	0.021	0.005	0.00029	2.0
37			2 mA	2.01 mA	0.07 mA	0.01 mA	0.0002 mA	2.0
38	DC Current	20 mA	10	10.04	0.15	0.04	0.0011	2.0
39			18	18.07	, 0.23	0.07	0.0020	2.0
40			20 mA	20.1 mA	0.8 mA	0.1 mA	0.0054 mA	2.0
41		200 mA	100	100.4	2.0	0.4	0.0270	2.0
42			180	180.8	3.2	0.8	0.0486	2.0
43			1 A	1.01 A	0.13 A	0.01 A	0.0006 A	2.0
44		10A	5	5.06	0.25	0.06	0.0055	2.0
45			9	9.10	0.37	0.10	0.0099	2.0
46			20 V	20.1 V	1.2 V	0.1 V	0.0086 V	2.0
47		200 V	100	100.6	2.2	0.6	0.0230	2.0
48	AC Voltage		180	180.8	3.2	8.0	0.0414	2.0
49	@ 50 Hz		60 V	61 V	11 V	1 V	0.0138 V	2.0
50		600 V	300	301	14	1	0.0690	2.0
51			540	542	16	2	0.1890	2.0

Note:-

Diode & Continuity functions are checked & found satisfactory.

#### Conclusion Remarks:-

- 1 Measured readings are reported.
- 2 Measurement uncertainty reported is at 95.45 % confidence level.
- 3 All the readings are within the specified accurecy limit and found ok.

Calibrated By

Checked By

Navya (Calibration Engineer) Hemanth (Lab In-Charge)

Authorised By Gangadhar C.K.



## VAIDYANATHESHWARA INSTRUMENTS HOC-MRA CERTIFICATE OF CALIBRATION





No. 301/A, 9th Main Road, 3rd Cross, Rajiv Gandhi Nagar, J.B. Kaval, Nandhini Layout Post, Bangalore - 560 096. Contact: 080-23377266, Mob: 9986586789 / 9448080177 / 9964308118 | Email: info@viplgroup.com Web: www.viplgroup.com

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Certificate No.

