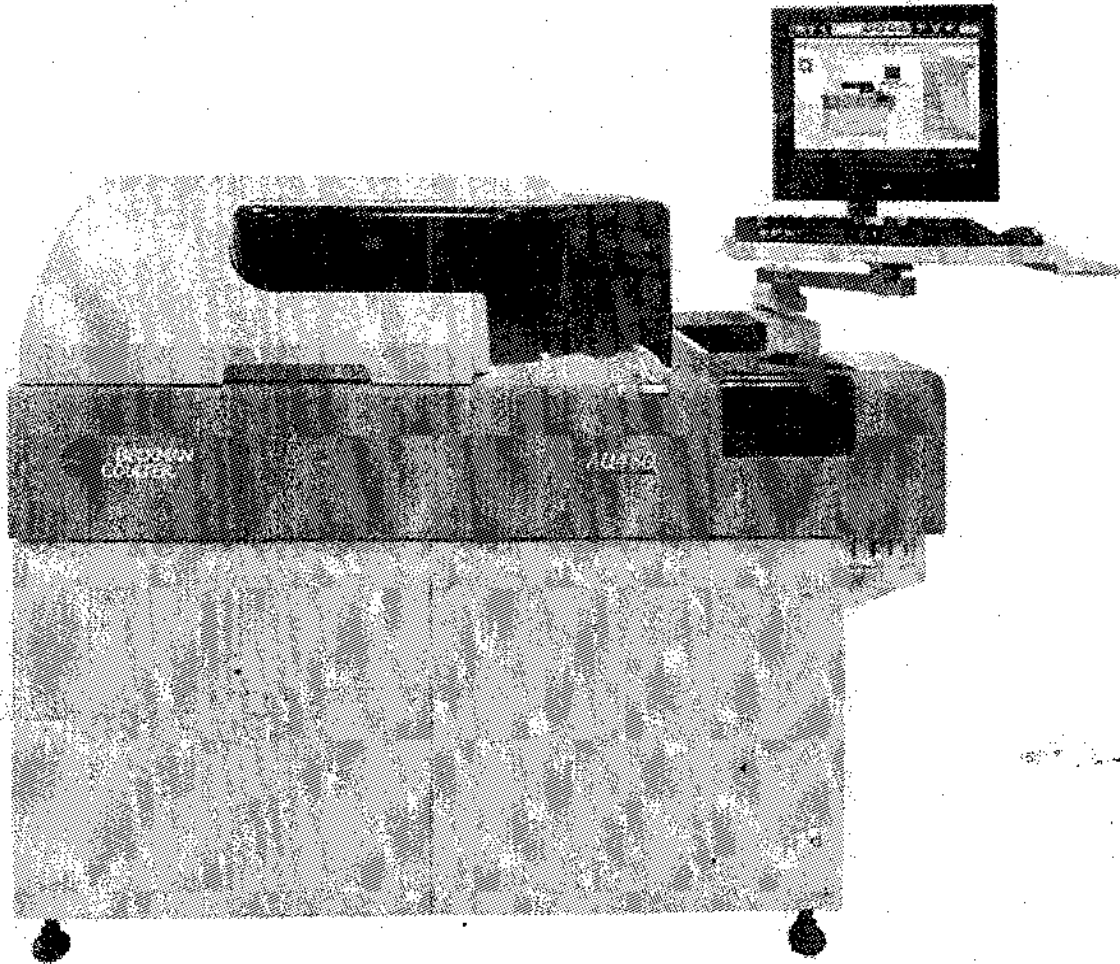


# AU 480

Installation / Operation/Performance Qualification

---



**MPUH Hospital Nadiad**

**Installation Qualification  
Operation Qualification  
Performance Qualification**

# AU 480

## Installation / Operation/Performance Qualification

---

The AU480 Clinical Chemistry System is a fully automated, computer-controlled clinical chemistry analyzer designed for the in vitro determination of a variety of general chemistries, electrolytes, proteins, therapeutic drugs, drugs of abuse and other chemistries.

With a throughput of 400 photometric tests per hour (up to 800 with electrolytes) and an on board capacity of 63 different analytes the AU480 Chemistry System is the ideal main analyzer for small to medium sized laboratories. As part of the AU family, the AU480 Chemistry System can also fit as a special chemistry or STAT analyzer in large laboratories as well.

The AU480 Chemistry System offers a maximum flexibility and workload efficiency, ease of operation, ease of sample management with integrated bar code reading, primary tube sampling, continuous sample loading, easy reagent handling, proven reliability with low maintenance and advanced data management and bi-directional Host Query interfacing.

The AU480 Chemistry System provides the ultimate opportunity for workstation consolidation. It can work as an autonomous workstation or together with the Beckman REMISOL Advance System data management or a Laboratory Information system and other AU systems.

# AU 480

## Installation / Operation/Performance Qualification

---

### FEATURES

#### Chemistry Menu Capacity:

- Full menu capability (general chemistry, proteins, electrolytes, TDM, DAT, proteins/serology's, urine chemistries and CSF chemistries)
- Bar coded Beckman Coulter reagents for more than 120 chemistries

#### System Configuration Capacity:

- Up to 120 chemistry reagents may be configured at any given time
- Up to 120 UDR (User Defined Reagents) may be defined at any given time.

#### On-Board Chemistry Capacity:

- Total of 63 chemistries
- Up to 60 photometric tests
- ISE, 3 single electrodes (Sodium, Potassium, Chloride).

Throughput: Maximum 800 tests/hour (400 photometric and 400 ISE tests/hour).

#### STATS interrupt capability:

- A refrigerated 22 sample turntable can be used for immediately STAT process. Additional priority sample racks can be loaded continuously.

#### Sample Handling Features:

- Sample Flexibility: 10 samples/rack.  
Intermix of Sample Containers (PTS, micro tubes, cups, microtainer) and sample tubes size ( length inner diameter 55 to 102 mm; Outer diameter 9 to 15 mm; Maximum diameter of the brim of a sample tube 11.5 to 16 mm less than 17.5 mm) on racks
- Built In Sample Bar Code reader  
Auto discrimination of the following symbologies:  
Code 39 (Code 3 of 9 or SD-3)  
Code 128 (USD-6)  
Interleaved 2 of 5 (USD-1)  
Standard 2 to 5  
JAN
- Sample Rack Load Capability of 80 samples at one time with continuous sample, plus 22 samples in the STAT turntable.
- Sample Security  
Micro Sampling (down to 1ul) with Level Sensing Detection. Ideal for pediatric and geriatric sample  
Automatic Sample Clot and Crash Detection  
Serum Indices Capability (Test Specific)

#### Reagent and Calibration Handling Features:

# AU 480

## Installation / Operation/Performance Qualification

---

- Bar Coded Liquid Ready to Use Reagents for more then 120 Chemistries
- Various kit size availability to fulfill workload requirement
- Real Time Reagent Tracking Management
- More then 30 days On Board Stability for most chemistries.
- Long Calibration Stability with single lot calibration for most Chemistries
- On board Calibrators & QC capability on the STAT turntable with programmable auto calibration and auto QC capability
- Advanced Calibration (up to 5 reagent kit can be calibrated in advanced)

### Data Management Features:

- Efficient Data handling with real time sample completion notification.
- Easy Results Review.
- Absorbance versus Time Plot for all results.
- Customized special Calculations.
- Automatic rerun capability for critical results.
- Automatic rerun with sample volume increase-, decrease and sample pre dilution functions.
- Programmable sample dilution at the first run
- Reflex capability
- Full QC package.

### Software & Service

- Ease of use with colored alerts, keyboard, mouse, touch screen, bar code reader, and LIS data entry.
- Full bidirectional and host query LJS communications.
- Minimal automated maintenance & easy components replacements (no tools needed).
- On line maintenance log and operating manual and procedures and videos.

**Facility: Muljibhai Patel Urology Hospital**

**Location: MPUH hospital Dr. Virendra Desai road Nadiad**

# AU 480

## Installation / Operation/Performance Qualification

---

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**Facility: Igenetic Diagnostic Pvt Ltd.**

**Location:** 1st Floor, Krislon House, Krishanlal Marwah Marg, Ganesh Nagar, Marol, Andheri East, Mumbai, Maharashtra 400072.

