

CALIBRATION CERTIFICATE

This is to certify that the Mindray BS 240E (SL.No. BC8-35000391) installed at **MEDICARE DIAGNOSTIC LABORATORY, KONNI** has been calibrated as per the recommended procedures. The system parameters are found to be within the specified ranges. The System has passed the performance tests. The system is ready for calibration of the Chemistries with the respective calibrators. The validation of the chemistry results has to be done with multi levels of commercially available controls.

Calibration validity: 12 Months

Last Calibration Done on: 20/07/2023
Next Calibration Due on: 19/07/2024

For Mindray Medical India Pvt. Ltd.,

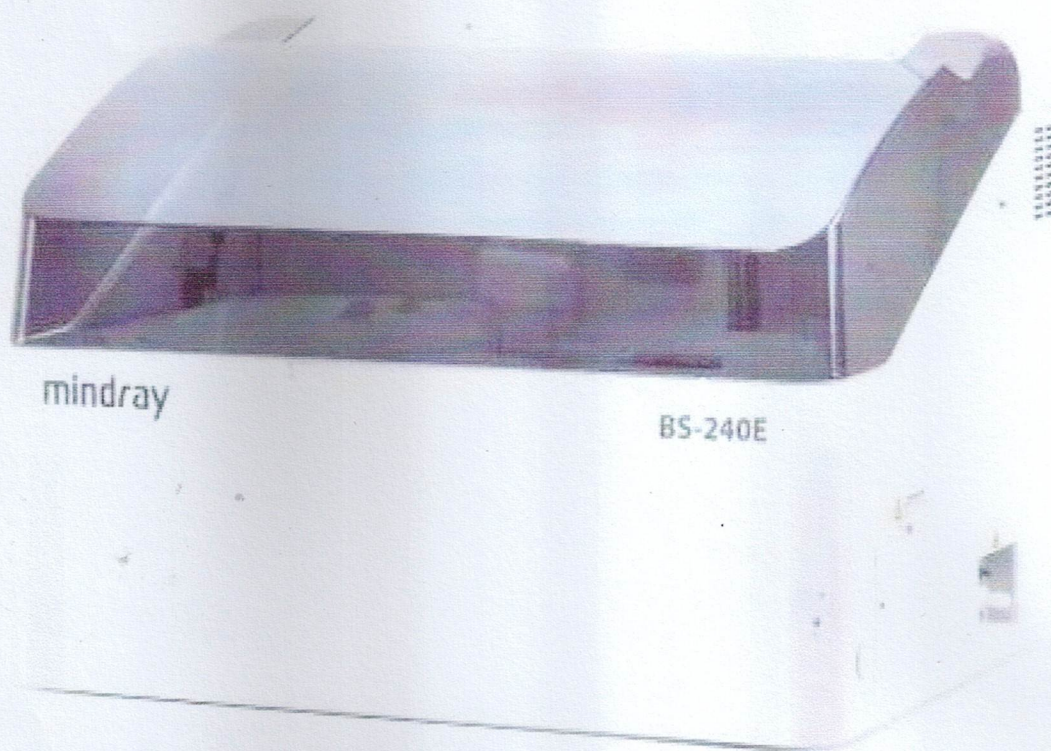
AJAY P. S.
SERVICE ENGINEER

SIVA MEDICAL SERVICES

"Palathinkara", TC No. 28/1838(1) & 28/1838,
TENRA - 22, Thycaud, Thiruvananthapuram - 695014
Kerala, India. Tel: 0471 2338959, 828 111 0354
Mail: ivdsales@sivamedicals.com

www.sivamedicals.com

BS 240 E CHEMISTRY ANALYZER



Installation Qualification / Operation Qualification / Performance Qualification
INSTALLATION QUALIFICATION

INSTRUCTIONS:

1. This document is to be completed at time the system is unpacked and setup for operation.
2. An authorized Mindray representative will checkout each module and verify the alignment.
3. All deviations from normal specification to include any problems with installation will be noted in the comments section.
4. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by Mindray.

INSTALLATION QUALIFICATION PROTOCOL:

This Installation Qualification protocol will be performed on the Instrument installed at,
MEDICARE LABORATORY KONNI, PATHANANTHITTA

This protocol will define the documentation that will be used to evaluate the instrument documented in accordance with manufacture's specifications and identified use.

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

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 determined that the system described in this document meets all criteria outlined in this Installation. Qualification protocol, 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: MINDRAY REPRESENTATIVE

Name: AJAY PS

Title: INSTALLATION QUALIFICATION

Company: SIVA MEDICAL SERVICES

Signature:




Service Engineer
Siva Medical Services
Thycaud, Thiruvananthapuram

Customer Authorization:

Name: MEDICARE LABORATORY

Title: INSTALLATION QUALIFICATION

Signature:

CERTIFICATION OF INSTALLATION - REPORT

INSTRUMENT NAME: BS-240E

SERIAL NUMBER: BC8-35000391

CUSTOMER NAME & ADDRESS:

MEDICARE LABORATORY, KONNI, PATHANAMTHITTA, KERALA ,689691 (pin)

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

AUTHORIZED ENGINEER,

SIGNATURE:


Service Engineer
Siva Medical Services
Thyssen Biru Ananthapuram

NAME: AJAY.PS

DESIGNATION: SERVICE ENGINEER

COMPANY: SIVA MEDICAL SERVICES

NOTE: Installation Service Report Should be attached with this manual for Documentation.

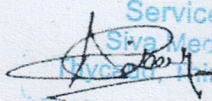
INSTALLATION VERIFICATION REPORT

This is to certify that the following checks mentioned in the installation verification protocol have been performed and found to be satisfactory.

1. PRE- INSTALLATION CHECK	
A) Carton arrival	PASS
B) Spare and accessibility	PASS
C) Electrical input	PASS
D) Ambient temperature and Humidity	PASS
E) Ventilation	PASS
F) Drainage	PASS
2. UNPACKING & INSTALLING THE CONSOLE	PASS
3. INSTALLING THE ELECTRICAL CABLES	PASS
4. UNPACKING & INSTALLING THE ANALYTICAL UNIT	PASS
5. SETTING THE ANALYTICAL UNIT	PASS
6. ALIGNMENTS VERIFICATION	PASS

ENGINEER NAME & SIGNATURE

AJAY P.S


Service Engineer
Siva Medical Services
Kuvempu, Mysuru, Karnataka
Mysuru, Karnataka

MEDICARE LABORATORY

CUSTOMER NAME & SIGNATURE





OPERATIONAL QUALIFICATION

SYSTEM CERTIFICATION:

Study date has determined that the system described in this document either meets all criteria outlined in this Operational Qualification protocol. All exceptional conditions if any have been addressed. The system is ready for specified usage.

Protocol performed by: **MINDRAY REPRESENTATIVE**

Name: AJAY P.S

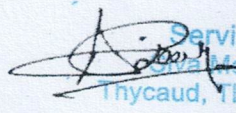
Title: OPERATIONAL QUALIFICATION

Company: SIVA MEDICAL SERVICES

Customer Authorization:

Name: MEDICARE LABORATORY

Title: OPERATIONAL QUALIFICATION


Service Engineer
Siva Medical Services
Thycaud, Thiruvananthapuram

AUTHORIZED ENGINEER SIGNATURE

DATE: 20/7/2023 DATE:20-07-2023




CUSTOMER SIGNATURE



OPERATIONAL QUALIFICATION - SYSTEM VERIFICATION REPORT

This is to certify that the following checks mentioned in the operational verification protocol have been performed and found to be satisfactory.

<u>OPERATIONAL QUALIFICATION PROTOCOL</u>	<u>REMARKS</u>
1] CHECKING THE ANALYTICAL UNIT	
A] SOFTWARE BOOTING & INITIALIZATION	PASS
B] BASIC SYSTEM CHECKS& VERIFICATION	PASS
2] IMPORTING & CALIBRATING THE CHEMISTRIES	PASS
3] RUNNING CONTROLS	PASS
4] TRAINING THE OPERATORS (BASIC/ADVANCED)	PASS

ENGINEER NAME AND SIGNATURE AJAY P.S  Service Engineer Ajay P.S. Technical Services The Chennai Medical Services Chennai	CUSTOMER NAME AND SIGNATURE MEDICARE LABORATORY  2017/123 
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NOTE: FOR ABOVE MENTIONED PERFORMANCE VERIFICATION PROTOCOLS, INSTRUMENT RAW DATA PRINTOUTS & SUPPORTING DOCUMENTS NEED TO BE ATTACHED WITH THIS MANUAL

OPERATIONAL QUALIFICATION PROCEDURES

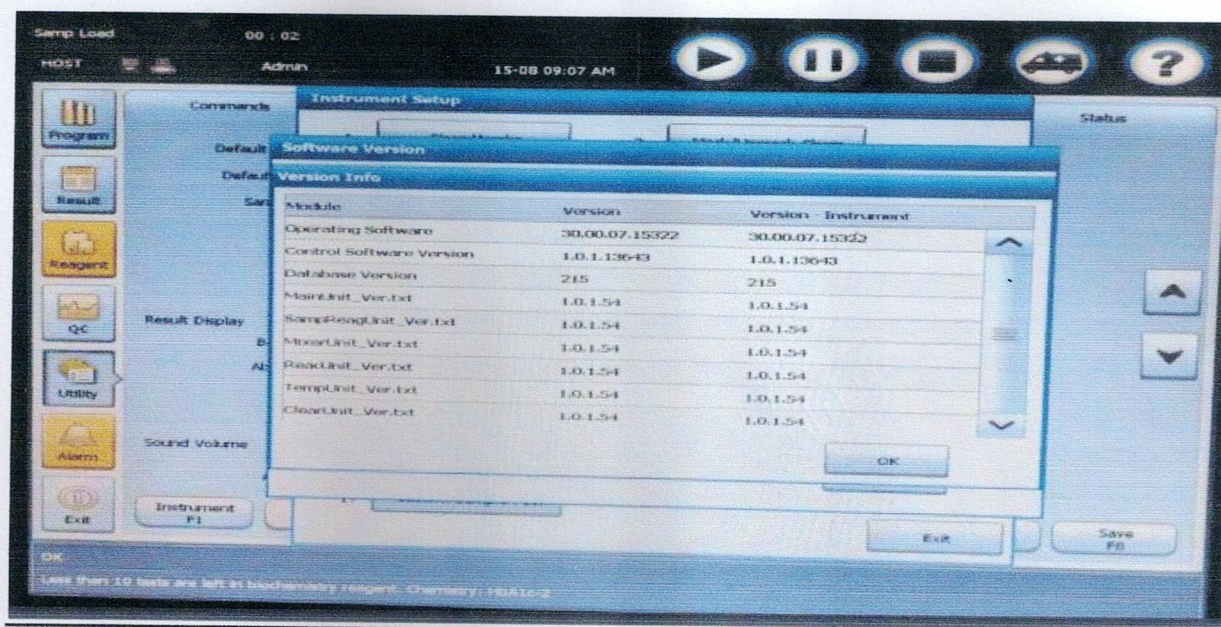
The Operational Qualification procedure specifies the methodology for the installation of the specified system after successful Installation qualification. Successful completion of the specified protocols and is ready for operation and subsequent performance analysis.

OQ PROCEDURES:

1. System software loading.
2. System Booting and Initialization
3. Basic System Checks.
4. Importing Chemistries & Calibrating Chemistries.
5. Running Controls.
6. Operators Training Schedule.