VI/21-22/0105-07

Page No: 2 of 3

#### Results:

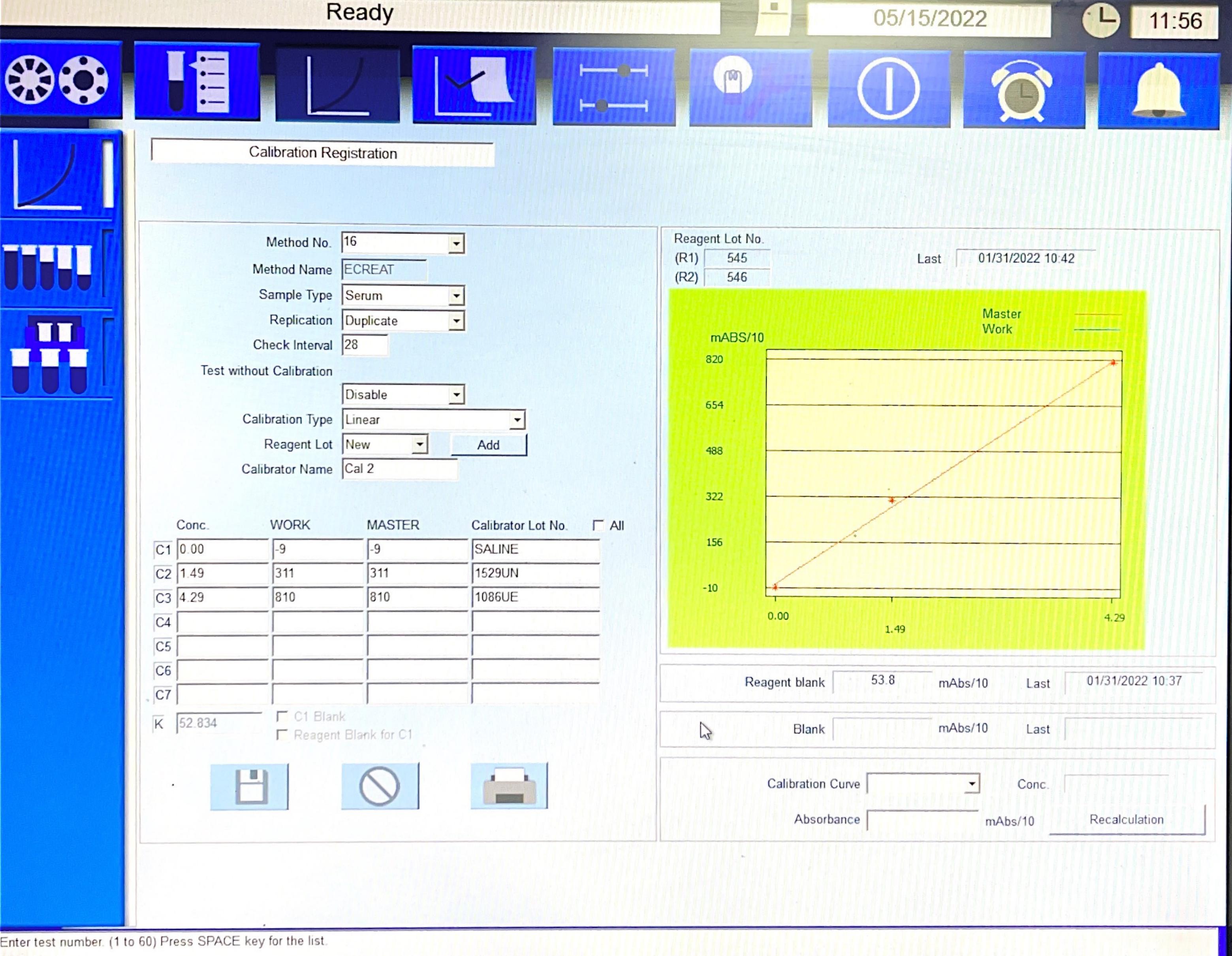
Results	5:							
SI. No.	Parameter	Range	STD	DUC	Error	Error	Measurement	K
31. 140.	ratameter	range	Input	Reading	Claimed (±)	Observed	Uncertainty (±)	Factor
1			20 mV	20.1 mV	0.4 mV	0.1 mV	Vm 8000.0	2.0
2		200mV	100	100.4	0.8	0.4	0.0039	2.0
3			180	180.5	1.2	0.5	0.0070	2.0
4			0.2 V	0.203 V	0.004 V	0.003 V	0.000003 V	2.0
5		2 V	1.0	1.005	0.008	0.005	0.000016	2.0
6			1.8	1.807	0.012	0.007	0.000029	2.0
7			2V	2.01 V	0.04 V	0.01 V	0.000032 V	2.0
8	DC Voltage	20 V	10	10.04	0.08	0.04	0.000160	2.0
9			18	18.06	0.12	0.06	0.000288	2.0
10			20 V	20.1 V	0.4 V .	0.1 V	0.00046 V	2.0
11		200 V	100	100.2	0.8	0.2	0.00230	2.0
12			180	180.6	1.2	0.6	0.00414	2.0
13		600 V	60 V	61 V	5 V	1 V	0.00138 V	2.0
14			300	301	7	1	0.00690	2.0
15			540	541	9	1	0.01242	2.0
16		200 Ω	20 Ω	20.1 Ω	0.7 Ω	0.1 Ω	0.0008 Ω	2.0
17			100	100.2	1.3	0.2	0.0040	2.0
18			180	180.5	1.9	0.5	0.0072	2.0
19			0.2 kΩ	0.201 kΩ	0.004 kΩ	0.001 kΩ	0.00001 kΩ	2.0
20		2 kΩ	1.0	1.003	0.010	0.003	0.00004	2.0
21			1.8	1.805	0.016	0.005	0.00006	2.0
22			2 kΩ	2.01 kΩ	0.04 kΩ	0.01 kΩ	0.00007 kΩ	2.0
23	Resistance	istance 20 kΩ	10	10.04	0.10	0.04	0.00035	2.0
24			18	18.08	0.16	0.08	0.00063	2.0
25		200 kΩ	20 kΩ	20.1 kΩ	0.4 kΩ	0.1 kΩ	0.00070 kΩ	2.0
26			100	100.2	1.0	0.2	0.00350	2.0
27			180	180.6	1.6	0.6	0.00630	2.0
28			0.2 ΜΩ	0.201 MΩ	0.007 MΩ	0.001 MΩ	0.00001 MΩ	2.0
29		2 ΜΩ	1	1.003	0.015	0.003	0.00004	2.0
30			1.8	1.808	0.023	0.008	0.00007 SHWA	2.0