# AU 480

## Installation / Operation/Performance Qualification

---

### Table of contents

#### 1. Installation Qualification (IQ)

1.1. <u>Pre-site Installation and Installation checklist</u>	5
1.2. <u>System Components</u>	6
1.3. <u>System Initialization check list</u>	9

#### 2. Operation Qualification (OQ)

2.1. <u>Mechanism Movement Check</u>	12
2.2. <u>Routine Operator Training</u>	15
2.3. <u>Maintenance schedules</u>	15
2.4. <u>Approval For Customer Evaluation</u>	16
2.5. <u>Approval for Routine Operation</u>	17

#### 3. Performance Qualification (PQ)

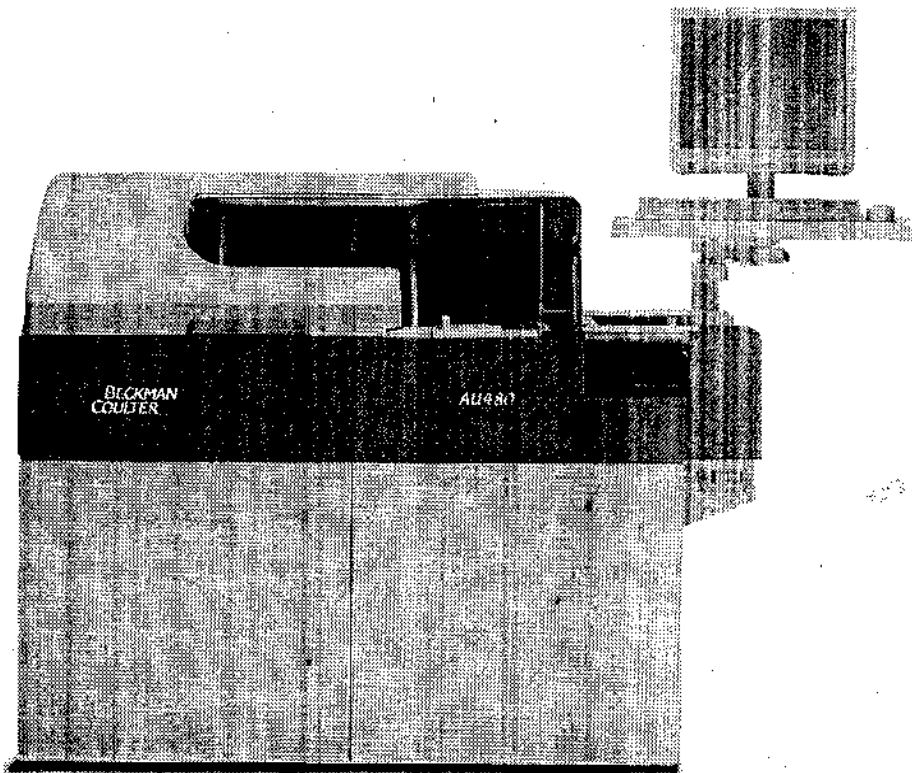
3.1. <u>Performance assay run</u>	19
3.2. <u>Approval certification</u>	20

# AU 480

Installation / Operation/Performance Qualification

---

## 1.0 INSTALLATION QUALIFICATIONS



# AU 480

## Installation / Operation/Performance Qualification

---

### 1.1. Pre-site Installation and Installation Checklist

#### A) ENVIRONMENTAL REQUIREMENT

##### 1. Installation Environment Conditions

- Place should not be subjected to direct sunlight
- Place should be flat and minimum of dust.

##### 2. Power And Noise Conditions

- The place for instrument should be less than 10 m away from the drainage hoses.
- The power supply for the instrument should be nearer to the instrument (less than 10m)
- The switchboard connector should be 30A industrial type connector.
- The power supply should be from a 10Kva online UPS

##### 3. Temperature And Humidity Conditions

- The temperature of the analyzer room should be between 18- 27 C
- The temperature fluctuation during the analysis should be +\_2 C

##### 4. Water Supply And Drainage Conditions

- Inner diameter of the drainage hose should be greater than 48mm
- The purity of the DI water must under a conductivity of 2  $\mu$ s/cm or less.
- The height of the drainage system should be below the lower level of the analyzer.
- Average amount of water required: 20L/hr (with full load).

##### 5. Dimensions Of System Main Units (Unit: mm)

- Analyzer Width 1450 x Depth 760 x Height 1205

##### 6. Power Supply

- Voltage 230/50 Hz (India)
- Power 3.5 KVA



# AU 480

## Installation / Operation/Performance Qualification

---

### B)SYSTEM ENVIRONMENT CONDITIONS

		REMARKS
1. POWER SUPPLY	:	230/50 Hz AS PER REQUIREMENTS
2. UPS	:	AVAILABLE
3. DRAINAGE WITHIN 5 M	:	AS PER REQUIREMENTS
4. WATER CONDUCTIVITY	:	AS PER REQUIREMENTS
5. RESISTIVITY	:	AS PER REQUIREMENTS
6. BACTERIA FILTER	:	AVAILABLE
7. DEIONIZER	:	AVILABLE
8. ANALYSER SPACE AVILABILITY	:	AS PER REQUIREMENTS
9. DETERGENT	:	AVAILABLE

### 1.2 SYSTEM COMPONENTS

A)Instrument Model: AU 480

S/N: 2018122392

B)Software:

AU 480:

Revision : 1.91

# AU 480

## Installation / Operation/Performance Qualification

---

### C)Analyzer PC Qualification:

MAKER :Lenovo

COM PORTS AVILABLE :YES

ONLINE POSSIBLE :YES

PROCESSOR SPEED :1GHz

STORAGE CAPACITY :20 Gb

MONITOR :15"INCH

MAKER :Lenovo

TOUCH SCREEN FACILITY : AVAILABLE

OPERATING SYSTEM :WINDOWS 7

SOFTWARE CD :AVAILABLE

PRINTER PORT :AVAILABLE

PRINTER : AVAILABLE

MAKER :HP

MODEL :1020

Comments:

# AU 480

## Installation / Operation/Performance Qualification

### 1.3. System Initialization check list

- Check level of Water.
- Click on AU 480 s/w, verify for all fields, should be in green.
- Prepare all required reagents and controls according to the package insert.
- Select parameter to be calibrated.
- Verify curve.
- Run QC's.

THIS IS TO CERTIFY THAT THE INSTALLATION SPACE IS MEETING ALL THE ABOVE MENTIONED REQUIREMENT FOR OPERATING THE AU480 FULLY AUTOMATED BIOCHEMISTRY ANALYZER IN THE CUSTOMER PLACE.

Date: 28/03/2022

Engineer Signature: Anil

Engineer Printed Name: Anil Mayani

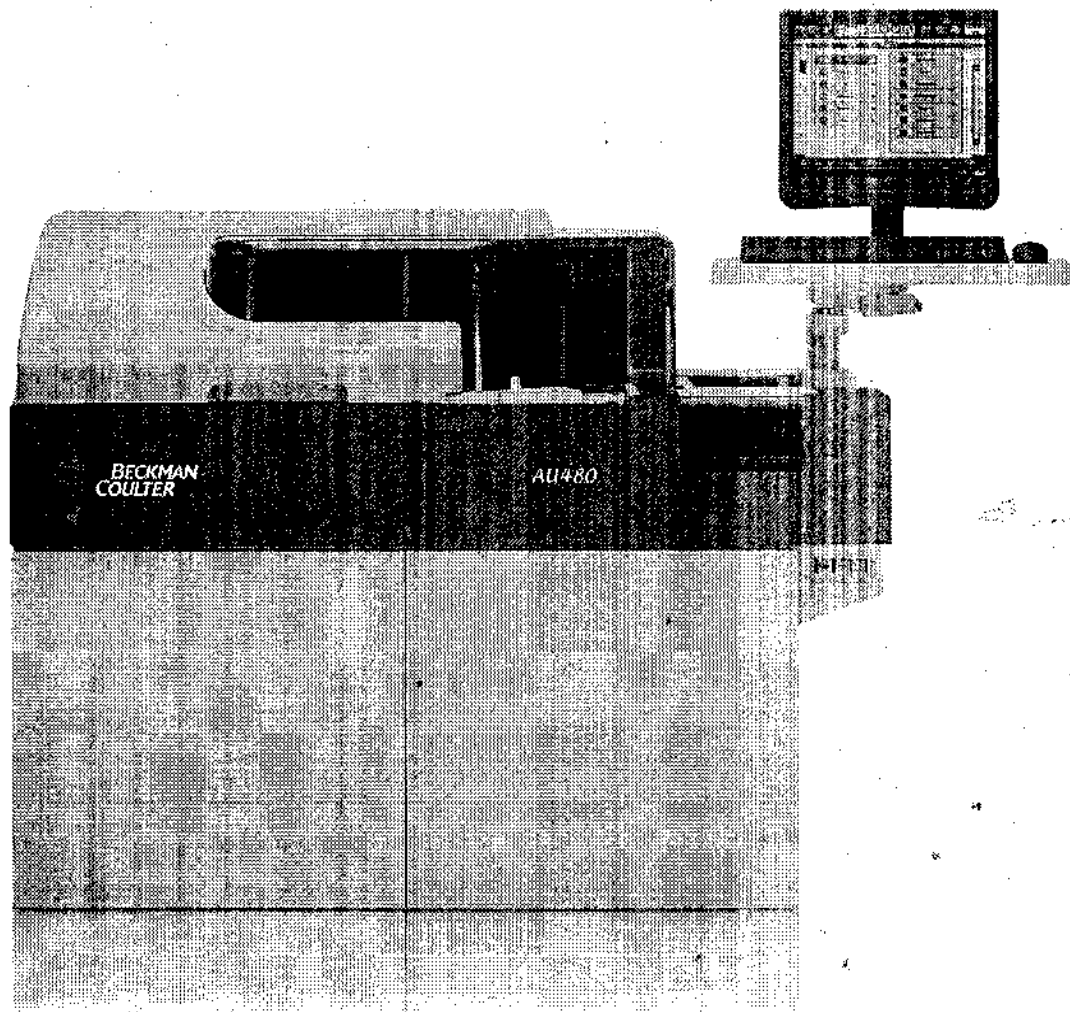
INSTALLATION COMPLETED SUCESSFULLY. INSTALLATION QUALIFICATION PASSED.