References:

1. *Operation Manual -BS - 240E CHEMISTRU ANALYZER*
2. *Service Manual - BS-240E CHEMISTRU ANALYZER*



Operational Qualification Notes:

Performance Qualification Notes:

Running 00 : 18
HOST Admin 15-08 09:08 AM

Reagent/Calibration Biochemistry Calibration Reagent Carousel Status Cal Setup

Chem ALL

Current History

Cal Date 15-08-2023 15-08-2023

Chem	Flag	Cal Status	Cal Date/Time	R0	K	A
GLU-G		Calibrated	20-07-2023 06:18:57 PM	55.2416	0.0280	
T-Bil V		Calibrated	21-07-2023 11:58:40 AM	-92.2410	0.0041	
D-Bil V		Calibrated	21-07-2023 11:58:10 AM	28.1747	0.0040	
ALT		Calibrated	21-07-2023 11:58:08 AM	-0.0497	0.4732	
AST		Calibrated	21-07-2023 11:59:08 AM	-10.5091	0.4745	
ALP		Calibrated	08-08-2023 03:28:25 PM	11.5454	0.6510	
γ-GT		Calibrated	09-08-2023 04:47:24 PM	4.9140	0.2500	
TP		Calibrated	24-07-2023 12:41:58 PM	10.0190	0.0060	
ALB II		Calibrated	24-07-2023 12:37:02 PM	626.1859	0.0004	
TC		Extended	20-07-2023 06:17:57 PM	32.0165	0.0399	

Search F1 Cal Curve F2 Rec. Curve F3 Edit F4 Archive F5 Trend F6 Print F7

Select a Chemistry
Less than 10 tests are left in biochemistry reagent. Chemistry: 18A1c-2

Running 00 : 18
HOST Admin 15-08 09:08 AM

Reagent/Calibration Biochemistry Calibration Reagent Carousel Status Cal Setup

Chem ALL

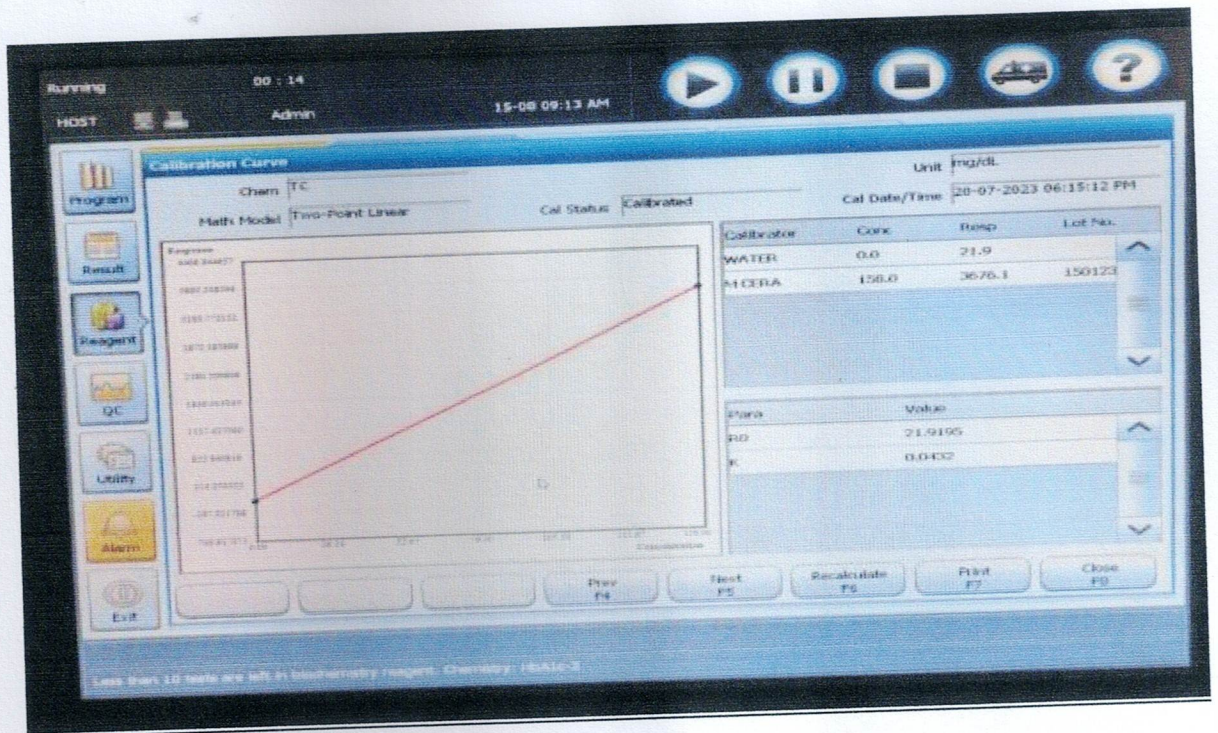
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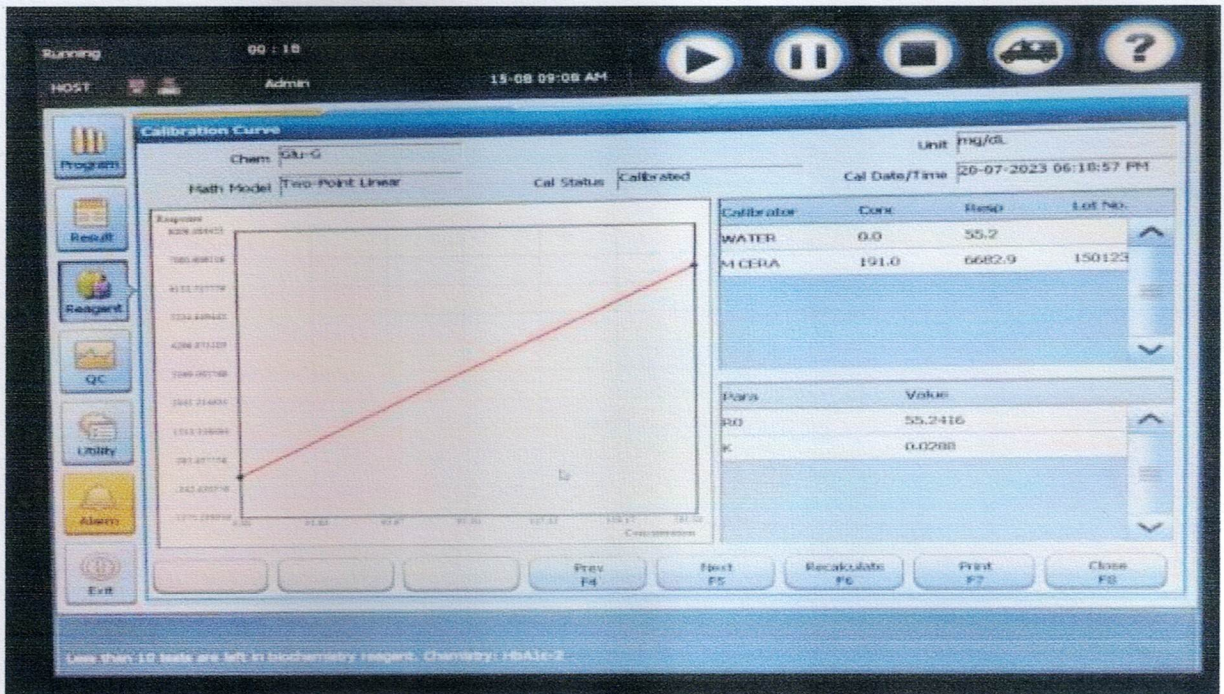
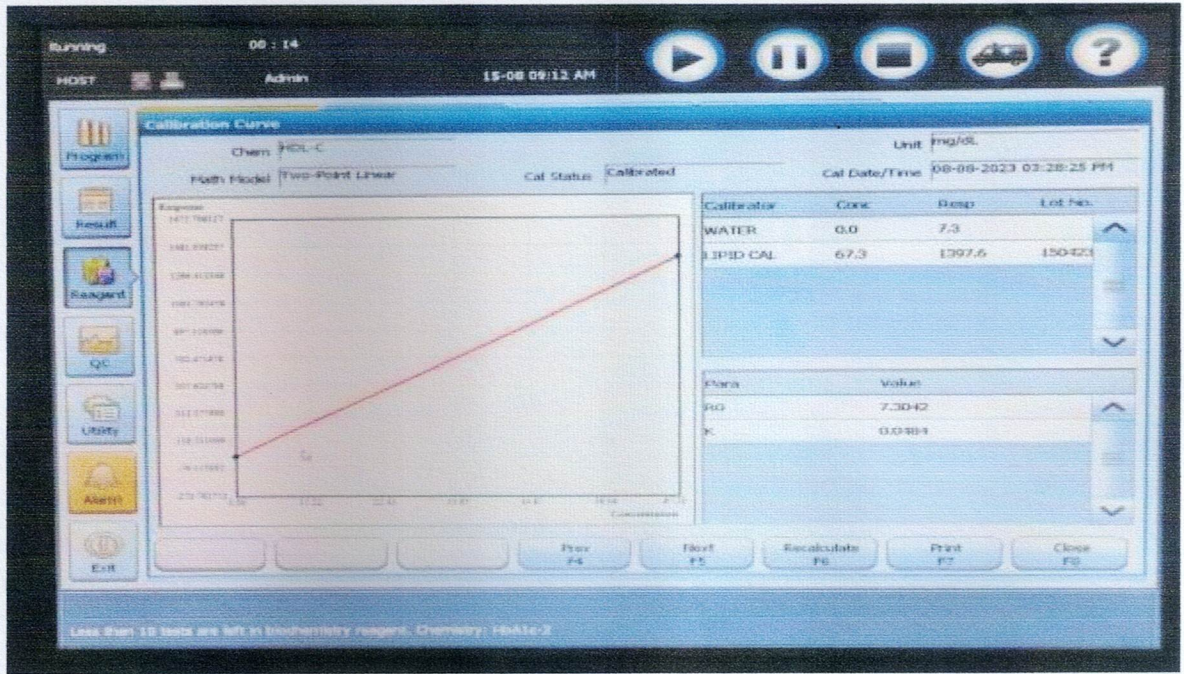
Cal Date 15-08-2023 15-08-2023

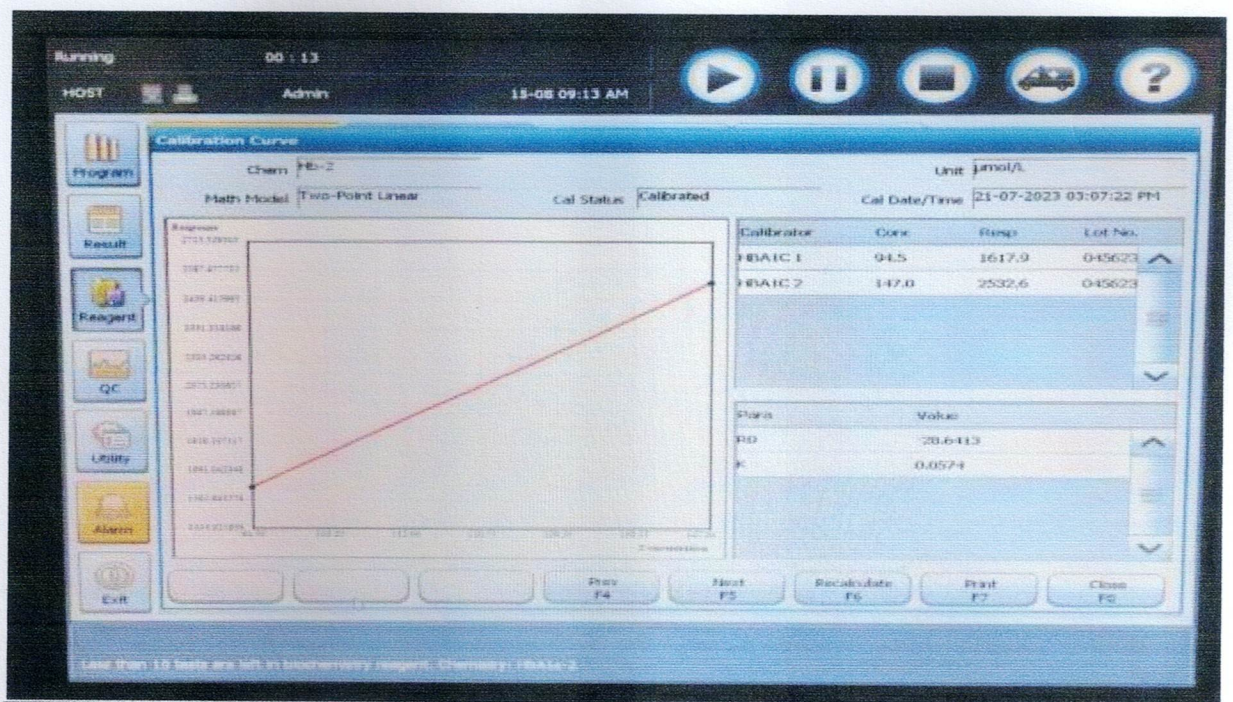
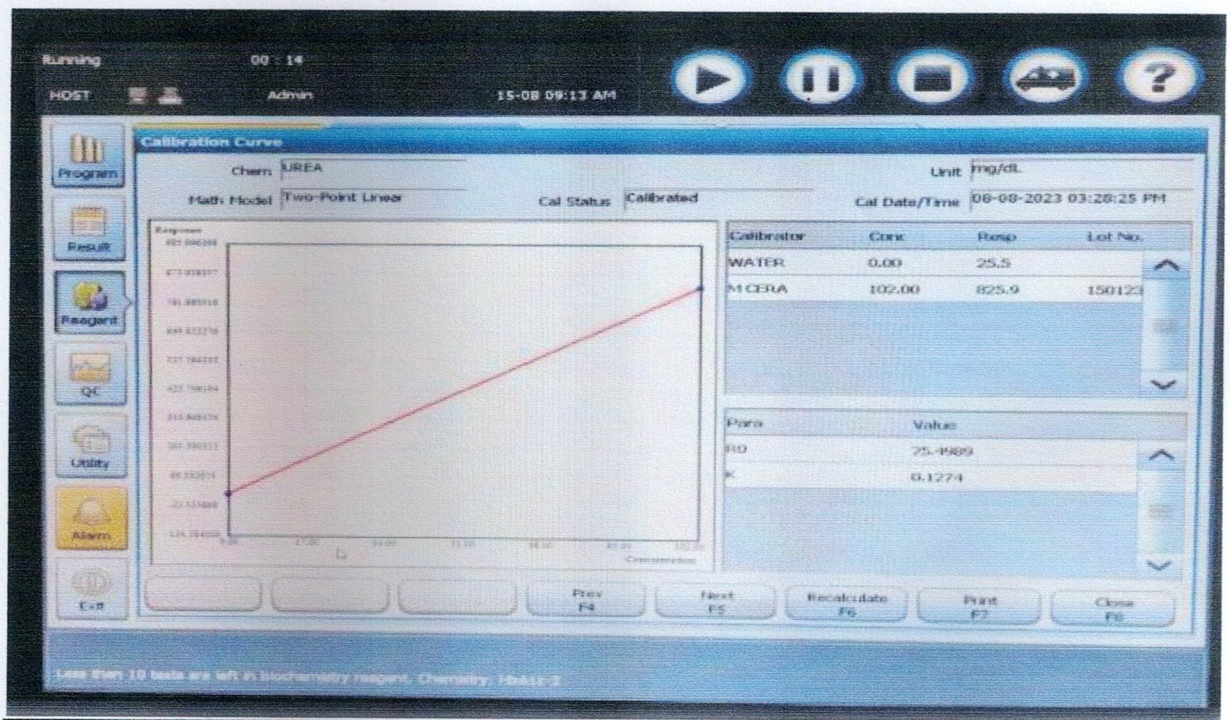
Chem	Flag	Cal Status	Cal Date/Time	R0	K	A
LDL-C		Calibrated	21-07-2023 05:20:57 PM	11.1334	0.0504	
HDL-C		Calibrated	08-08-2023 03:28:25 PM	7.3042	0.0464	
TC		Calibrated	20-07-2023 06:15:12 PM	21.9195	0.0432	
UA		Calibrated	21-07-2023 12:34:23 PM	73.2986	0.0079	
UREA		Calibrated	08-08-2023 03:28:25 PM	25.4989	0.1274	
Hb-2		Calibrated	21-07-2023 03:07:22 PM	-28.6413	0.0574	
HbA1c-2		Calibrated	21-07-2023 03:12:38 PM	66.9629	0.0146	
Ca		Calibrated	21-07-2023 11:50:09 AM	-164.0361	0.0024	
CREA-S		Calibrated	21-07-2023 12:01:38 PM	67.5546	0.0032	
GPP II		Calibrated	08-08-2023 12:02:03 PM	387.5299	0.0340	