Calibrated By

Navya (Calibration Engineer) Checked By

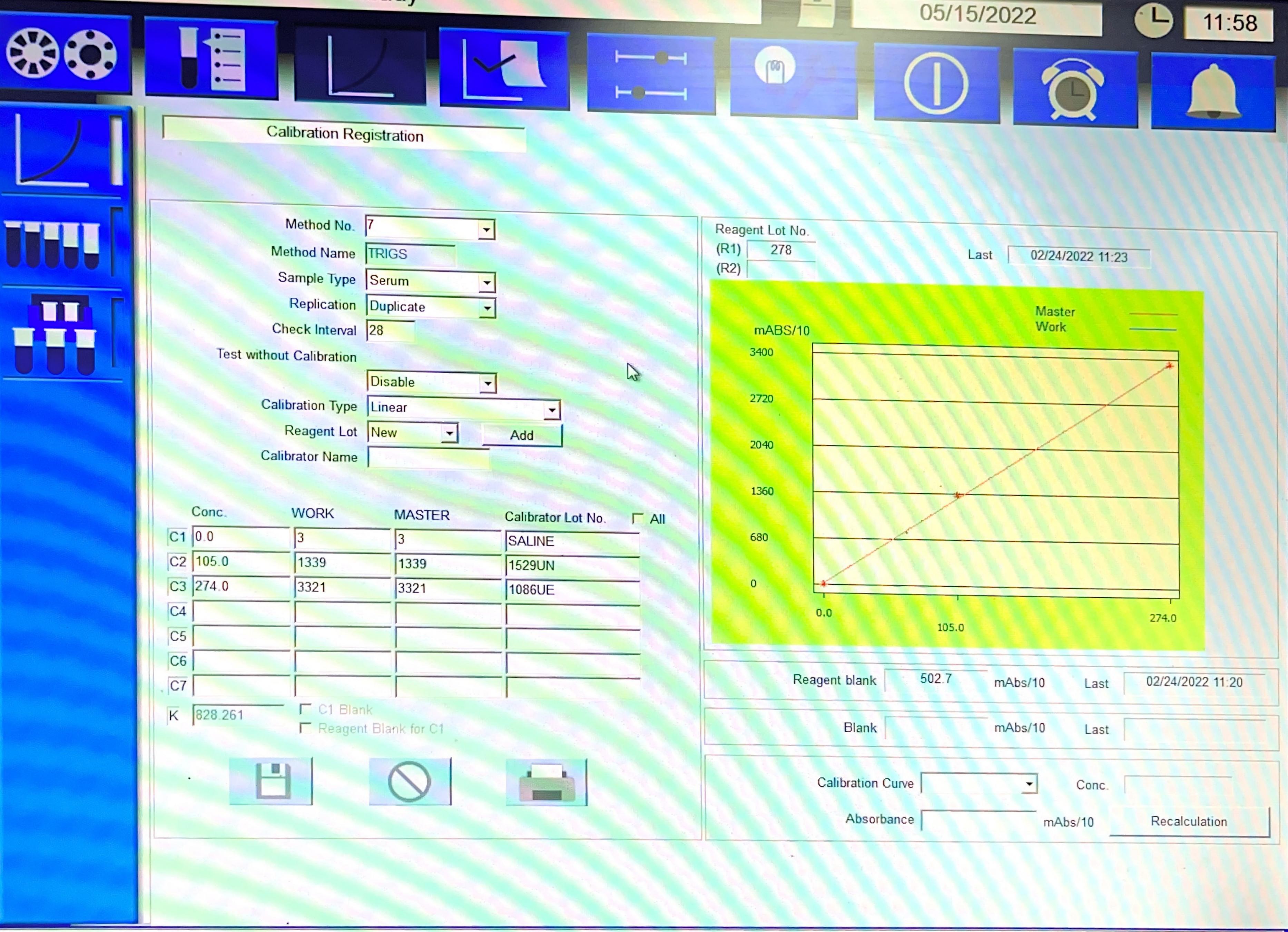
Hemanth (Lab In-Charge) Authorised By

Gangadhar C.K.