# AU 480

Installation / Operation/Performance Qualification

---

## 2.0 OPERATION QUALIFICATIONS



# AU 480

## Installation / Operation/Performance Qualification

---

### SYSTEM INFORMATION

SERIAL NO : 2018122392  
AU SOFTWARE VERSION : 1.91  
OS VERSION : WINDOWS 7

### 2.1 MECHANISM MOVEMENT CHECK

#### RACK MOVEMENT CHECK

#### REMARK

- |  |    |
|--|----|
| <input type="checkbox"/> SAMPLE FEEDER MOVEMENT              | OK |
| <input type="checkbox"/> SAMPLE RACK DETECTOR                | OK |
| <input type="checkbox"/> SAMPLE BARCODE DETECTOR             | OK |
| <input type="checkbox"/> SAMPLE BARCODE CLAW FEED UNIT       | OK |
| <input type="checkbox"/> SAMPLE CUP DETECTOR                 | OK |
| <input type="checkbox"/> SAMPLE POSITION CLAW FEEDER         | OK |
| <input type="checkbox"/> SAMPLE RECEIVER (AFTER MEASUREMENT) | OK |
| <input type="checkbox"/> RACK RECEIVER FULL DETECTOR         | OK |
| <input type="checkbox"/> REPEAT RUN RECEIVER                 | OK |

#### STAT TABLE UNIT

- |   |    |
|---|----|
| <input type="checkbox"/> SAMPLE CUP SENSOR          | OK |
| <input type="checkbox"/> STAT SAMPLE BARCODE READER | OK |
| <input type="checkbox"/> STAT SAMPLE ROTATION       | OK |

#### REAGENT COMPARTMENT

- |   |      |
|---|------|
| <input type="checkbox"/> BOTTLE SENSOR          | GOOD |
| <input type="checkbox"/> REAGENT BARCODE READER | GOOD |
| <input type="checkbox"/> REAGENT ROTATION       | OK   |

# AU 480

## Installation / Operation/Performance Qualification

---

### REACTION CUVETTE UNIT

- |  |                          |
|--|--------------------------|
| <input type="checkbox"/> CUVETTE CONDITION | GOOD(attached photocal)  |
| <input type="checkbox"/> CUVETTE ROTATION  | GOOD                     |
| <input type="checkbox"/> LAMP              | GOOD                     |
| <input type="checkbox"/> BATH TEMPARATURE  | OK                       |
| <input type="checkbox"/> CUVETTE WASHING   | GOOD (attached photocal) |
| <input type="checkbox"/> CUVETTE OVERFLOW  | NOT HAPPENING            |

### REAGENT PROBE MECHANISM

- |  |    |
|--|----|
| <input type="checkbox"/> WASH POT ALIGNMENT                  | OK |
| <input type="checkbox"/> REAGENT ASPIRATION POSITION (INNER) | OK |
| <input type="checkbox"/> REAGENT ASPIRATION POSITION (OUTER) | OK |
| <input type="checkbox"/> PRE DILUTION BOTTLE ASPIRATION POSI | OK |
| <input type="checkbox"/> CUVETTE DISPENSE POSITION           | OK |
| <input type="checkbox"/> PROBE WAHING                        | OK |
| <input type="checkbox"/> PROBE LIQUID LEVEL DETECTION        | OK |

### SAMPLE PROBE MECHANISM

- |   |      |
|---|------|
| <input type="checkbox"/> WASH POT ALIGNMENT             | OK   |
| <input type="checkbox"/> SAMPLE ASPIRATION POSITION     | OK   |
| <input type="checkbox"/> STAT ASPIRATION POSITION       | OK   |
| <input type="checkbox"/> ISE DISPENSING POSITION        | NA   |
| <input type="checkbox"/> CUVETTE DISPENSE POSITION      | OK   |
| <input type="checkbox"/> PRE DILUTION DISPENSE POSITION | OK   |
| <input type="checkbox"/> PROBE WASH                     | OK   |
| <input type="checkbox"/> SAMPLE LEVEL DETECTION         | OK   |
| <input type="checkbox"/> SAMPLE CLOT DETECTION          | GOOD |

### WATER AND DETERGENT TANK

- |  |    |
|--|----|
| <input type="checkbox"/> WATER LEVEL SENSORS     | OK |
| <input type="checkbox"/> DETERGENT LEVEL SENSORS | OK |
| <input type="checkbox"/> WATER FILTERS           | OK |

# AU 480

## Installation / Operation/Performance Qualification

### SYRINGE CONDITION

- |   |    |
|---|----|
| <input type="checkbox"/> SAMPLE SYRINGE MOVEMENT  | OK |
| <input type="checkbox"/> SAMPLE SYRINGE LEAK      | NO |
| <input type="checkbox"/> REAGENT SYRINGE MOVEMENT | OK |
| <input type="checkbox"/> REAGENT SYRINGE LEAK     | NO |
| <input type="checkbox"/> ISE SYRINGE MOVEMENT     | OK |
| <input type="checkbox"/> ISE SYRINGE LEAK         | NO |

Date: 28/03/2022

Signature: *Amil*

Comments:

ALL MECHANICAL ALIGNMENTS ARE OK.

# AU 480

## Installation / Operation/Performance Qualification

### 2.2 Routine Operator Training:

- a) Operator Training Manual                      SOFT COPY GIVEN
- b) Operator Training certificates              Provided
- c) AU 480 training checklist                      NA

### 2.3 Maintenance Schedules:

- a) Daily Maintenance ✓
- b) Weekly Maintenance ✓
- c) Monthly Maintenance ✓
- d) Six monthly Maintenance ✓
- e) Service eng PM checklist ✓

Date: 28/03/2022

Signature: Amal

Comments:



# AU 480

## Installation / Operation/Performance Qualification

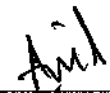
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### 2.4 Approval for Customer Evaluation

After the satisfactory system initialization, the AU 480 system can be approved for customer evaluation.

System Released for evaluation      N/A       Complete

Date: 28/03/2022

Signature:   
Beckman Coulter Representative

Date: 28/3/2022

Signature:   
Facility Representative

Comments:

# AU 480

## Installation / Operation/Performance Qualification

---

### 2.5 Approval for Routine Operation

According to the test results that are comprised in this document the AU 480 system can be approved for routine operation.