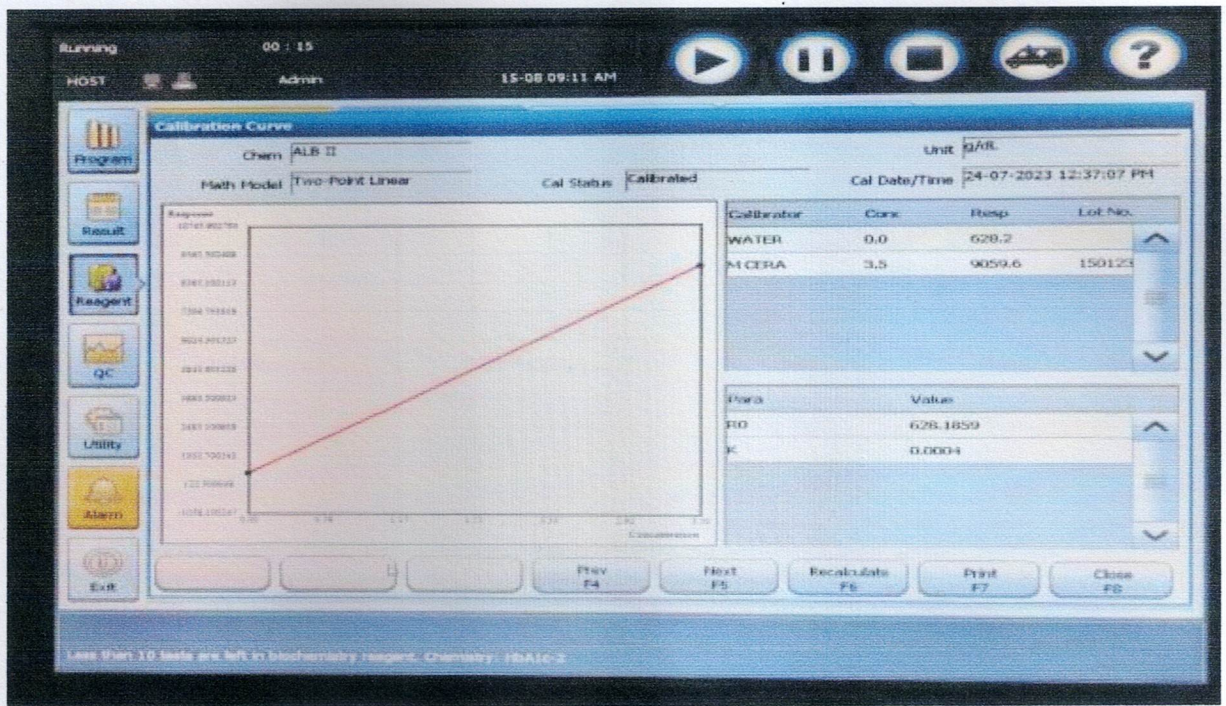
Search F1 Cal Curve F2 Rec. Curve F3 Edit F4 Archive F5 Trend F6 Print F7

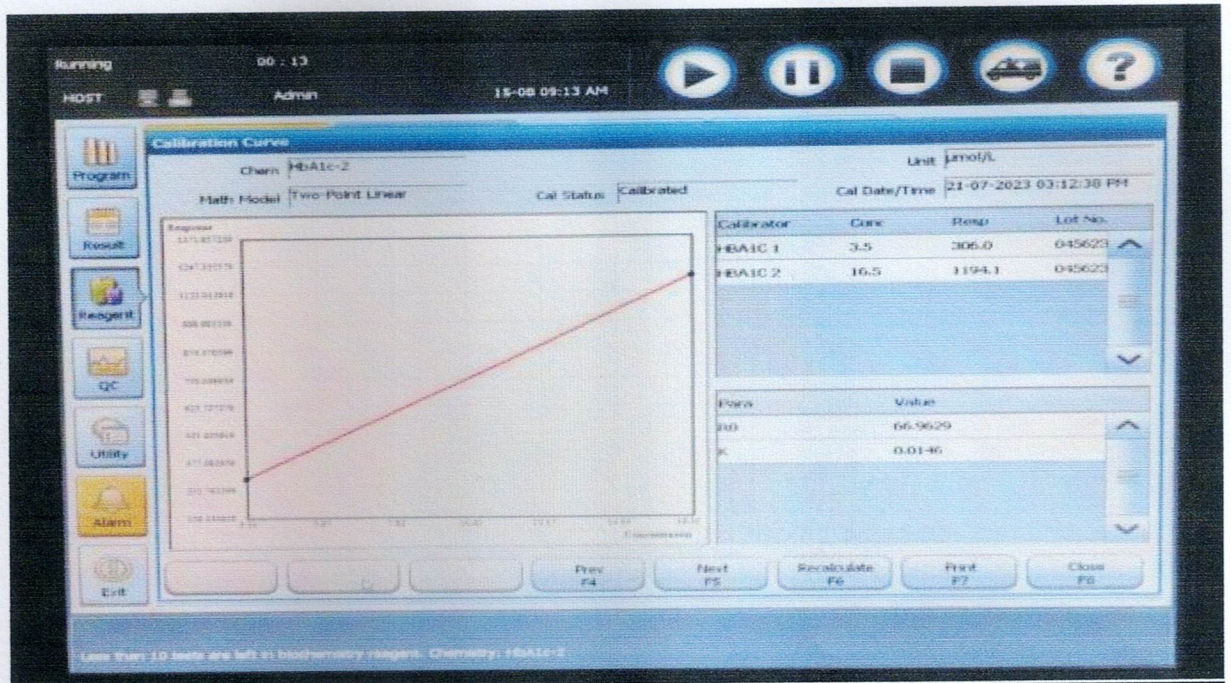
Less than 10 tests are left in biochemistry reagent. Chemistry: 18A1c-2

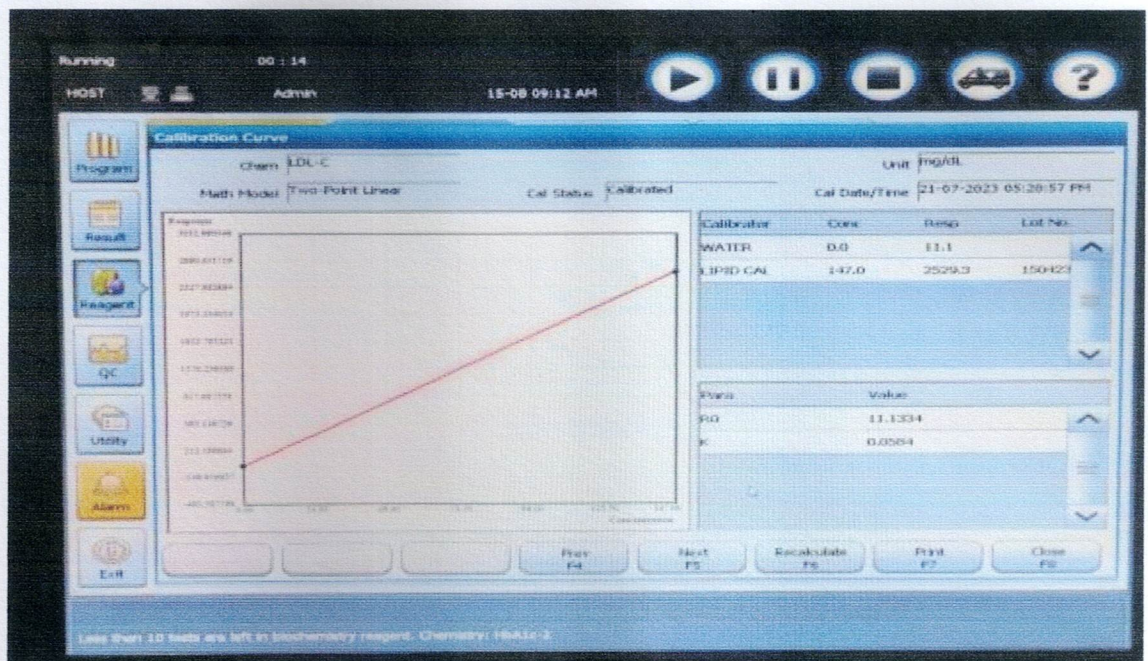
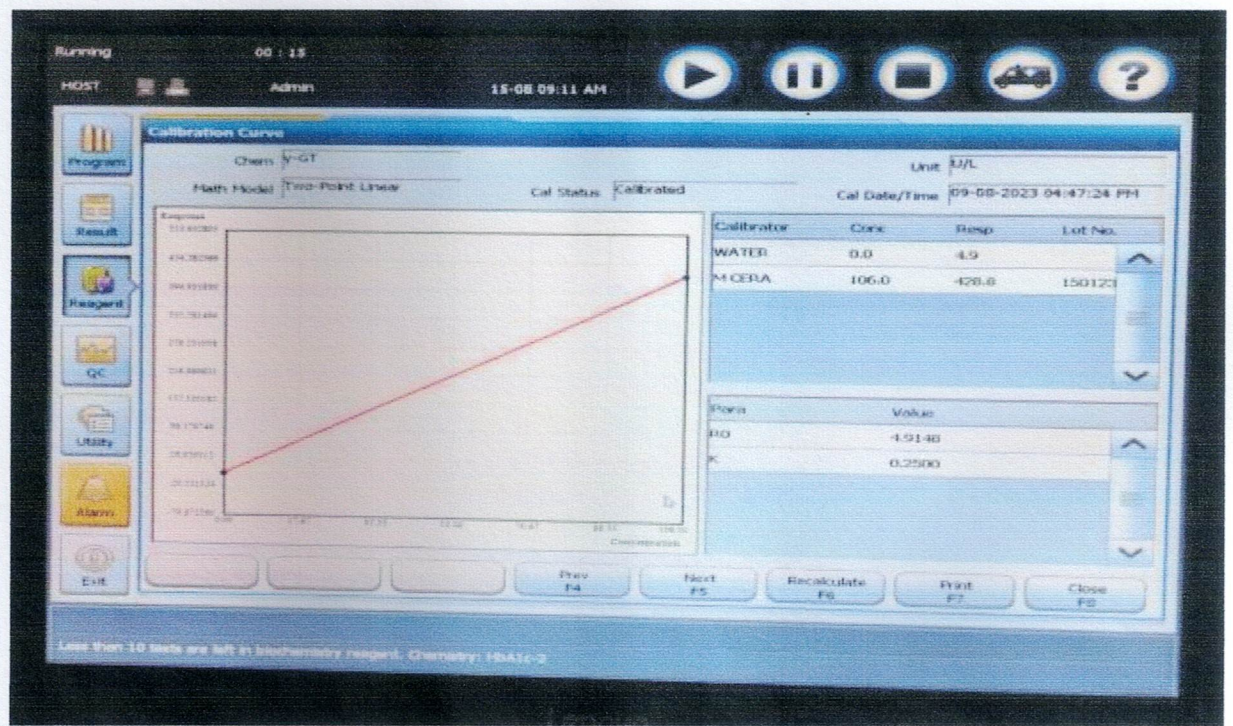