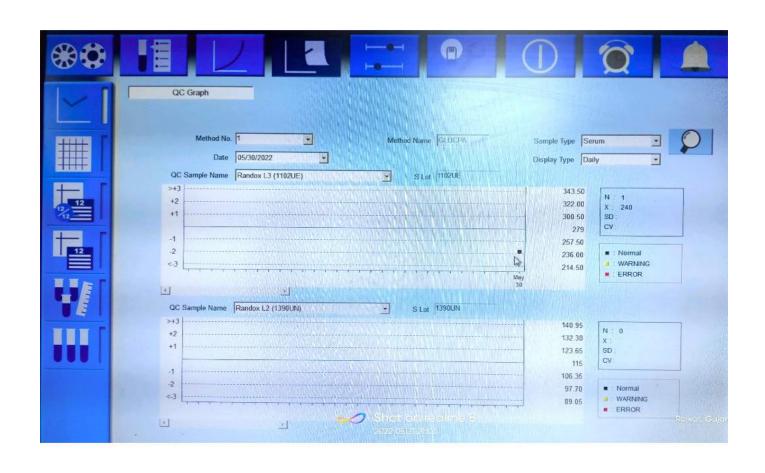


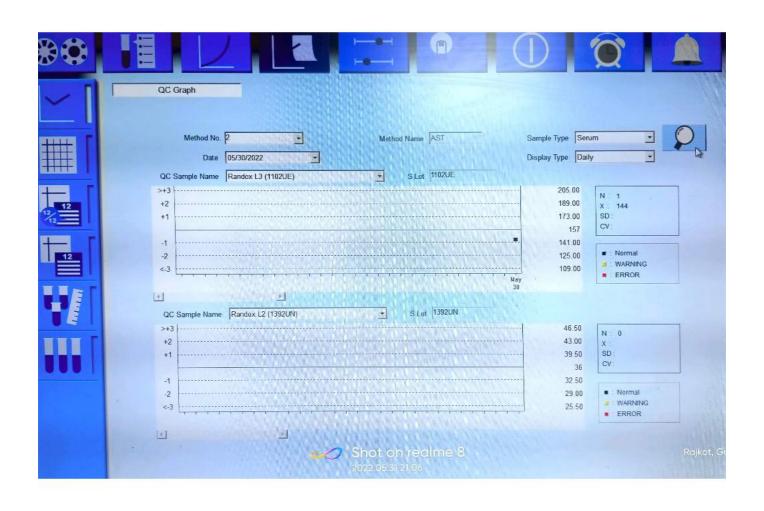






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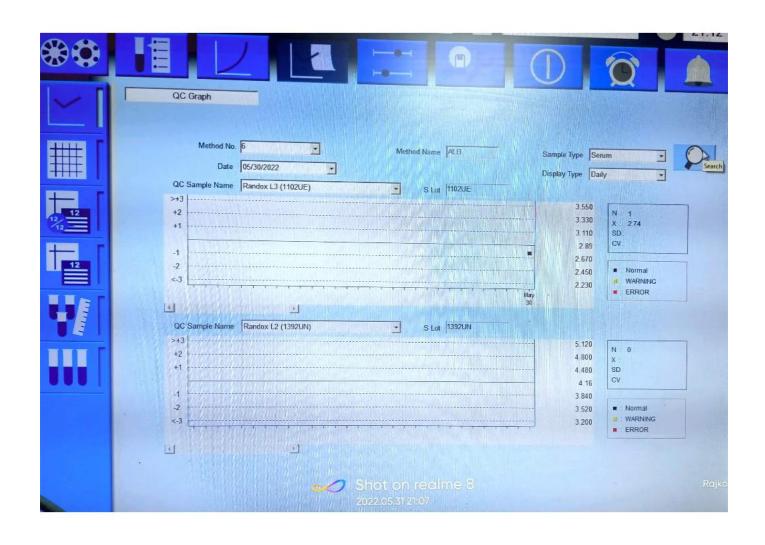