System Released for Routine Operation

N/A

Complete

Date: 28/03/2022

Signature: *Amil*  
Beckman Coulter Representative

Date: 28/3/2022

Signature: *[Signature]*  
Facility Representative

Comments:

Maintenance

Consumption

Photocal Monitor

Photocal Measurement: 03/09/2022 11:47

W2 Execution: 03/09/2022 11:24

1	2	3	4	5	6	7	8	9	10	11
12	13	14	15	16	17	18	19	20	21	22
23	24	25	26	27	28	29	30	31	32	33
34	35	36	37	38	39	40	41	42	43	44
45	46	47	48	49	50	51	52	53	54	55
56	57	58	59	60	61	62	63	64	65	66
67	68	69	70	71	72	73	74	75	76	77
78	79	80	81	82	83	84	85	86	87	88

Expand/Check Error

Detail

Print



MEASURE 2



03/09/2022

16:44

Routine

Data Monitor

Reaction Monitor

Data Statistics

Correlation Chart

Main

Statistics

Chart View

Data View

Histogram

lex: 03/09/2022 10:59

03/09/2022 10:59

Sample Kind	Type	Range of Sample No.	Sample ID	Num of Samples
Routine	Serum	0001 0022		
Sex	Age			
(M)	0	0	150	11

Test Name	Num of Data	Mean	SD	CV(%)	Range	Max	Min
73.97.DM							
74.55.DM							
75.W340	22	-2.1	1.39	-65.08	6	1	-5
76.W380	22	-2.4	1.40	-58.22	6	1	-5
77.W600	22	2.1	1.11	53.03	4	4	0
78.W480	22	0.7	0.65	94.80	2	2	0

Sorting List

Print

Routine

Data Monitor

Reaction Monitor | **Data Statistics** | Correlation Chart

Main | **Statistics** | Chart View | Data View | Histogram

Index: 03/09/2022 10:59      03/09/2022 10:59

Sample Kind	Type	Range of Sample No.	Sample ID	Num of Samples
Root/Line	Serum	0022 - 0044 *		
	Age			
(All)	0	0	150	11

Test Name	Num of Data	Mean	SD	CV(%)	Range	Max	Min
75.W340	23	-2.3	1.36	-59.96	5	0	-5
76.W380	23	-4.2	1.24	-29.44	5	-2	-7
77.W600	23	2.6	0.72	27.69	3	4	1
78.W480	23	-0.3	0.86	-33.32	4	2	-2

Sorting List

Print

Routine

Data Monitor

Reaction Monitor | **Data Statistics** | Correlation Chart

Main

Statistics

Chart View

Data View

Histogram

Index: 03/09/2022 10:59

03/09/2022 10:59

Sample Ord	Type	Range of Sample No.	Sample ID
1	0	150	11

Test Name	Num of Data	Mean	SD	CV(%)	Range	Max	Min
75.W340	22	-2.0	1.40	-49.75	6	0	-6
76.W380	22	-4.2	1.37	-26.39	4	3	-7
77.W600	22	7.8	1.92	24.54	6	11	5
78.W180	22	0.6	0.49	77.37	1	1	0

Export List

Print

Print | [Icons]

MEASURE 1

03/09/2022

18:09

Routine

Data Monitor

Reaction Monitor

Data Statistics

Correlation Chart

Main

Statistics

Chart View

Data View

Histogram

Index 03/09/2022 10:59

03/09/2022 10:59

Sample kind	Type	Range of Sample No.		Sample ID	Num of Samples
Routine	Genam	0001	0088		88
Sex	AGE				
(All)	0	0	150	11	

Test Name	Num of Data	Mean	SD	CY(%)	Range	Max	Min
73.B2.Del							
74.B5.Del							
75.W340	88	-2.5	1.36	-54.49	7	1	-6
76.W380	88	-4.2	1.68	-40.88	8	1	-7
77.W600	88	4.1	3.06	74.66	13	13	0
78.W480	87	0.2	0.79	328.87	1	2	-2

Sorting List

Print

MEASURE 2

03/09/2022  
16:43



Routine

Data Monitor

Reaction Monitor    Data Statistics    Correlation Chart

Main

Statistics

Chart View

Data View

Histogram

03/09/2022 10:59

03/09/2022 10:59

Sample Kind	Type	Range of Sample No.		Sample ID
Routine	Serum	0089	0160	
Sex	Age			
(All)	U	U	150	11

Test Name	Num of Data	Mean	SD	CV(%)	Range	Max
71.R150	80	8780.6	35.10	0.40	160	8853
72.S104						8693

Sorting List

Print



**Routine** **Data Monitor**

Reaction Monitor **Data Statistics** Correlation Chart

Main **Statistics** Chart View Data View Histogram

Index 03/09/2022 10:59 03/09/2022 10:59

Sample Kind	Type	Range of Sample No.	Sample ID	Num of Samples
Routine	Serum	0169 0248		80
(All)	Age	150	11	

Test Name	Num of Data	Mean	SD	CV(%)	Range	Max	Min
71.R150							
72.S1.0ml	80	9303,5	70.65	0.76	338	9473	9135

Sorting List

Print







MEASURE 2

03/09/2022

19:36

Routine

Data Monitor

Reaction Monitor

Data Statistics

Correlation Chart

Main

Statistics

Chart View

Data View

Histogram

Index 03/09/2022 10:59

03/09/2022 10:59

Sample Kind	Type	Range of Sample No.	Sample ID	Num of Samples
Routine	Serum	0249 - 0328		80
Sex	Age			
(All)	0	0 - 150	11	

Test Name	Num of Data	Mean	SD	CV(%)	Range	Max	Min
73.S2.0ul	88	5200.2	20.55	0.40	97	5241	5144
74.S5.0ul	88	12470.8	41.63	0.33	188	12561	12373
75.W340							
76.W380							
77.W600							
78.W480							

Sorting List

Print



MEASURE 2



03/09/2022  
19:34

Routine

Data Monitor

Reaction Monitor

Data Statistics

Correlation Chart

Main

Statistics

Chart View

Data View

Histogram

Index 03/09/2022 10:59

03/09/2022 10:59

Sample Kind	Type	Range of Sample No.		Sample ID	Num of Samples
Routine	Serum	0329	0368		40
Sex	Age				
(All)	0	0	150	11	

Test Name	Num of Data	Mean	SD	CV(%)	Range	Max	Min
97.Na	40	140.01	0.427	0.30	2.0	140.0	138.8
98.K	40	4.165	0.0124	0.30	0.06	4.19	4.13
99.Cl	40	109.4	0.54	0.49	2	110	108

Sorting List

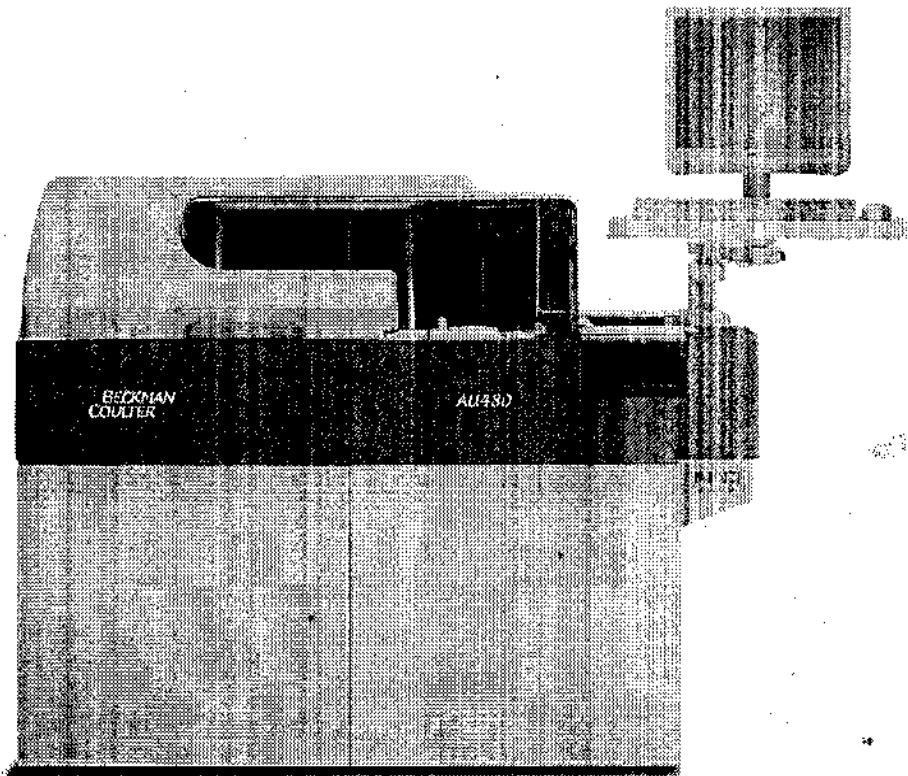
Print

# AU 480

Installation / Operation/Performance Qualification

---

## 3.0 PERFORMANCE QUALIFICATION (PQ)



# AU 480

## Installation / Operation/Performance Qualification

---

### 3.1 Performance assay run

#### PQ Instructions

PQ is performed as needed. Please complete each PQ section and attach any documents that are requested to be completed.