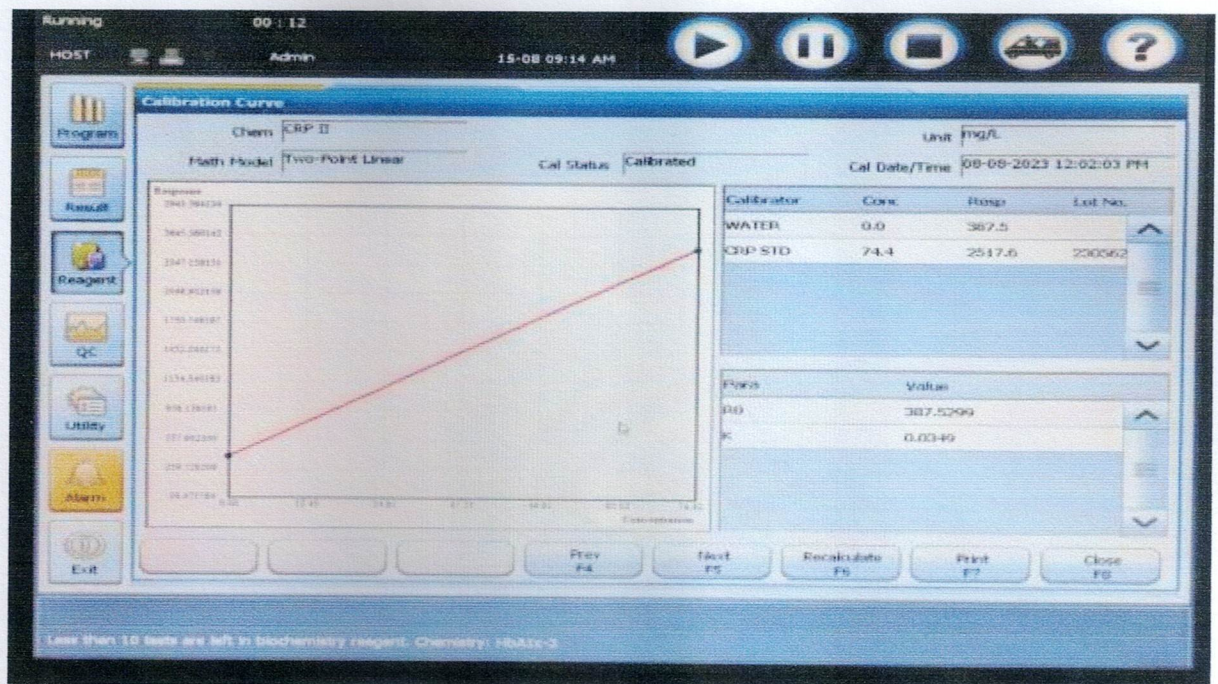
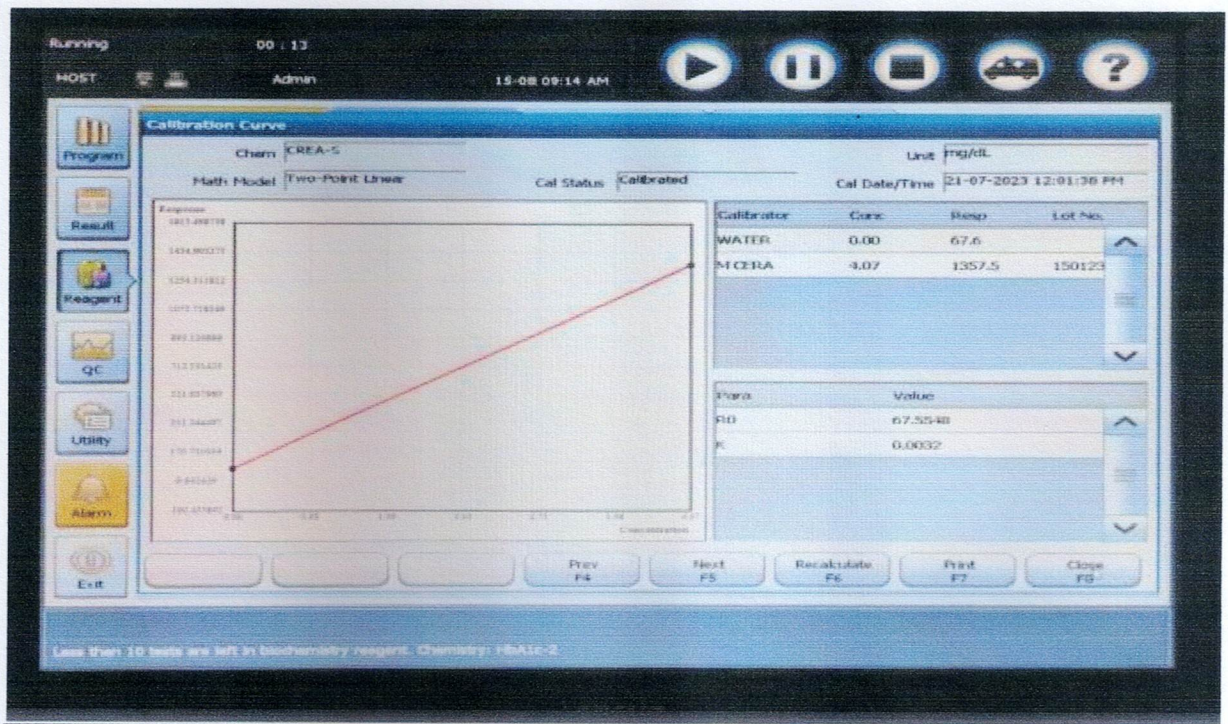


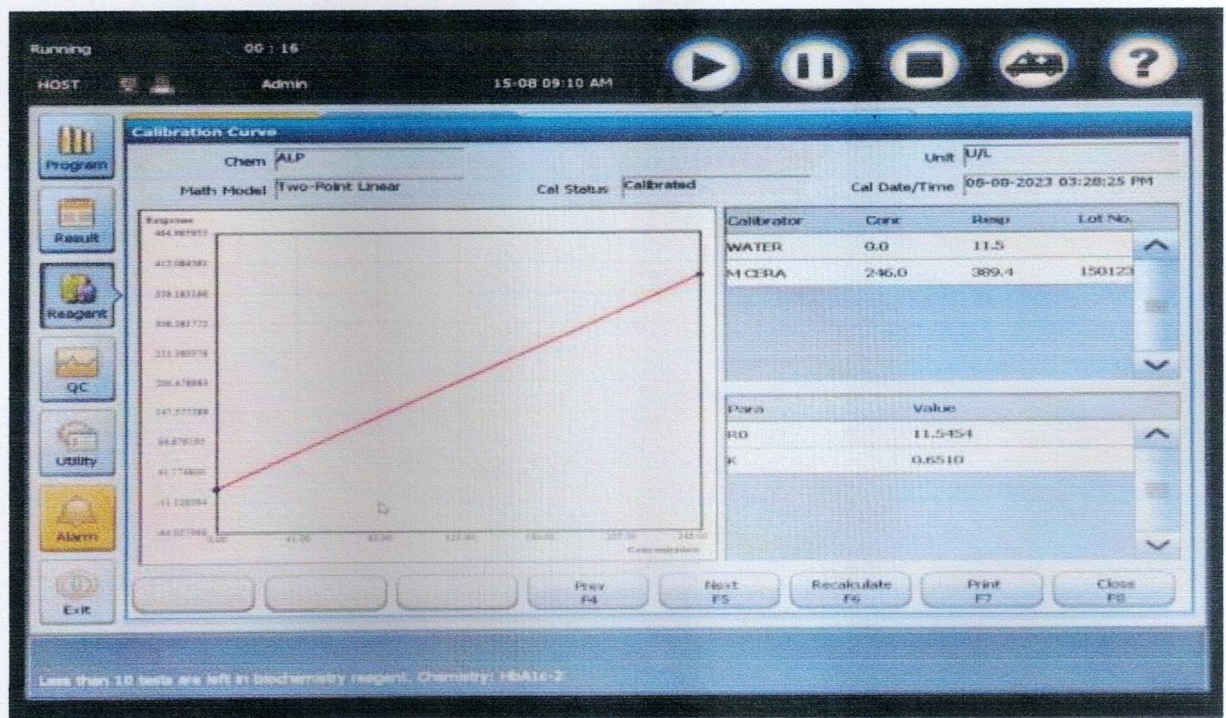












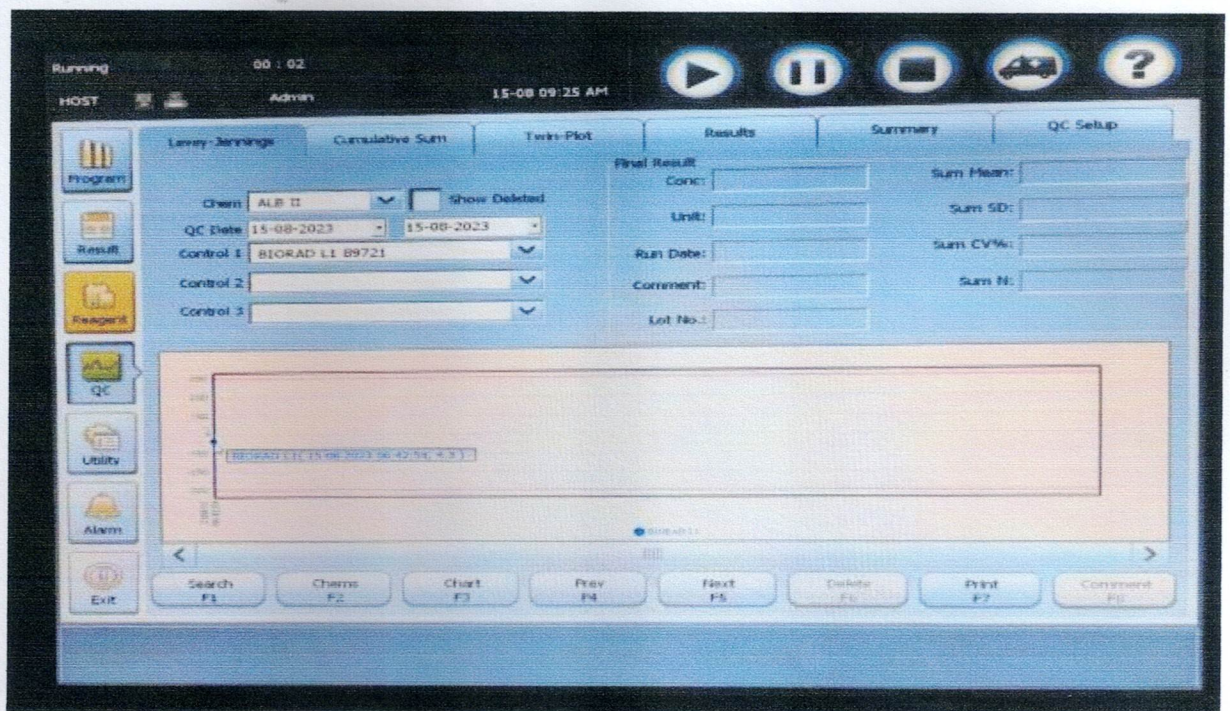
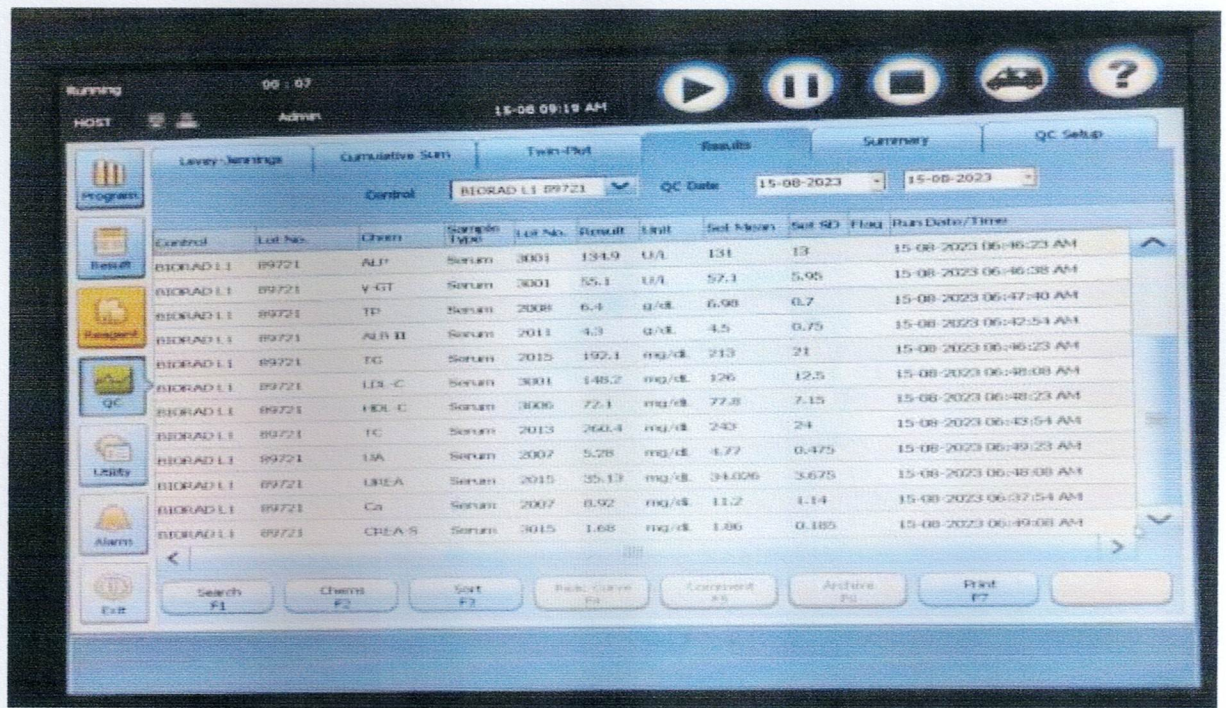
Running 00:08
HOST Admin 15-08-2023 09:19 AM