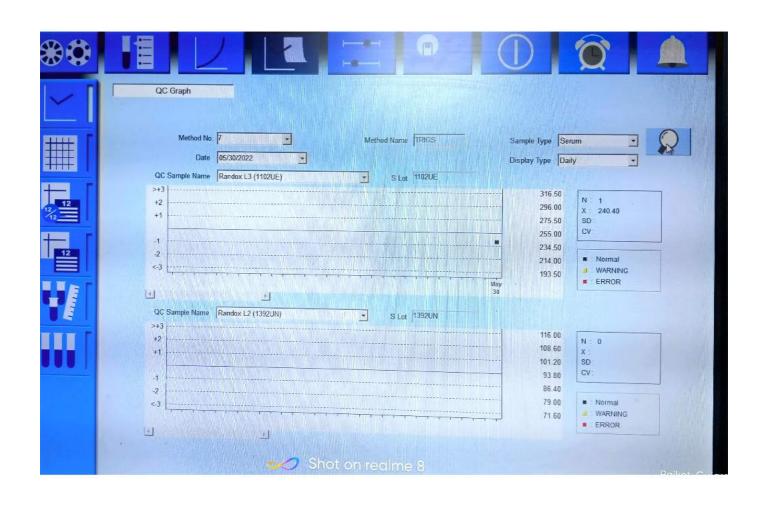


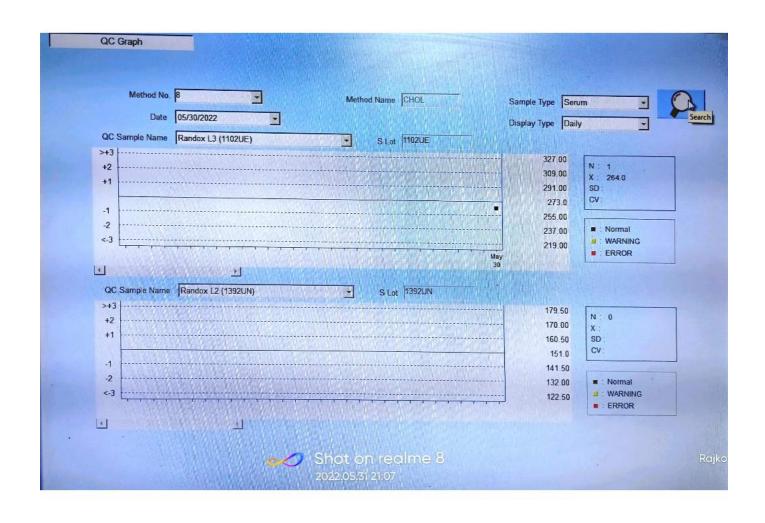




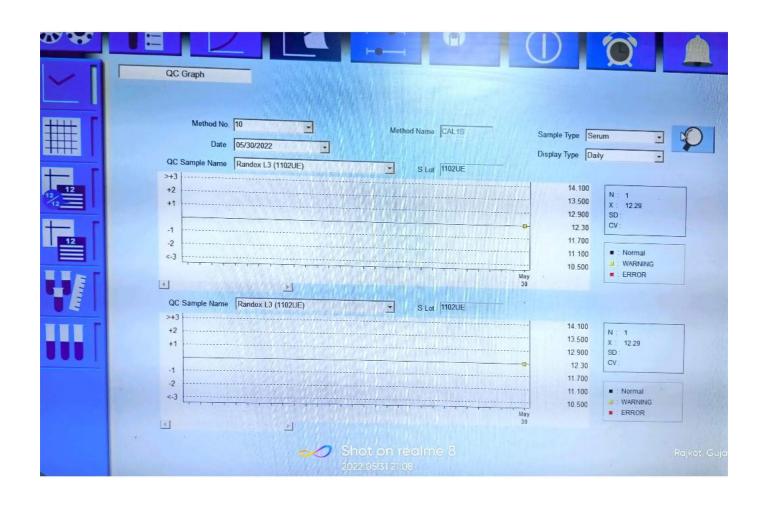


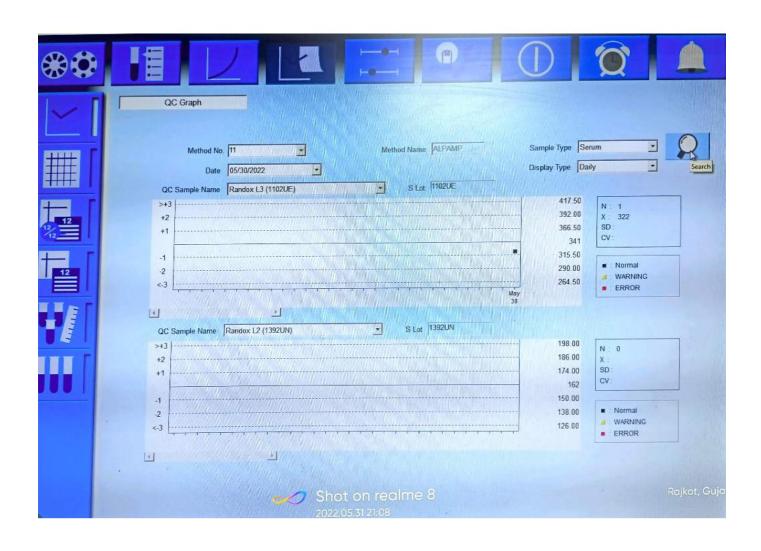


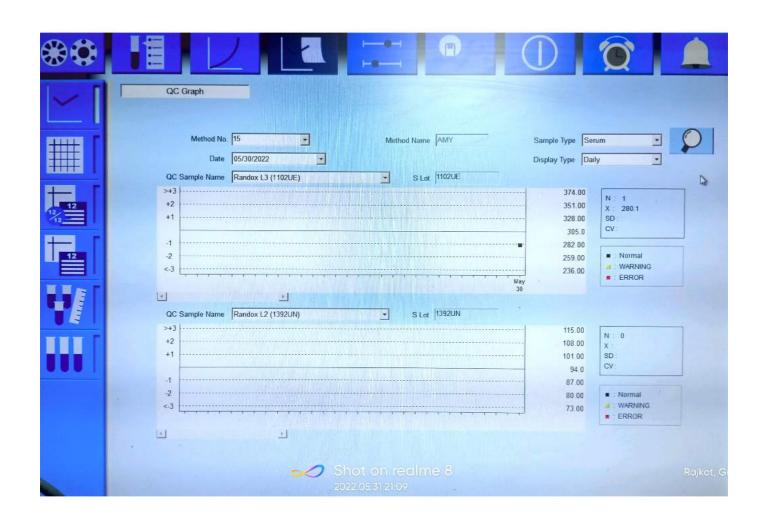


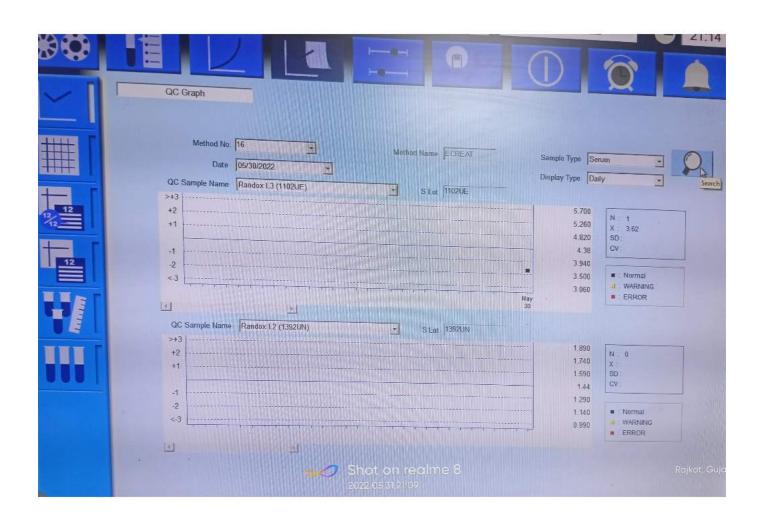


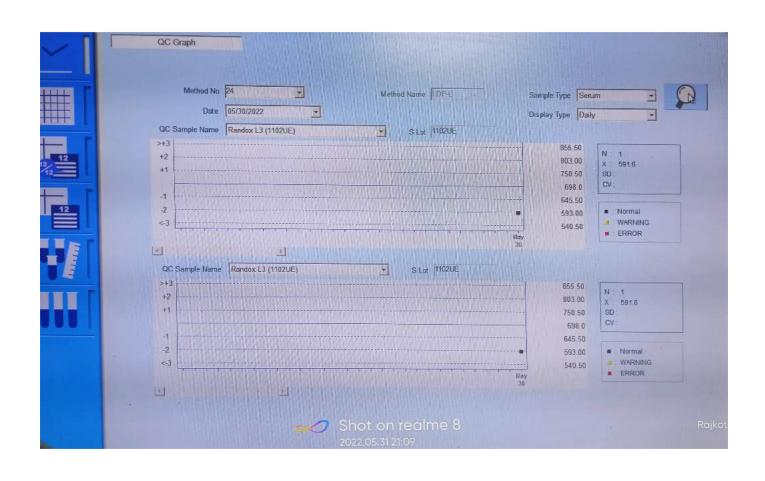


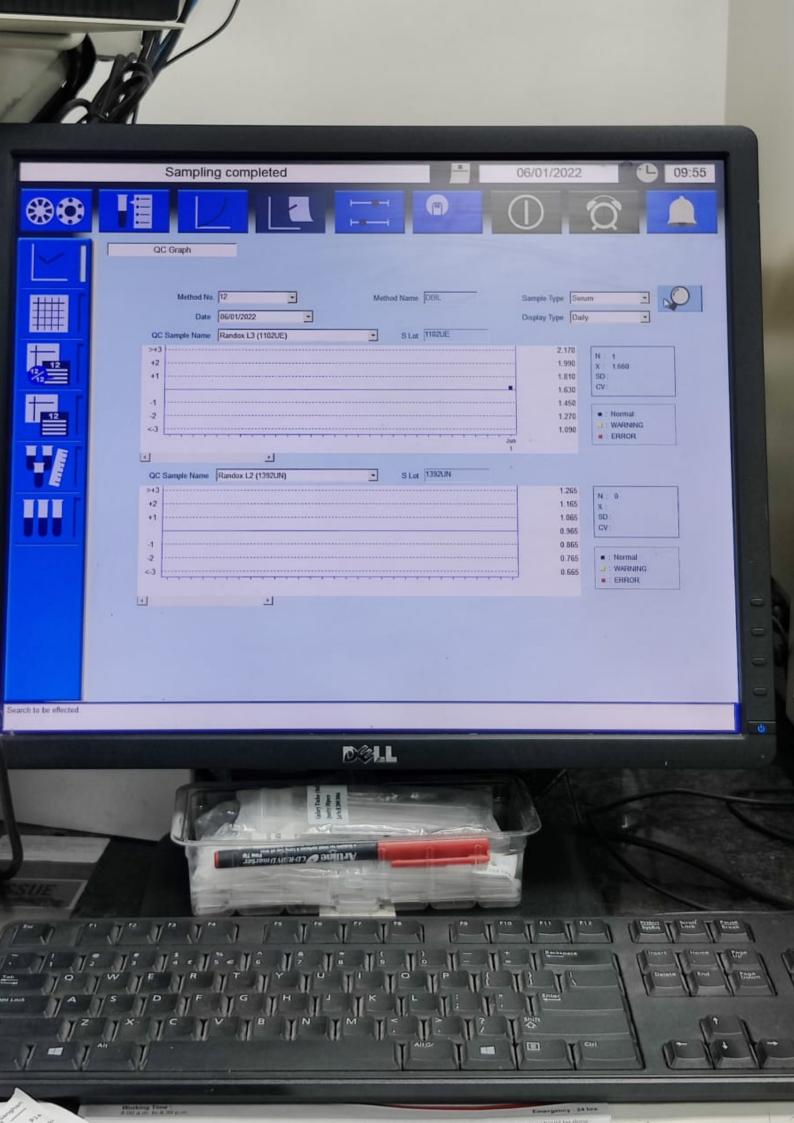


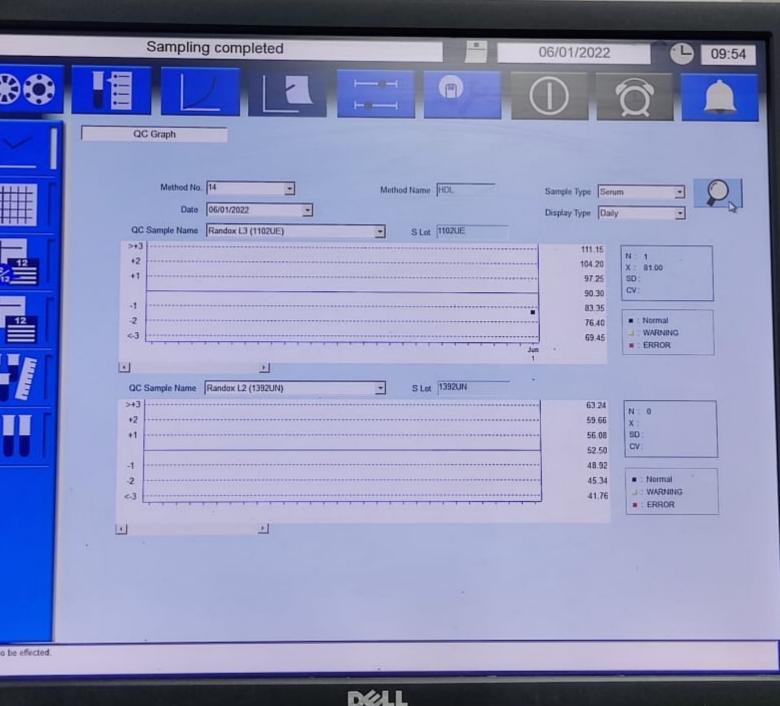