1. Calibration report ✓
2. QC report ✓
3. Precision report ✓
4. Others if any NA

Date: 28/03/2022

Signature: 

Comments:

# AU 480

## Installation / Operation/Performance Qualification

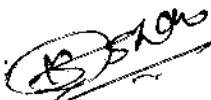
### 3.2 Approval certification

According to the assay results that are comprised in this document the AU 480 system can be approved for routine operation.

System Released for routine operation.      N/A       Complete

#### Beckman Coulter Representatives:

Date: 28/03/2022

Application Specialist Signature: 

Application Specialist Name : Kamlesh Shah

#### Facility Representative:

Date: 28/3/2022

Signature: 

Name: Dr. Amit Tojara

Comments:



## PRECISION STUDY

AU480 with ISE

Instrument Serial no. 2021124539

Sr. No.	Parameters							
	ALB	CALCIUM	ALT	GLUCOSE	CRE	Potass(um(K)	Sodium(NA)	PHOS
1	3.88	9.27	25.08	105.71	0.91	3.94	136.01	2.59
2	3.85	9.05	25.49	104.53	0.92	3.94	136.45	2.54
3	3.88	9.04	25.57	104.29	0.90	3.93	135.93	2.56
4	3.85	9.21	25.22	104.41	0.92	3.92	135.62	2.55
5	3.85	9.21	25.06	103.7	0.91	3.92	135.84	2.6
6	3.86	9.13	25.68	104.05	0.90	3.94	136.41	2.57
7	3.86	9.06	25.06	103.29	0.92	3.93	136.15	2.58
8	3.8	9.15	25.59	102.14	0.91	3.91	135.53	2.54
9	4.08	9.11	25	102.6	0.89	3.89	134.75	2.56
Mean	3.88	9.14	25.31	103.86	0.91	3.92	135.85	2.57
SD	0.08	0.08	0.27	1.08	0.01	0.02	0.52	0.02
CV	2.04	0.88	1.08	1.04	1.16	0.42	0.38	0.83
ACCEPTED CV%	<5	<5.0%	<10%	<3%	<6%	<5.0	<3.0%	<5.0%

### Sample Status

Detail

Realtime Display

Sample No.	Serum	Sample ID					
0002-1	Serum	Sample ID					
GLUC	104.34	UREA	40.5	CRE	1.19	TP	3.97
ALB	2.50	IRON	646.4	CALA	9.04	PHOS	6.55
UA	5.97	ALT	45.71	AST	56.15	ALP04	
MG	2.51	CHOL	159.55	TRIG	151.74	Na	120.6
K	3.9	Cl	90.1	TBILC	1.41	DBILC	1.10
Sample No.	0009	Serum	Sample ID	900870-789		Nisrutkumar Patel	
TP	7.07	ALB	3.90	ALT	25.42	TBILC	1.01
DBILC	0.22	GLB	3	A/G	1	TBIL1	1
0010	Serum	Sample ID	PRECISION CHECK				
GLUC	105.71	CRE	0.91	TP	7.04	ALB	3.88
CALA	9.27	PHOS	2.59	ALT	25.00	ALP04	
MG	2.42	Na	136.0	K	3.9	GLB	3
A/G	1						
0011	Serum	Sample ID	PRECISION CHECK				
GLUC	104.53	CRE	0.92	TP	6.99	ALB	3.85
CALA	9.05	PHOS	2.54	ALT	25.49	ALP04	
MG	2.40	Na	135.5	K	3.9	GLB	3
A/G	1						
0012	Serum	Sample ID	PRECISION CHECK				
GLUC	104.29	CRE	0.90	TP	7.00	ALB	3.88
CALA	9.04	PHOS	2.56	ALT	25.57	ALP04	
MG	2.38	Na	135.9	K	3.9	GLB	3
A/G	1						
0013	Serum	Sample ID	PRECISION CHECK				
GLUC	104.41	CRE	0.92	TP	6.99	ALB	3.85
CALA	9.21	PHOS	2.55	ALT	25.22	ALP04	
MG	2.39	Na	135.6	K	3.9	GLB	3
A/G	1						

All

Quick

ISE

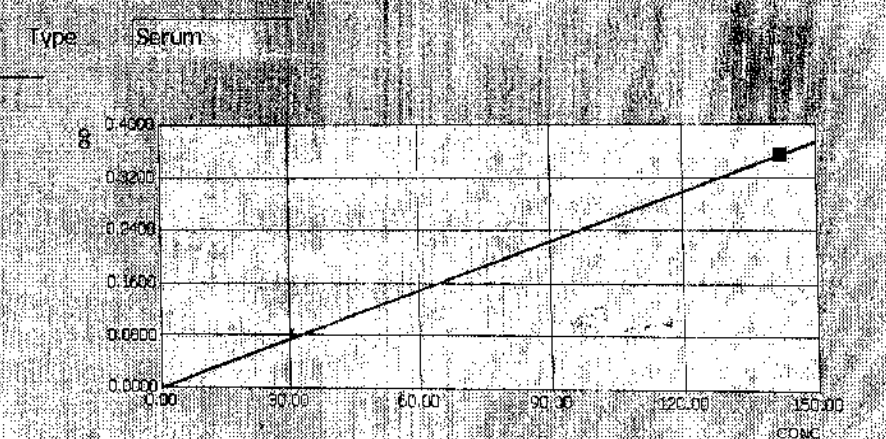
Sample No.	Serum	Sample ID	PRECISION	
0014				
GLUC	103.70	CRE	0.91	TP
CALA	9.21	PHOS	2.60	ALT
MG	2.43	Na	135.8	K
A/G	1			
Sample No.	Serum	Sample ID	PRECISION	CHE
0015				
GLUC	104.05	CRE	0.90	TP
CALA	9.13	PHOS	2.57	ALT
MG	0.07 u G	Na	136.4	K
A/G	1			
Sample No.	Serum	Sample ID	PRECISION	CHE
0016				
GLUC	103.29	CRE	0.92	TP
CALA	9.06	PHOS	2.58	ALT
MG	0.09 u G	Na	136.1	K
A/G	1			
Sample No.	Serum	Sample ID	PRECISION	CHE
0017				
GLUC	102.14	CRE	0.91	TP
CALA	9.15	PHOS	2.54	ALT
MG	0.04 u G	Na	135.5	K
A/G	1			
Sample No.	Serum	Sample ID	PRECISION	CHE
0018				
GLUC	102.60	CRE	0.89	TP
CALA	9.11	PHOS	2.56	ALT
MG	0.00 u G	Na	134.8	K
A/G	1			
Sample No.	Serum	Sample ID	PRECISION	CHE
0019				
GLUC	101.08	CRE	0.88	TP
CALA	8.90	PHOS	2.46	ALT
MG	0.00 u G	Na	133.6	K
A/G	0 G			

Calibration

Calibration Monitor

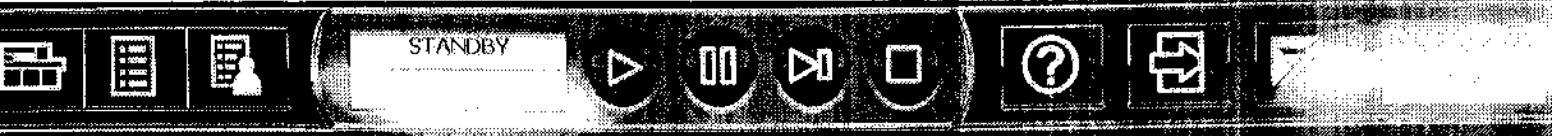
Status RB History RB Detail Calibration History Calibration Detail

Test Name: 5.GLUC  
 Date/Time: 03/10/2022 16:30 Passed  
 Reagent: Lot No. 2599 Bottle No. 7769  
 R1(R1-1) 2599 7769  
 R2(R2-1) 2599 6902  
 Cal Expiration Date: 04/09/2022 16:30  
 Reagent Blank: 03/10/2022 16:24  
 Cal Type: AB  
 Measure Type: Rack  
 Formula: Y=AX+B  
 A = .03183E002  
 B = 0.0000E000