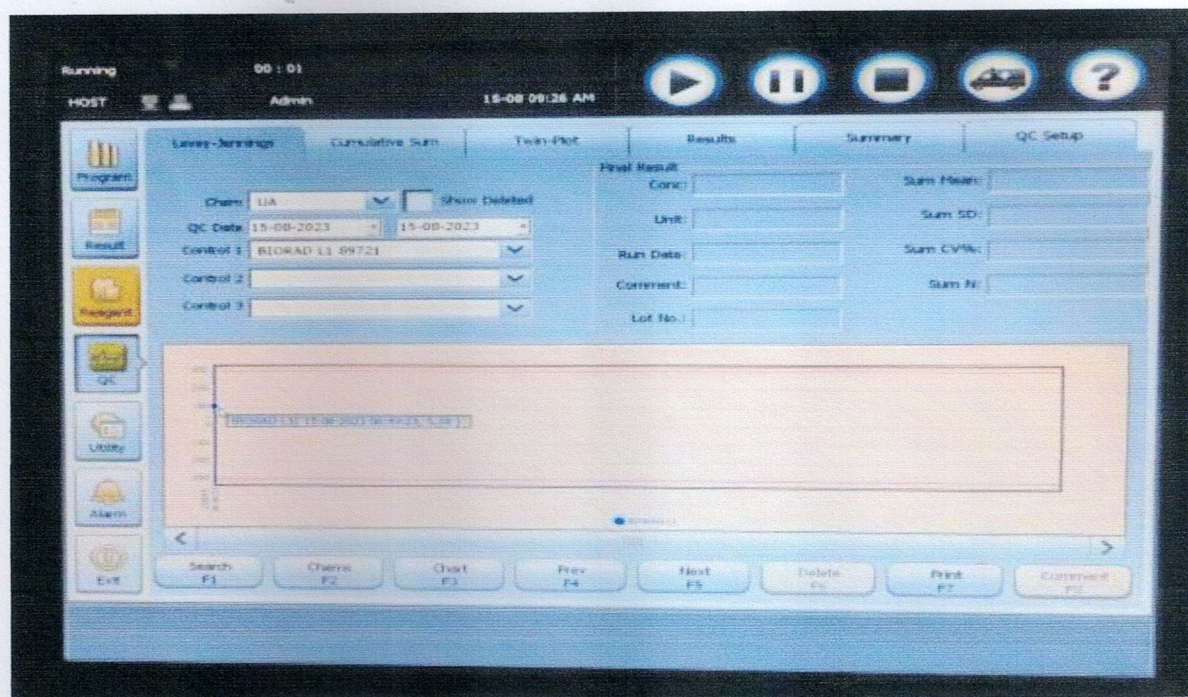
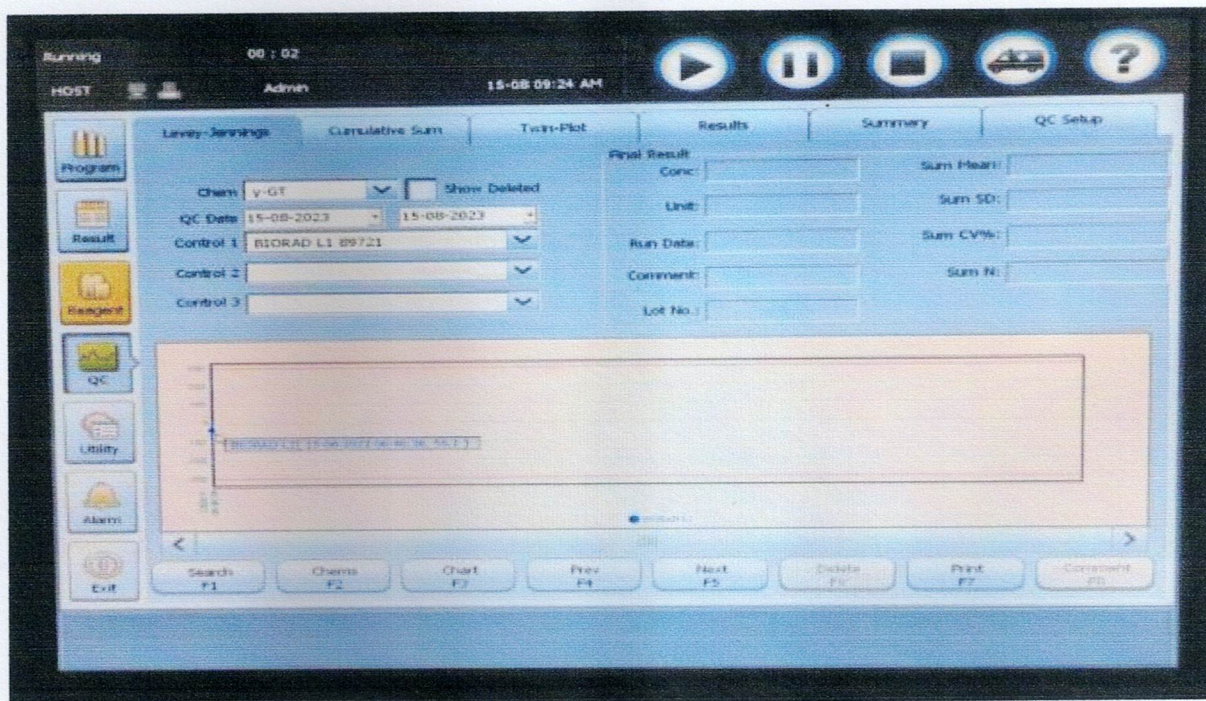
Levey-Jenings Cumulative Sum Twin-Plot Results Summary QC Setup

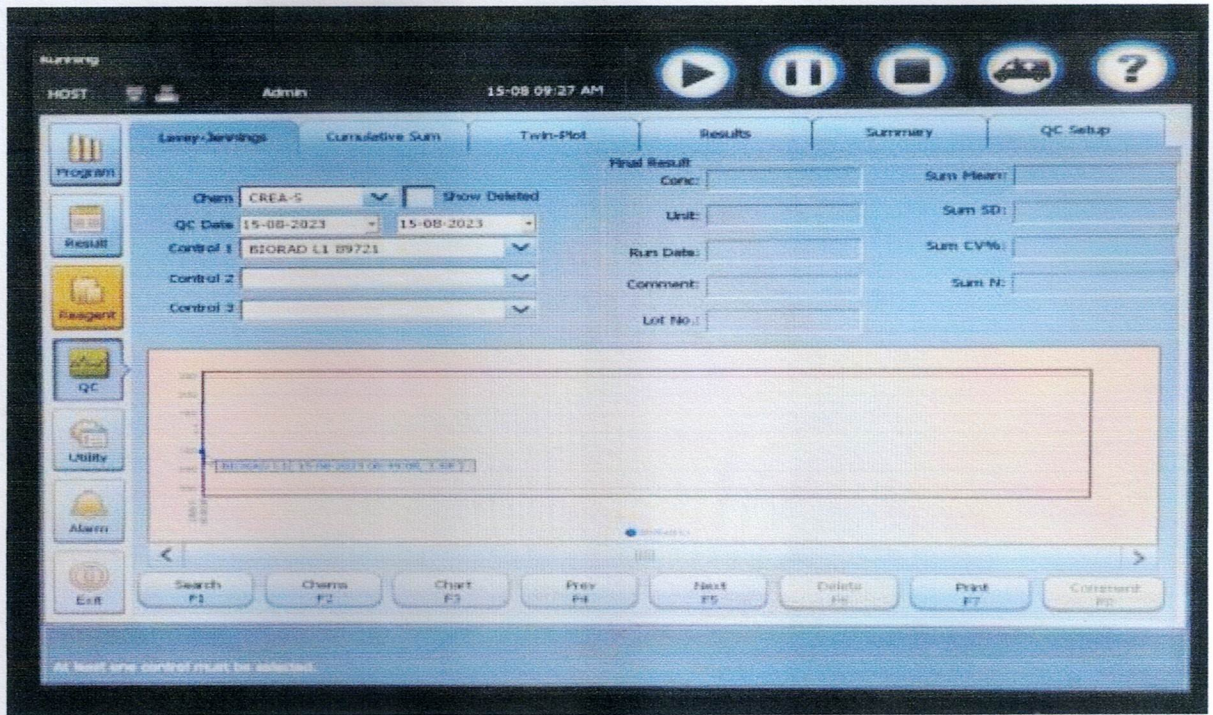
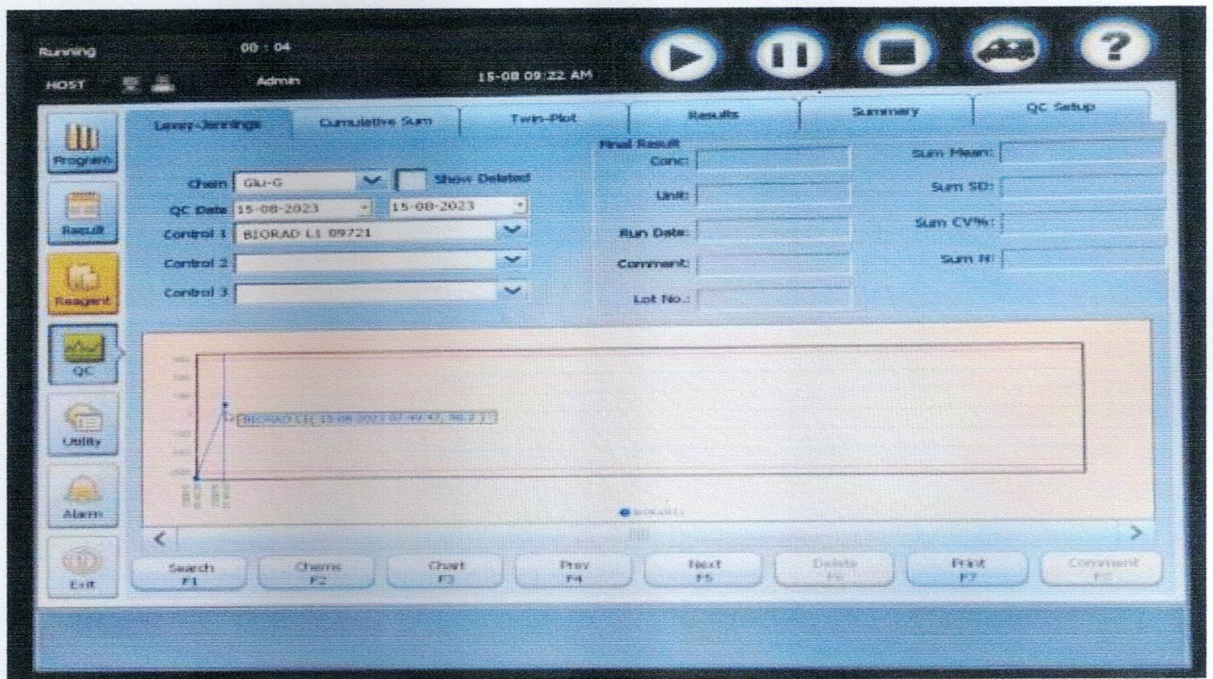
Control: BIORAD L1 89721 QC Date: 15-08-2023 15-08-2023