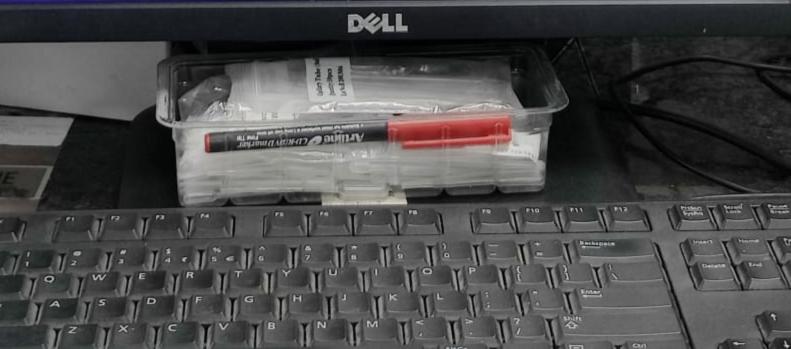


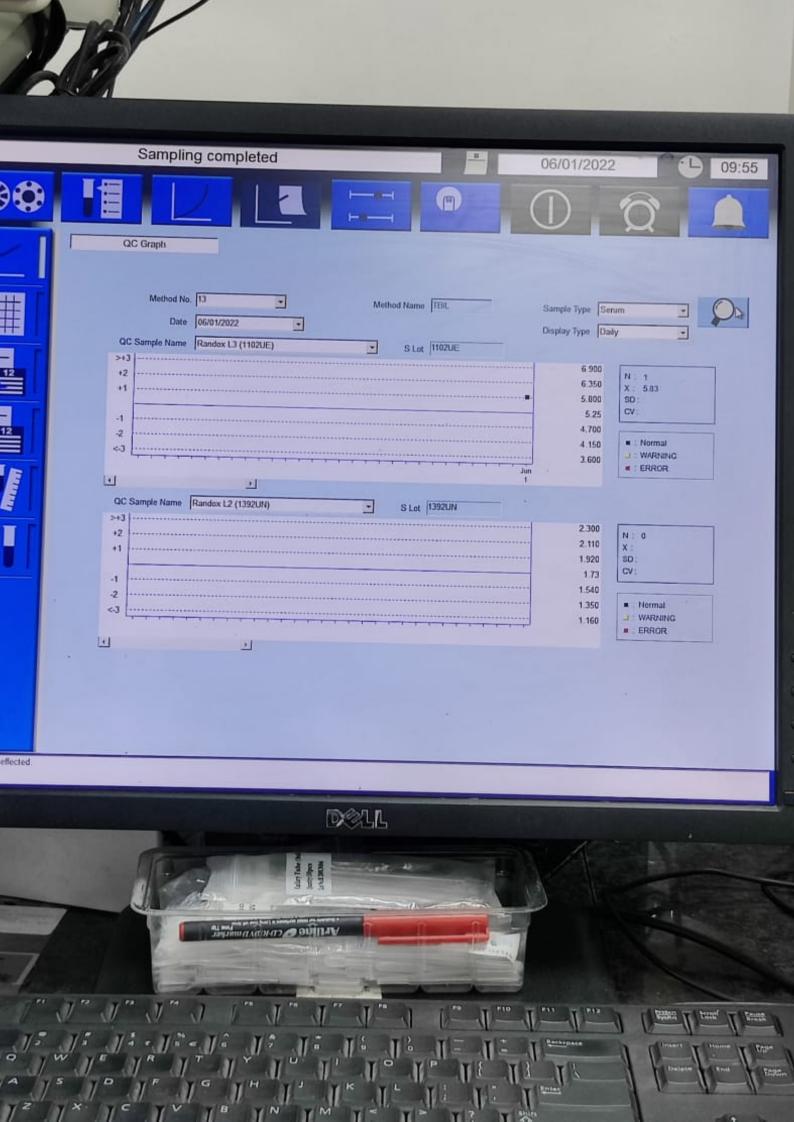












		Analyte	vande							
		Salicylate	unit	Target	low	high	1SD	2SD	methods	
			mmol/l	0.87	0.70	1.04	0.09	0.17	Gravimetric	
		Sodium	mg/dl	12.0	9.59	14,4	1,21	2,41		LEVEL 3
			mmol/I	155	147	163	4.00	8,00	Ortho Vitros Microslide Systems	DO STYLANA