Cal No.	CONC	OD
1	142.00	0.3534

Comment



Calibration

Calibration Monitor

Status

RB History

RB Detail

Calibration History

Calibration Detail

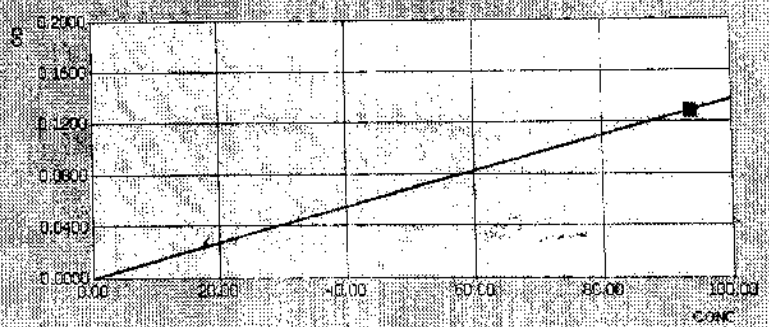
T Name 6.UREA

Type Serum

Date/Time 03/10/2022 16:30

Passed

Reagent Lot No. Bottle No.  
 R1(R1-1) 1234 1234  
 R2(R2-1) 1234 1234



Cal Expiration Date  
 Reagent Blank 03/10/2022 16:21  
 Cal Type AB  
 Measure Type Rack  
 Formula Y=AX+B  
 Factor  
 A = 7.2649E002  
 B = 0.0000E000

Cal No.	CONC	OD
1	93.60	0.1288

Comment

Lot to Lot Calibration

RB/CAL Selection

Data Select

Comment

Graph Scale

Print



Calibration

Calibration Monitor

Status

RB History

RB Detail

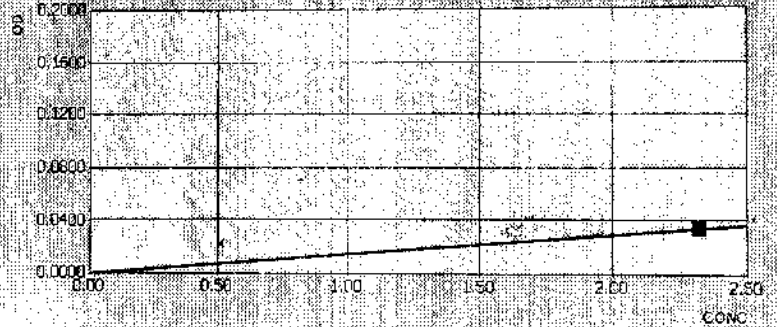
Calibration History

Calibration Detail

Name: 3.CRE  
 Date/Time: 03/26/2022 10:08  
 Reagent: Lot No. 1234, Bottle No. 1234  
 R1(R1-1): 1234  
 R2(R2-1): 1234

Type: Serum

Passed



Cal Expiration Date: 03/27/2022 10:08  
 Reagent Blank: 03/26/2022 10:04  
 Cal Type: AB  
 Measure Type: Rack  
 Formula: Y=AX+B  
 Factor:  
 A = .135E001  
 B = 0.0000E000

Cal No.	CONC	OD
1	2.32	0.0341

Comment

Lot to Lot Calibration  
 RB/CAL Selection  
 Data Select

Comment  
 Graph Scale  
 Print



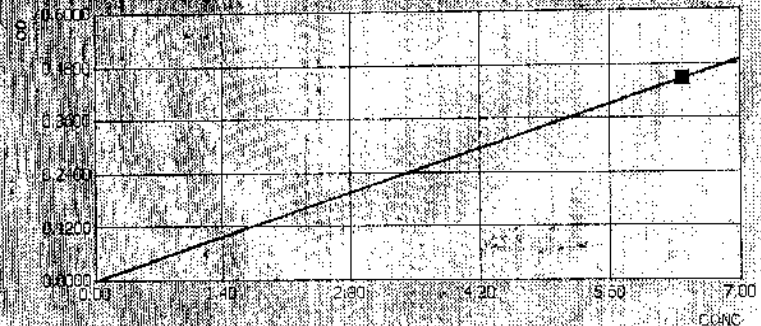
Calibration

Calibration Monitor

Status      RB History      RB Detail      Calibration History      Calibration Detail

T Name: 20.TP  
 Date/Time: 03/23/2022 18:07  
 Reagent: Lot No. 2601, Bottle No. 0164  
 R1(R1-1): 2601, 0164  
 R2(R2-1): 2601, 0161  
 Cal Expiration Date: 03/23/2022 18:04  
 Reagent Blank: 03/23/2022 18:04  
 Cal Type: AB  
 Measure Type: Rack  
 Formula: Y=AX+B  
 Factor:  
 A = 1.4283E001  
 B = 0.0000E000

Type: Serum  
 Status: Passed



Cal No.	CONC	OD
1	6.38	0.4467

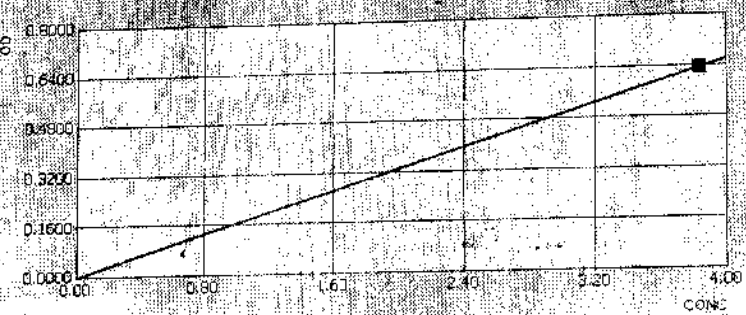
Comment

Lot to Lot Calibration     
  RB/CAL Selection     
  Data Select     
  Comment     
  Graph Scale     
  Print

**Calibration** **Calibration Monitor**

Status RB History RB Detail Calibration History Calibration Detail

.t Name: 21.ALB Type: SerUm  
 Date/Time: 03/10/2022 16:31 Passed  
 Reagent: Lot No. 2567 Bottle No. J940  
 R1(R1-1)  
 R2(R2-1)  
 Cal Expiration Date:  
 Reagent Blank: 03/10/2022 16:23  
 Cal Type: AB  
 Measure Type: Rack  
 Formula: Y=AX+B  
 Factor:  
 A = 0.0545E000  
 B = 0.0000E000



	Cal No.	CONC	OD
1	1	3.83	0.6326
.			

Comment





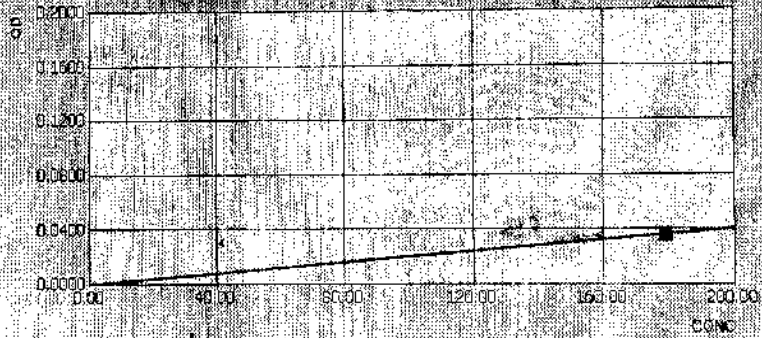
Calibration

Calibration Monitor

Status      RB History      RB Detail      Calibration History      Calibration Detail

Tr Name: 38.IRON  
 Date/Time: 03/10/2022 16:34  
 Reagent: R1(R1-1) 1500, R2(R2-1) 1500

Type: Serum  
 Passed



Cal Expiration Date: 03/10/2022 16:26  
 Reagent Blank: AB  
 Measure Type: Rack  
 Formula: Y=AX+B  
 A = 4.9095E003  
 B = 0.0000E000

Cal No.	CONC	OD
1	179.00	0.0365

Comment:

Lot to Lot Calibration      RB/CAL Selection      Data Select      Comment      Graph Scale      Print

Test Name: 39.UIBC

Di Time: 03/25/2022 09:48

Reagent: R1(R1-1) R2(R2-1)