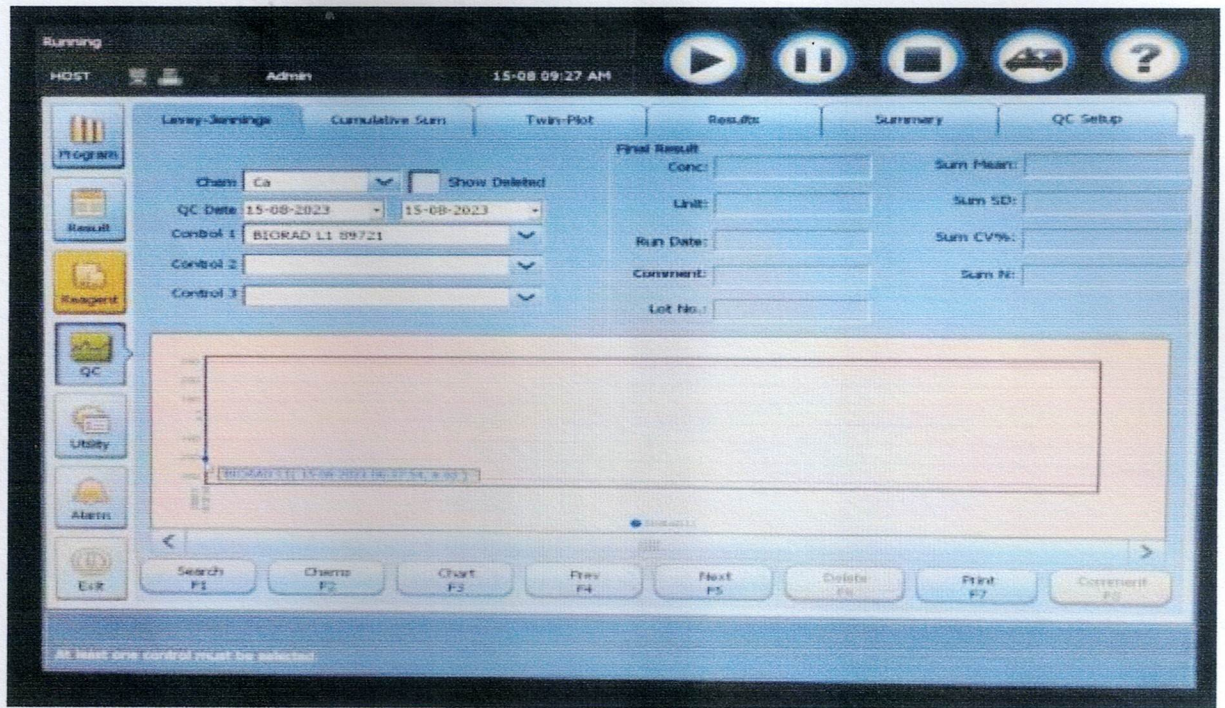
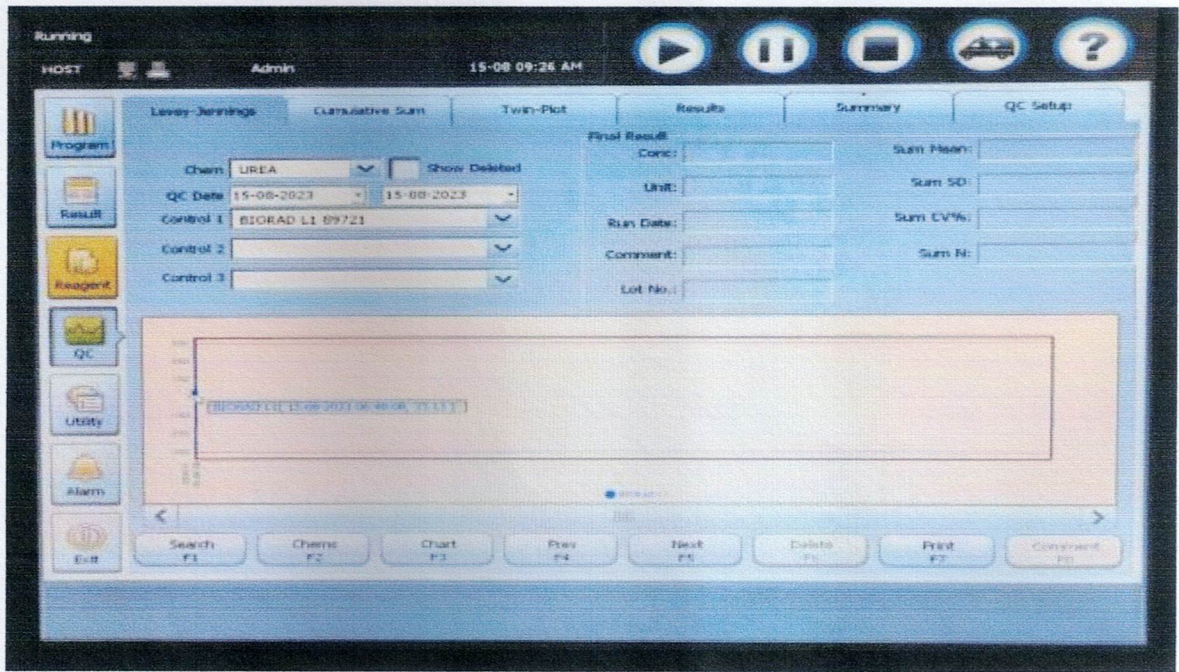
Control	Lot No.	Chem	Sample Type	Lot No.	Result	Unit	Set Mean	Set SD	Flag	Run Date/Time
BIORAD L1	89721	Glucose	Serum	3004	88.2	mg/dL	85.6	4.7		15-08-2023 07:49:47 AM
BIORAD L1	89721	T-Bil V	Serum	2007	0.76	mg/dL	0.92	0.175		15-08-2023 06:46:25 AM
BIORAD L1	89721	D-Bil V	Serum	2013	0.22	mg/dL	0.239	0.0195		15-08-2023 06:46:40 AM
BIORAD L1	89721	ALT	Serum	3001	25.9	U/L	29	2.9		15-08-2023 06:45:53 AM
BIORAD L1	89721	AST	Serum	3004	43.0	U/L	45.7	4.6		15-08-2023 06:46:09 AM
BIORAD L1	89721	ALP	Serum	3001	134.9	U/L	131	13		15-08-2023 06:46:23 AM
BIORAD L1	89721	γ-GT	Serum	3001	55.1	U/L	57.1	5.95		15-08-2023 06:46:38 AM
BIORAD L1	89721	TP	Serum	2008	6.4	g/dL	6.98	0.7		15-08-2023 06:47:40 AM
BIORAD L1	89721	ALB II	Serum	2011	4.3	g/dL	4.5	0.25		15-08-2023 06:42:54 AM
BIORAD L1	89721	TG	Serum	2015	192.1	mg/dL	213	21		15-08-2023 06:46:23 AM
BIORAD L1	89721	LDL-C	Serum	3001	148.2	mg/dL	126	12.5		15-08-2023 06:48:08 AM
BIORAD L1	89721	HDL-C	Serum	3006	72.1	mg/dL	77.8	7.15		15-08-2023 06:48:23 AM

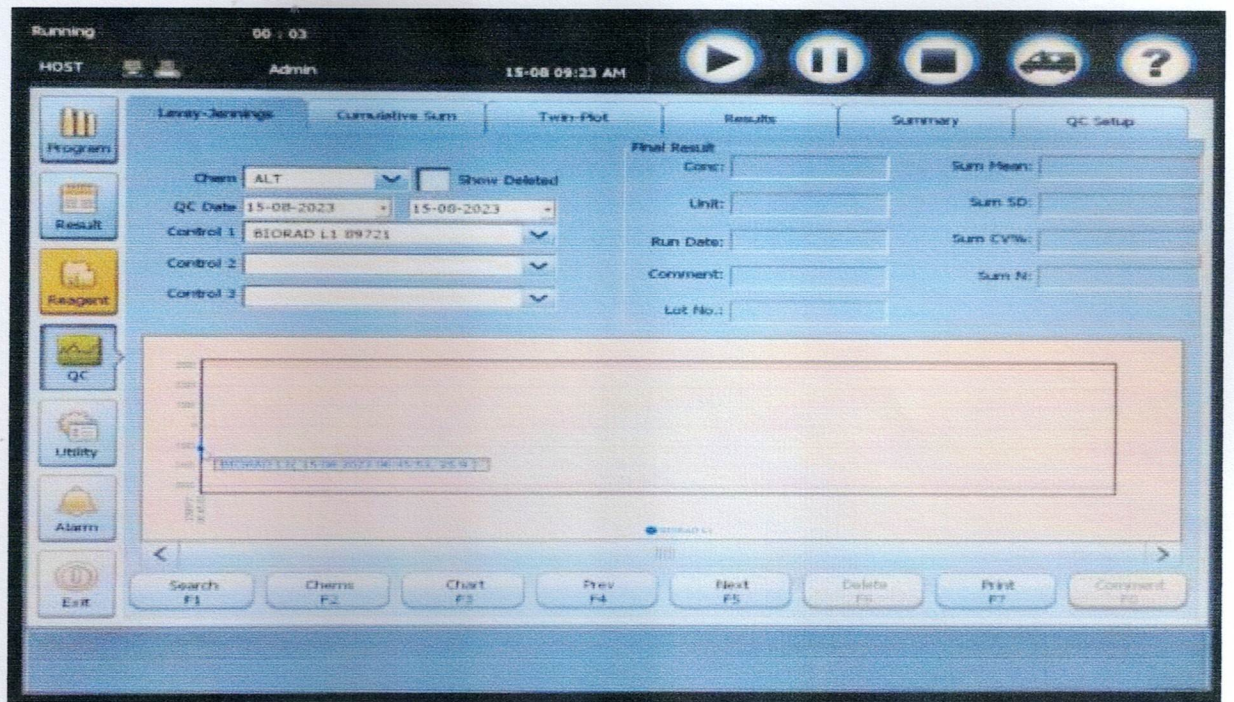
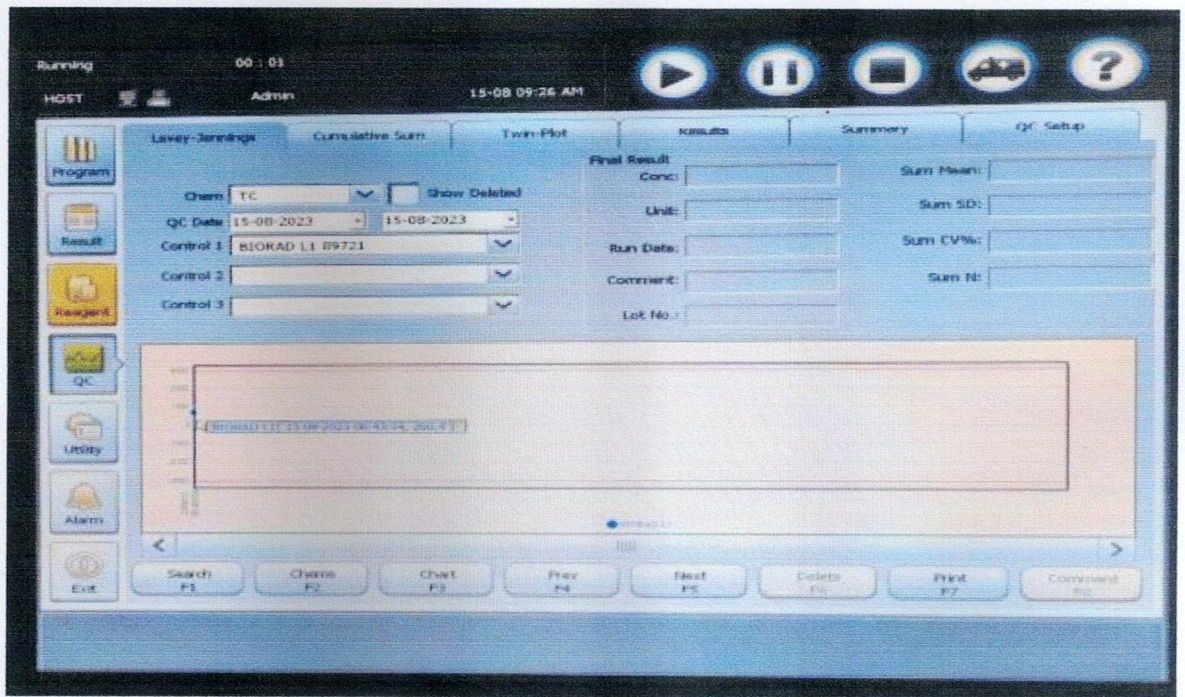
Buttons: Search (F1), Chems (F2), Sort (F3), Calc Curve (F4), Compare (F5), Archive (F6), Print (F7)

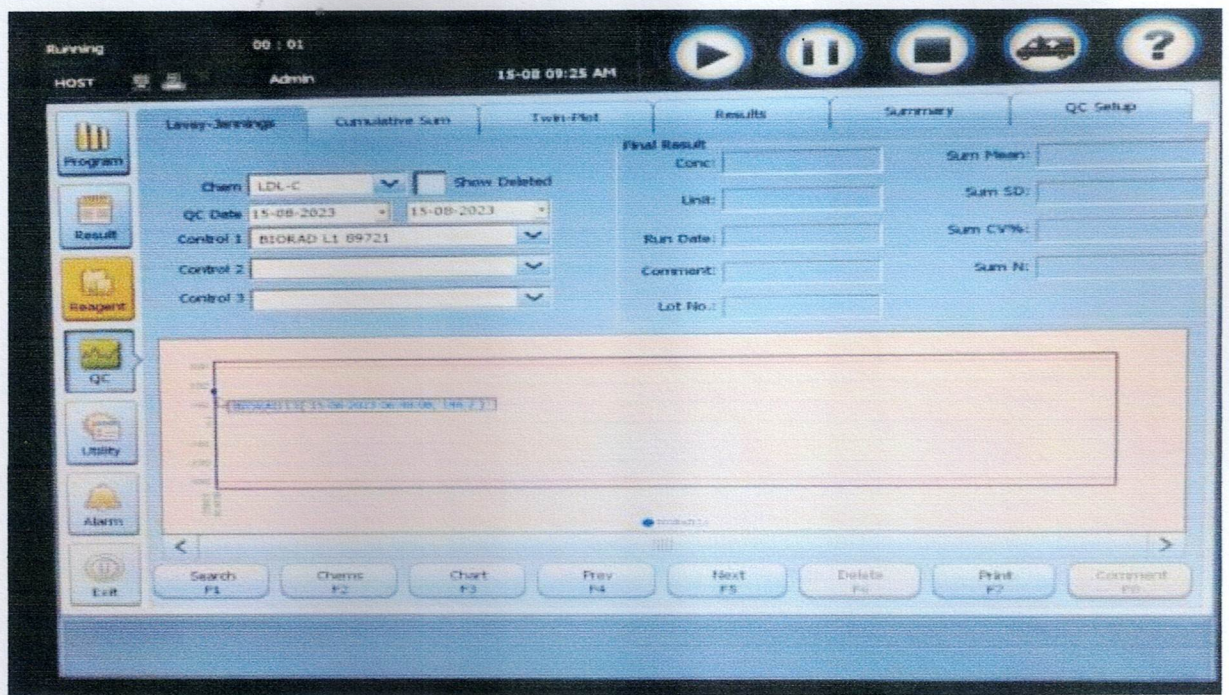
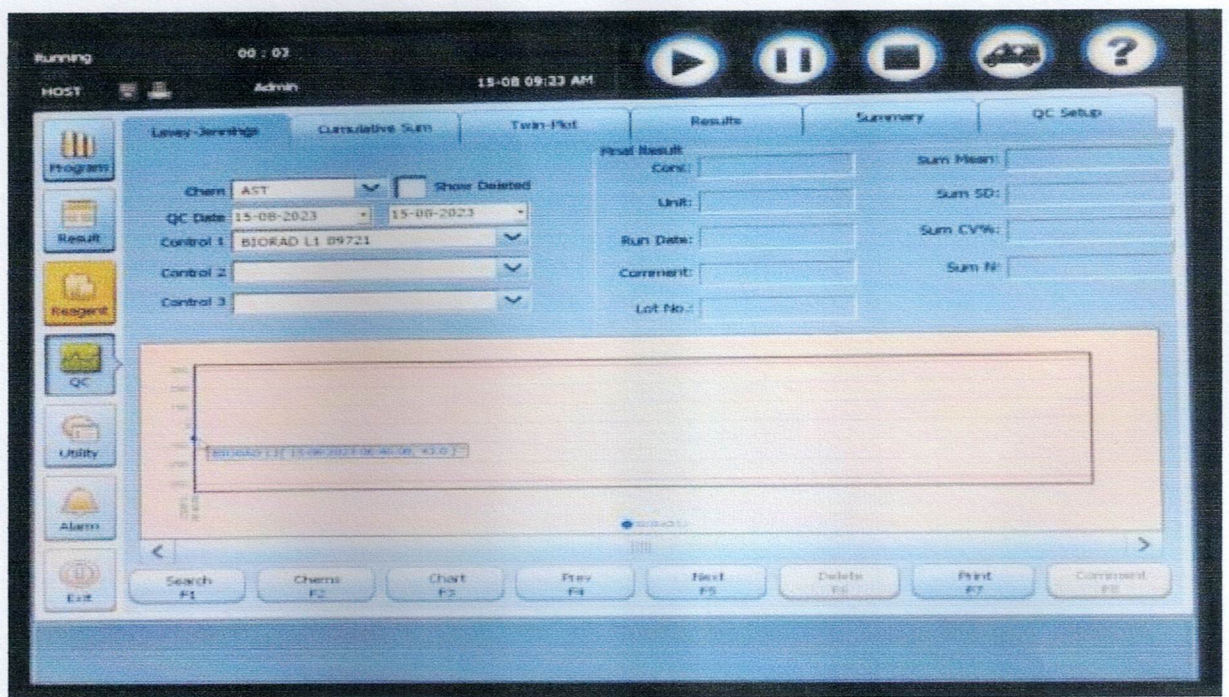