			mmol/I	159	151	167	4.00	8.00	Enzymatic	Na = 157. 1 mmo\/L
			mmol/l	157	150	164	3,50	7.00	ISE method - direct	K = 6.27
			mmol/I	159	151	167	4.00	8.00	ISE method - indirect	
			µmol/I	139	111	166	13.85	27.70	Gravimetric	May-30-22 08:53:25
			µg/ml	25.0	20.0	30.0	2.50	5.00		1
	- 2	Thyroid Stimulating Hormone	μU/ml =	0.96	0.76	1.15	0.10	0.19	Abbott Architect	LAST 1-25 QC RESULTS
	Pota	esslum	mmol/I	6.30	5.80	6.80	0.25	0.50	Ortho Vitros Microslide Systems	Na = 157.06 mmol/L
			mmol/l	6.53	6.01	7.05	0.26	0.52	Enzymatic	K = 6.274 mmol/L 1Ca= 1.039 mmol/L
			mmol/I	6.30	5.79	6,81	0.26	0.51	ISE method - direct	C1 = 0.000 mmo1/L
		~		6.37	5.86	6.88	0.26	0.51	ISE method - indirect	Li = 0.000 mmol/L
			mmol/I	0.37	25.00	62.0	4.50	9.00	Ortho Vitros Microslide Systems	pH = 0.000