Cal Expiration Date: 04/08/2022 09:48

Reagent Blank: 03/25/2022 09:45

Cal Type: AB

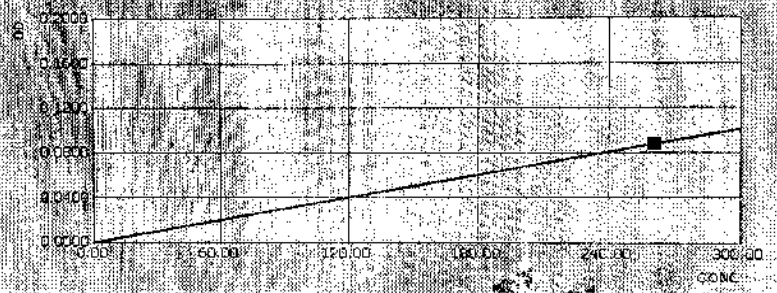
Measure Type: Rack

Formula: Y=AX+B

Factor:  
 A = 2.9642E003  
 B = 0.0000E000

Type: Serum

Cal No.	CONC	OD
1	261.00	0.0831



Comment















Daily Chart

Day to Day Chart

Twin Plot Chart

Monitor List

Chart View

Index

03/10/2022 09:06

03/26/2022 07:07

Test Name 12.CALA

Type Serum

Control Name

Statistics:

	Result	Base Value
N	4	
Mean	9.040	8.800
SD	0.1883	0.4850
CV(%)	2.08	5.51
Range	0.44	3.00

Detail Data

Index	
Measured Time	
Sample No.	
Rack / STAT	
Result	
Data Flags	
Reagent Inf. R1(R1-1)	
Reagent Inf. R2(R2-1)	



Change Index

Graph Scale

Print

Daily Chart

Day to Day Chart

Twin Factor

Monitor List

Chart View

Index

03/10/2022 09:06

03/26/2022 07:07

Test Name 13.MG

Type Serum

Control Name

Statistics

	Result	Base Value
N	3	
Mean	2.613	2.580
SD	0.1050	0.2050
CV(%)	4.02	7.93
Range	0.21	1.20

Detail Data

Index	Measured Time	Sample No.	Rack / STAT	Result	Data Flags
Reagent Inf. R1(R1-1)					
Reagent Inf. R2(R2-1)					

350  
250  
150  
50  
Near  
350  
250  
150  
50

03/10 17:31 2.61  
03/25 09:50 2.77  
03/26 07:05 2.51

Change Index

Graph Scale

Print

Daily Chart

Today's Day Chart

Twin Plot

Monitor List

Chart View

03/10/2022 09:06

03/26/2022 07:07

Test Name

14.JRIG

Type

Serum

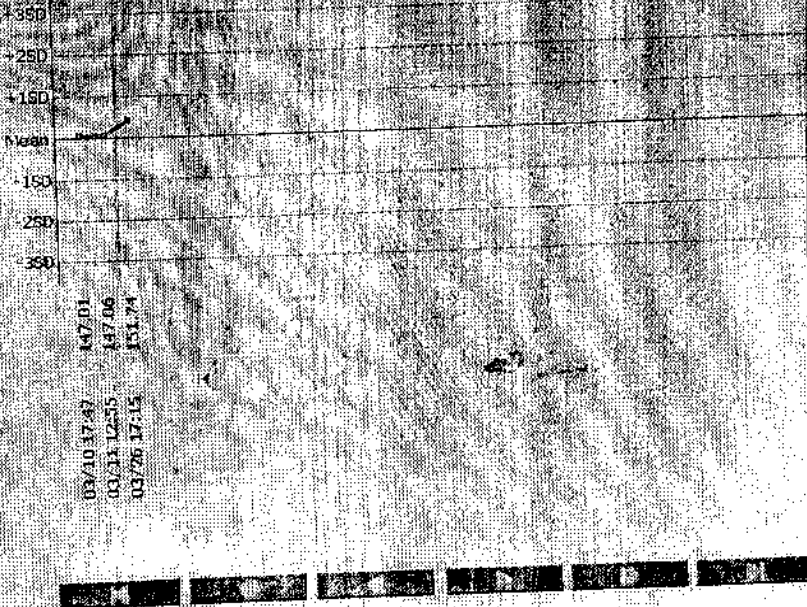
Control Name

Statistics

	Result	Base Value
N	3	
Mean	148.603	146.000
SD	2.7165	13.0000
CV(%)	1.85	8.90
Range	4.73	76.00

Detail Data

Index	Measured Time	Sample No.	Rack / STAT	Result	Date/Flags



Change Index

Graph Scale

Print





Monitor List

Chart View

Index 03/10/2022 09:06 - 03/26/2022 07:07

CHI.No.

Test Name **LS.CHOL**  

Type **Serum**

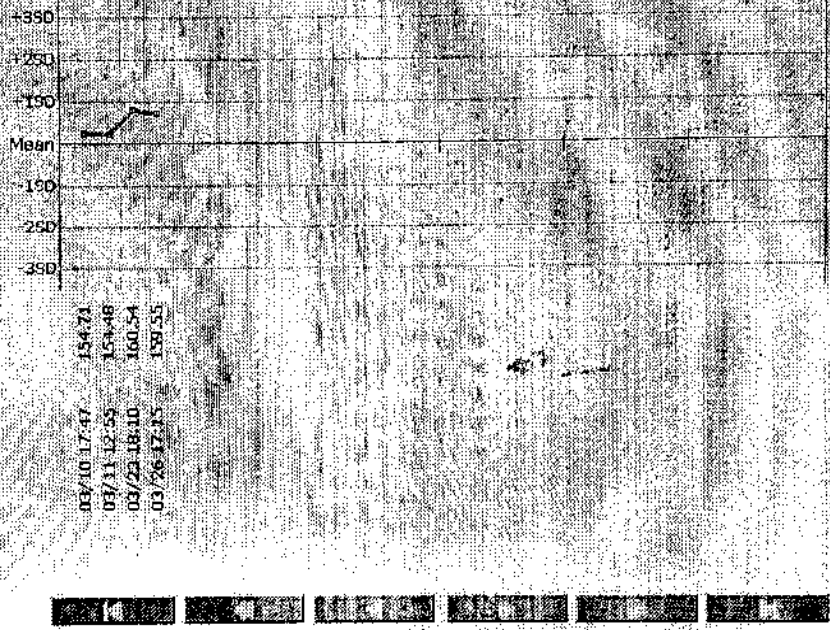
Control Name **AD-BMG**

Statistics

	Result	Base Value
N	4	
Mean	157.320	152.000
SD	3.1738	10.5000
CV(%)	2.02	6.91
Range	6.06	60.00

Detail Data

Index	Measured Time	Sample No.	Rock / STAT	Result	Data Flags



Change Index



Graph Scale



Print



Index

03/10/2022 09:06

03/26/2022 07:07

Cl.No.

Test Name 21.ALB

Type Serum

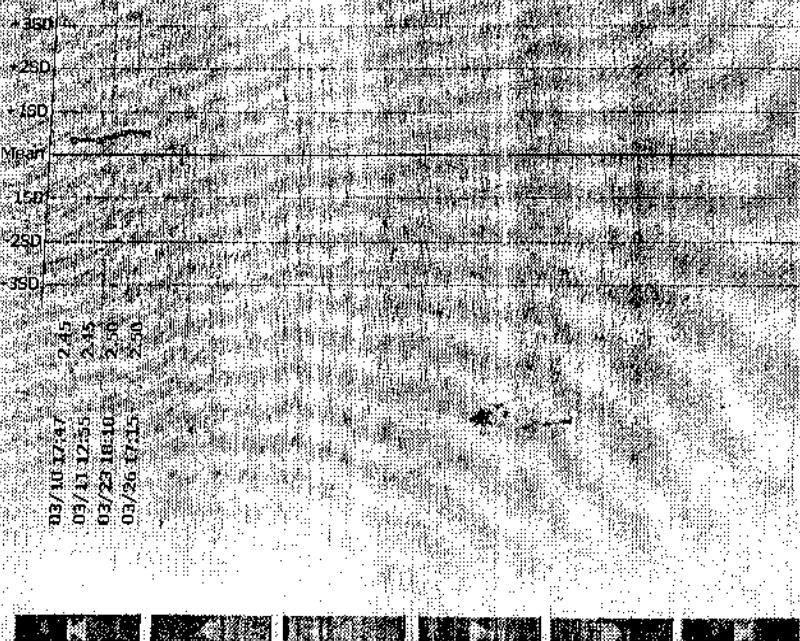
Control Name

Statistics

	Result	Dose Value
N	4	
Mean	2.475	2.360
SD	0.0289	0.2700
CV(%)	1.17	11.44
Range	0.05	1.20

Detail Data

Index	
Measured Time	
Sample No.	
Rack / STAT	
Result	
Date Flags	
Reagent Inf. R1(R1-1)	
Reagent Inf. R2(R2-1)	