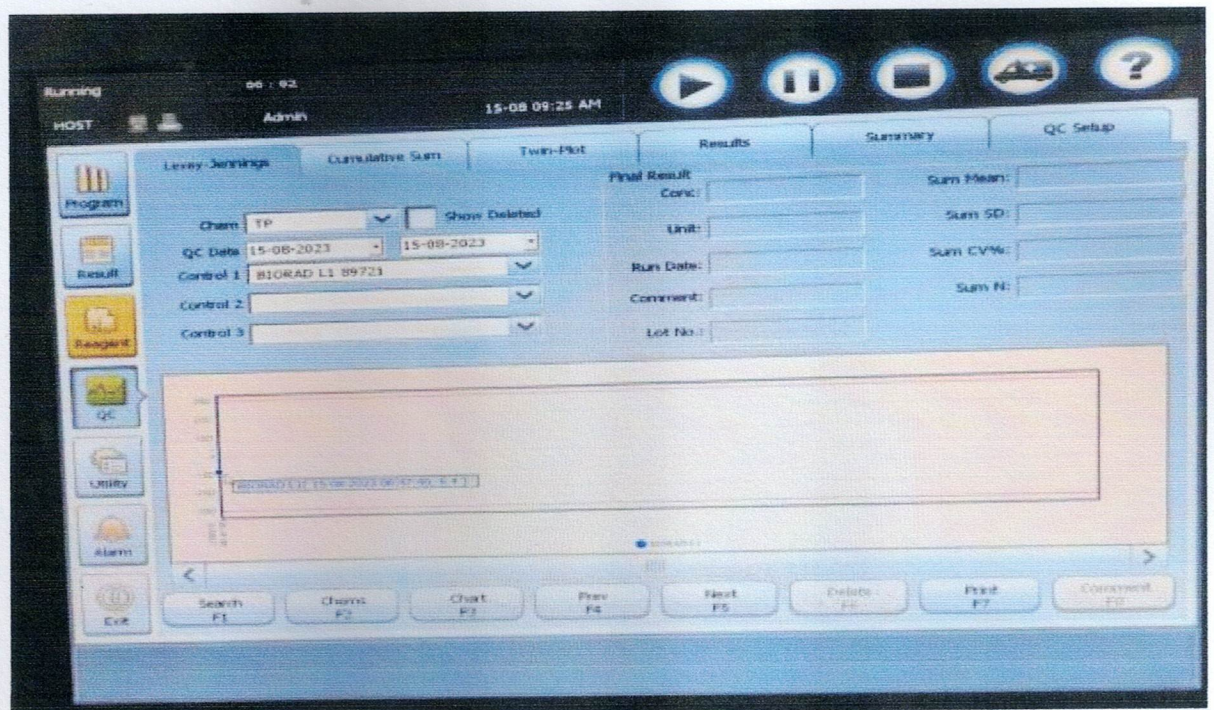
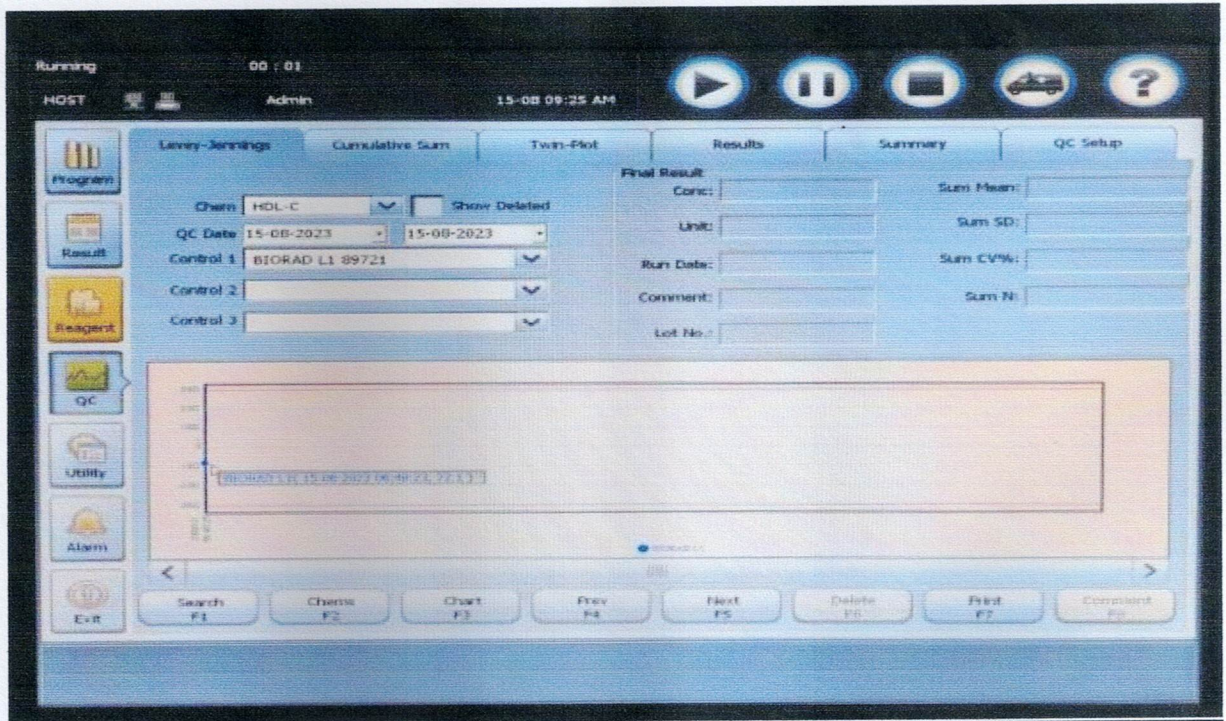


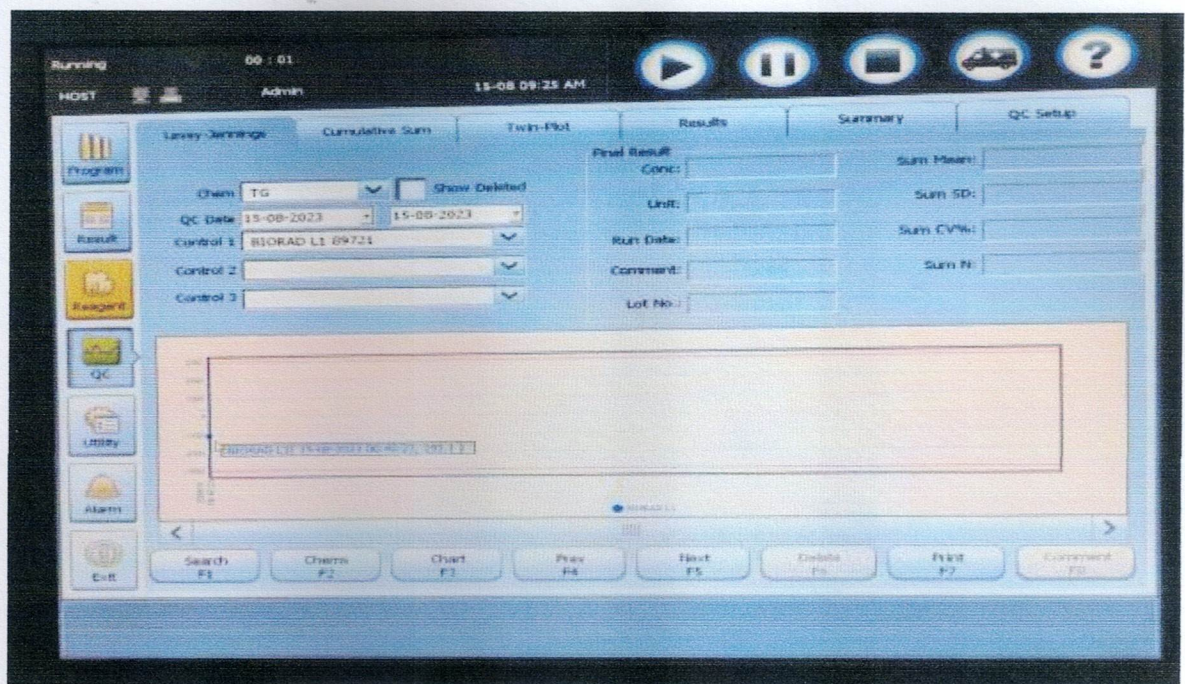
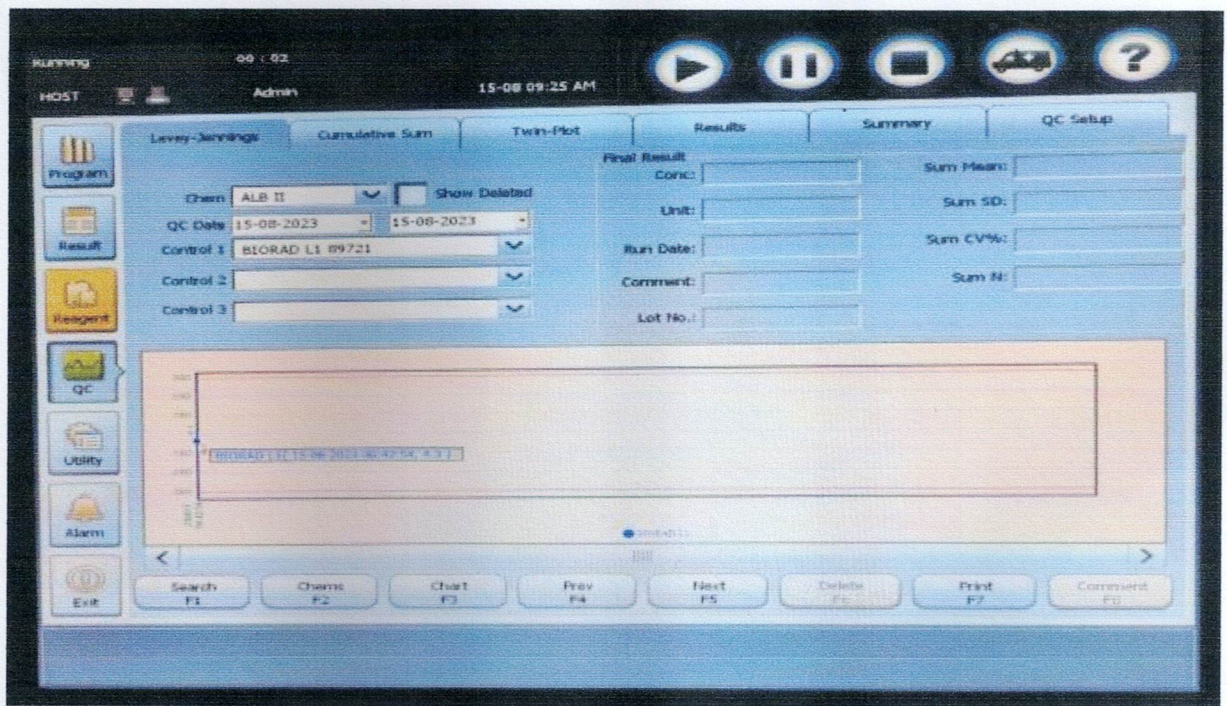


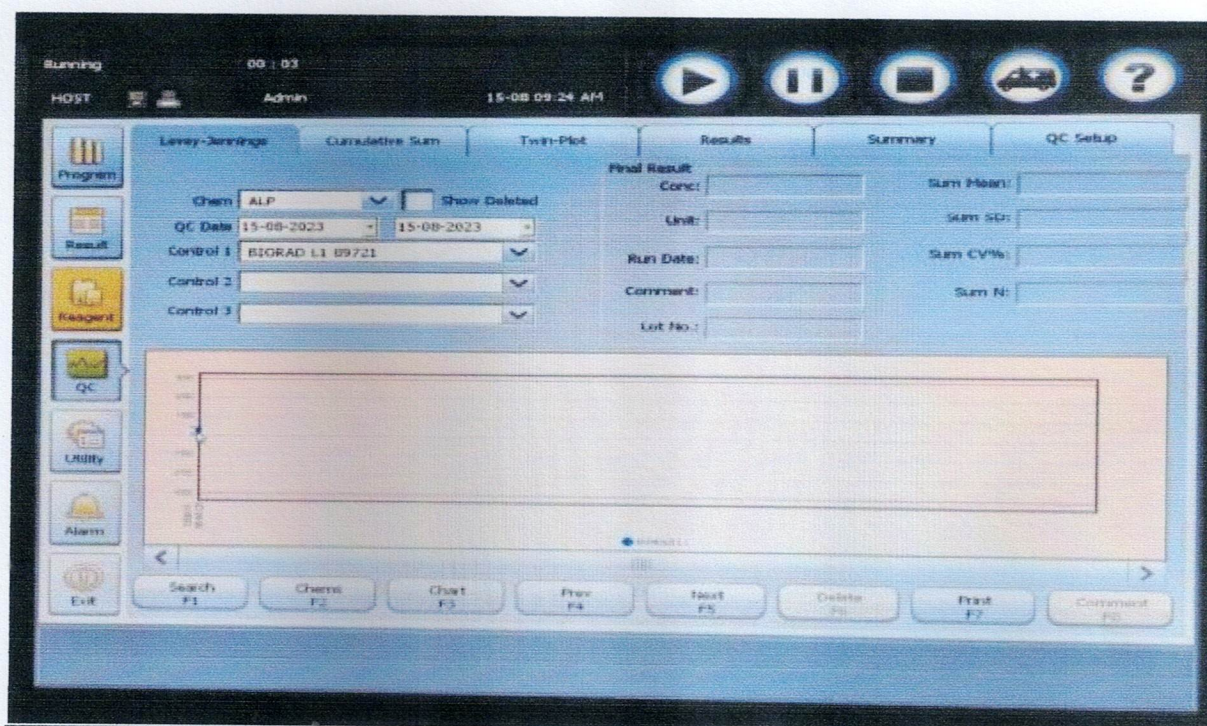












REPEATABILITY TEST VALUES



MEDICARE DIAGNOSTIC LABORATORY KONNI

REPEATABILITY TEST VALUES FOR GLUCOSE

NAME	TEST VALUE
ROJIN 28/M	92.0
ROJIN 28/M	91.0
ROJIN 28/M	92.0
ROJIN 28/M	91.8
ROJIN 28/M	92.01
ROJIN 28/M	92.0
ROJIN 28/M	92
ROJIN 28/M	91.8
ROJIN 28/M	92
ROJIN 28/M	92

REPEATABILITY TEST VALUES FOR CHOLESTEROL

NAME	TEST VALUE
ROJIN 28/M	173.3
ROJIN 28/M	173.2
ROJIN 28/M	173.2
ROJIN 28/M	173.6
ROJIN 28/M	173.3
ROJIN 28/M	173.2
ROJIN 28/M	173.4
ROJIN 28/M	173.1
ROJIN 28/M	173.0
ROJIN 28/M	173.3



MEDICARE DIAGNOSTIC LABORATORY KONNI

REPEATABILITY TEST VALUES FOR TRIGLYCERIDE

NAME	TEST VALUE
ROJIN 28/M	182.4
ROJIN 28/M	182.3
ROJIN 28/M	182.4
ROJIN 28/M	182.4
ROJIN 28/M	182.2
ROJIN 28/M	182.3
ROJIN 28/M	182.4
ROJIN 28/M	182.4
ROJIN 28/M	182.3
ROJIN 28/M	182.3

REPEATABILITY TEST VALUES FOR HDL

NAME	TEST VALUE
ROJIN 28/M	43.2
ROJIN 28/M	43.2
ROJIN 28/M	43.3
ROJIN 28/M	43.2
ROJIN 28/M	43.1
ROJIN 28/M	43.2
ROJIN 28/M	43.1
ROJIN 28/M	43.3
ROJIN 28/M	43.2
ROJIN 28/M	43.1



MEDICARE DIAGNOSTIC LABORATORY KONNI

REPEATABILITY TEST VALUES FOR LDL

NAME	TEST VALUE
ROJIN 28/M	118.2
ROJIN 28/M	118.4
ROJIN 28/M	118.3
ROJIN 28/M	118.2
ROJIN 28/M	118.4
ROJIN 28/M	118.2
ROJIN 28/M	118.3
ROJIN 28/M	118.2
ROJIN 28/M	118.3
ROJIN 28/M	118.2

REPEATABILITY TEST VALUES FOR T BILIRUBIN

NAME	TEST VALUE
ROJIN 28/M	1.16
ROJIN 28/M	1.18
ROJIN 28/M	1.15
ROJIN 28/M	1.16
ROJIN 28/M	1.15
ROJIN 28/M	1.18
ROJIN 28/M	1.17
ROJIN 28/M	1.18
ROJIN 28/M	1.16
ROJIN 28/M	1.17



MEDICARE DIAGNOSTIC LABORATORY KONNI

REPEATABILITY TEST VALUES FOR D BILIRUBIN

NAME	TEST VALUE
ROJIN 28/M	0.30
ROJIN 28/M	0.30
ROJIN 28/M	0.30
ROJIN 28/M	0.30
ROJIN 28/M	0.03
ROJIN 28/M	0.03
ROJIN 28/M	0.03
ROJIN 28/M	0.03
ROJIN 28/M	0.3
ROJIN 28/M	0.03
ROJIN 28/M	0.03

REPEATABILITY TEST VALUES FOR AST

NAME	TEST VALUE
ROJIN 28/M	38.1
ROJIN 28/M	38.2
ROJIN 28/M	38.1
ROJIN 28/M	37.9
ROJIN 28/M	38.2
ROJIN 28/M	38.1
ROJIN 28/M	38.2
ROJIN 28/M	38.1
ROJIN 28/M	38.3
ROJIN 28/M	38.1





MEDICARE DIAGNOSTIC LABORATORY KONNI

REPEATABILITY TEST VALUES FOR ALT

NAME	TEST VALUE
ROJIN 28/M	28.8
ROJIN 28/M	28.7
ROJIN 28/M	28.7
ROJIN 28/M	28.7
ROJIN 28/M	28.8
ROJIN 28/M	28.7
ROJIN 28/M	28.8
ROJIN 28/M	28.7
ROJIN 28/M	28.6
ROJIN 28/M	28.8

REPEATABILITY TEST VALUES FOR ALP

NAME	TEST VALUE
ROJIN 28/M	75.0
ROJIN 28/M	75.1
ROJIN 28/M	75.2
ROJIN 28/M	75.0
ROJIN 28/M	75.0
ROJIN 28/M	75.1
ROJIN 28/M	75.1
ROJIN 28/M	75.0
ROJIN 28/M	75.1
ROJIN 28/M	75.1
ROJIN 28/M	75.0
ROJIN 28/M	75.1
ROJIN 28/M	75.1



MEDICARE DIAGNOSTIC LABORATORY KONNI

REPEATABILITY TEST VALUES FOR TOTAL PROTEIN

NAME	TEST VALUE
ROJIN 28/M	7.7
ROJIN 28/M	7.7
ROJIN 28/M	7.6
ROJIN 28/M	7.7
ROJIN 28/M	7.6
ROJIN 28/M	7.7
ROJIN 28/M	7.7
ROJIN 28/M	7.6
ROJIN 28/M	7.6
ROJIN 28/M	7.6

REPEATABILITY TEST VALUES FOR ALBUMIN

NAME	TEST VALUE
ROJIN 28/M	5.1
ROJIN 28/M	5.1
ROJIN 28/M	5.2
ROJIN 28/M	5.1
ROJIN 28/M	5.1
ROJIN 28/M	5.1
ROJIN 28/M	5.1
ROJIN 28/M	5.2
ROJIN 28/M	5.1
ROJIN 28/M	5.2



MEDICARE DIAGNOSTIC LABORATORY KONNI

REPEATABILITY TEST VALUES FOR UREA

NAME	TEST VALUE
ROJIN 28/M	27.02
ROJIN 28/M	27.03
ROJIN 28/M	27.01
ROJIN 28/M	27.02
ROJIN 28/M	27.01
ROJIN 28/M	27.02
ROJIN 28/M	27.03
ROJIN 28/M	27.01
ROJIN 28/M	27.02
ROJIN 28/M	27.01

REPEATABILITY TEST VALUES FOR CREATININE

NAME	TEST VALUE
ROJIN 28/M	
ROJIN 28/M	0.91
ROJIN 28/M	0.92
ROJIN 28/M	0.91
ROJIN 28/M	0.93
ROJIN 28/M	0.91
ROJIN 28/M	0.91
ROJIN 28/M	0.91
ROJIN 28/M	0.91
ROJIN 28/M	0.92
ROJIN 28/M	0.91



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REPEATABILITY TEST VALUES FOR URIC ACID

NAME	TEST VALUE
ROJIN 28/M	4.11
ROJIN 28/M	4.12
ROJIN 28/M	4.11
ROJIN 28/M	4.11
ROJIN 28/M	4.11
ROJIN 28/M	4.11
ROJIN 28/M	4.11
ROJIN 28/M	4.11
ROJIN 28/M	4.12
ROJIN 28/M	4.11
ROJIN 28/M	4.11

REPEATABILITY TEST VALUES FOR CALCIUM

NAME	TEST VALUE
ROJIN 28/M	10.55
ROJIN 28/M	10.55
ROJIN 28/M	10.53
ROJIN 28/M	10.54
ROJIN 28/M	10.55
ROJIN 28/M	10.54
ROJIN 28/M	10.55
ROJIN 28/M	10.54
ROJIN 28/M	10.55
ROJIN 28/M	10.53
ROJIN 28/M	10.54
ROJIN 28/M	10.55



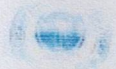
MEDICARE DIAGNOSTIC LABORATORY KONNI

REPEATABILITY TEST VALUES FOR CRP

NAME	TEST VALUE
ROJIN 28/M	1.7
ROJIN 28/M	1.71
ROJIN 28/M	1.62
ROJIN 28/M	1.73
ROJIN 28/M	1.7
ROJIN 28/M	1.6
ROJIN 28/M	1.7
ROJIN 28/M	1.7
ROJIN 28/M	1.68
ROJIN 28/M	1.72

REPEATABILITY TEST VALUES FOR GGT

NAME	TEST VALUE
ROJIN 28/M	37.7
ROJIN 28/M	37.6
ROJIN 28/M	37.4
ROJIN 28/M	37.7
ROJIN 28/M	37.7
ROJIN 28/M	37.4
ROJIN 28/M	37.6
ROJIN 28/M	37.4
ROJIN 28/M	37.6
ROJIN 28/M	37.7



Performance Qualification:

PERFORMANCE QUALIFICATION

SYSTEM CERTIFICATION:

Study data has determined that the system described in this document meets all criteria outlined in this Performance Qualification protocol, 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: **MINDRAY REPRESENTATIVE**

Name: AJAY P.S

Title: PERFORMANCE QUALIFICATION

Company: SIVA MEDICAL SERVICES

Customer Authorization:

Name: MEDICARE LABORATORY

Title: PERFORMANCE QUALIFICATION


Service Engineer
Siva Medical Services
Thycaud, Tiruvananthapuram

AUTHORIZED ENGINEER SIGNATURE

DATE:20-07-2023 DATE:20-07-2023


CUSTOMER SIGNATURE

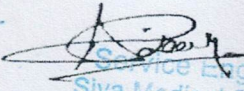



PERFORMANCE QUALIFICATION VERIFICATION REPORT

This is to certify that the following checks mentioned in the performance verification protocol have been performed and found to be satisfactory.

PERFORMANCE VERIFICATION PROTOCOL	REMARKS
1] CALIBRATION	PASS
2] PRECISION CHECK	PASS
3] CARRYOVER (OPTIONAL)	PASS
4] LINEARITY CHECK (OPTIONAL)	PASS
5] SAMPLE COMPARISON	PASS

NOTE: FOR ABOVE MENTIONED PERFORMANCE VERIFICATION PROTOCOLS, INSTRUMENT RAW DATA PRINTOUTS & SUPPORTING DOCUMENTS NEED TO BE ATTACHED WITH THIS MANUAL

AJAY P.S  Service Engineer Siva Medical Services Thycaud, Thiruvananthapuram ENGINEER NAME & SIGNATURE/DATE	MEDICRE LABORATORY  CUSTOMER NAME & SIGNATURE/DATE
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