Change Index

Graph Scale

Print

Monitor List

Chart View

Index 03/10/2022 09:06 03/26/2022 07:07

Test Name 22.TBILC

Type Serum

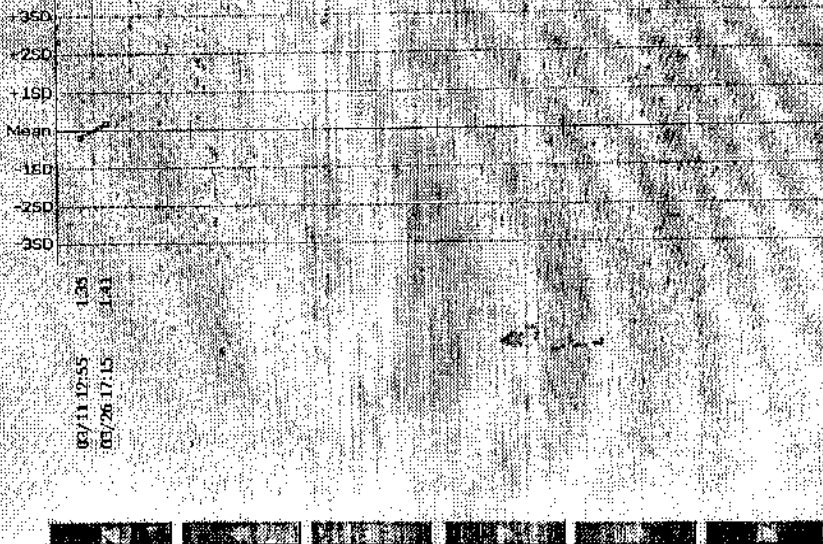
Control Name

Statistics

	Result	Base Value
N	2	
Mean	1.380	1.300
SD	0.0424	0.1800
PV(%)	2.07	13.04
Range	0.06	1.08

Detail Data

Index	
Measured Time	
Sample No.	
Rack / STAT	
Result	
Data Flags	
Reagent Inf. R1(R1-1)	
Reagent Inf. R2(R2-1)	



Change Index

Graph Scale

Print

Day Chart

Day to Day Chart

Twin Plot Chart

or List

23:11:11

03/10/2022 09:05

03/26/2022 07:07

Calibration No. 1000

Test Name: 107 NS



350  
250  
150  
50  
Mean

Type: Serum

Control Name: [REDACTED]

Statistics

	Result	Desc Value
N	3	
Mean	119.567	121.000
SD	1.6166	3.5000
CV(%)	1.35	2.89
Range	2.01	18.00

03/20/22 11:07  
03/16/22 12:53  
03/20/22 17:15

Detail Data

Index	
Measured Time	
Sample No.	
Rack / STAT	
Result	
Data Flags	
Reagent Inf. R1(R1-1)	
Reagent Inf. R2(R2-1)	

Change Index

Graph Scale

Print



03/10/2022 09:06 03/26/2022 07:07

Calibration Monitor

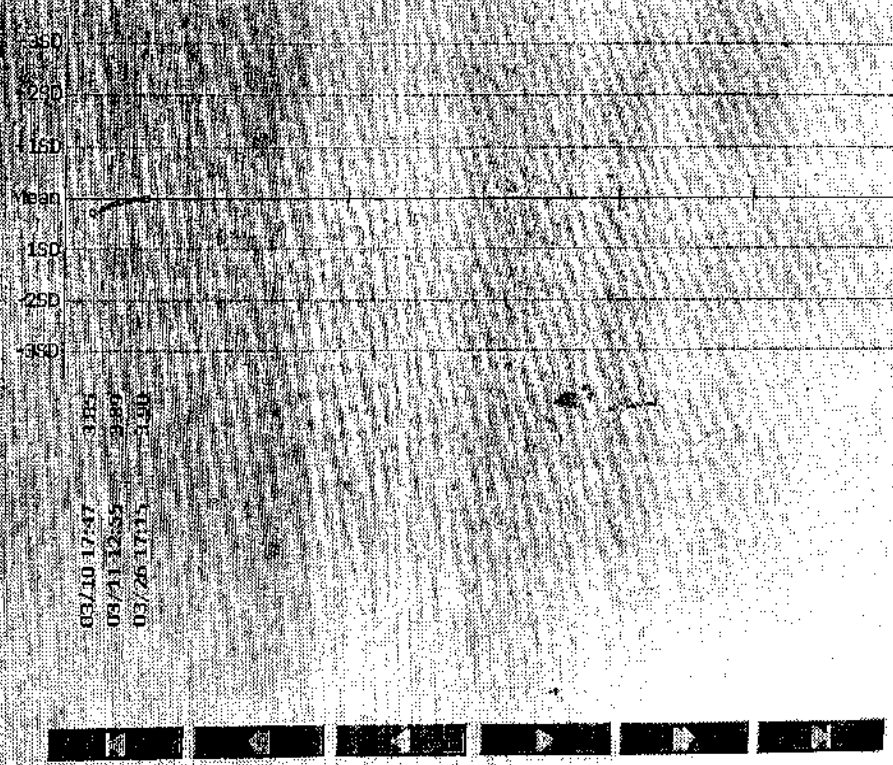
Test Name: 99:K  
 Type: Control  
 Control Name: [REDACTED]

Statistics

	Result	Base Value
Mean	3.900	3.900
SD	0.0265	0.1800
CV(%)	0.68	4.62
Range	0.05	1.50

Detail Data

Index	Measured Time	Sample No.	Rack / STAT	Result	Data Flags	Reagent Inf. R1(R1-1)	Reagent Inf. R2(R2-1)



Index

03/10/2022 09:06

03/26/2022 07:07

Reaction

Reactions: 100%

Ctl. No.

Test Name 99Cl

Type Serum

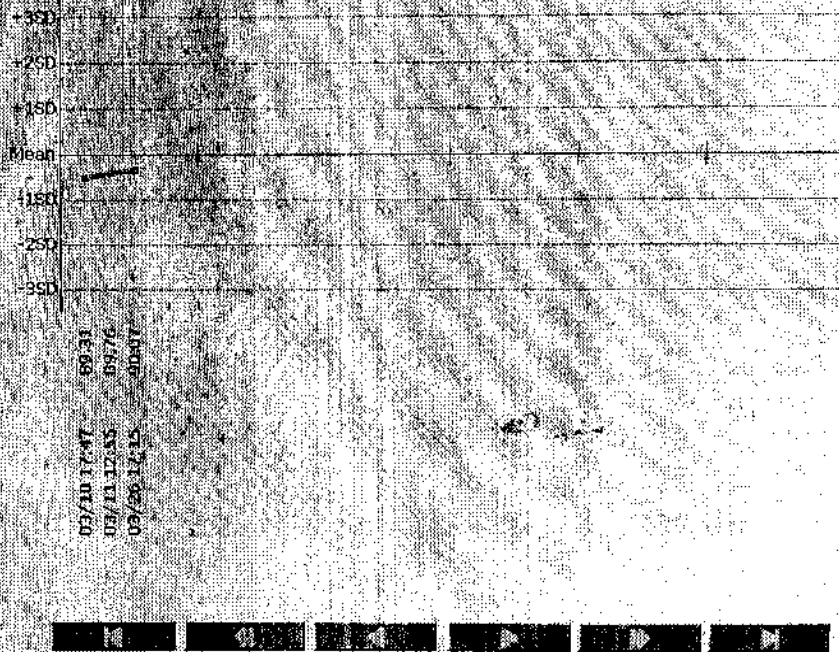
Control Name

Statistics

	Result	Base Value
N	3	
Mean	89.713	91.400
SD	0.3821	4.1000
CV(%)	0.43	4.49
Range	0.75	24.00

Detail Data

Index	
Measured Time	
Sample No.	
Rack / STAT	
Result	
Data Flags	
Reagent Inf. R1(R1-1)	
Reagent Inf. R2(R2-1)	



Change Index

Graph Scale

Print

ID	Sample Type	Sample ID	Value	Unit	Remarks
0003	Serum	RAJAT Q7856	3.14		
0005	Serum	9000709782	0.80		Heml Patel
0007	Serum	9000704609	1.52		Chandra Prakash Meo
0008	Serum	9000704657	3.76		Nathu Lal
0010	Serum	PRECISION CHECK	0.91		
0011	Serum	PRECISION CHECK	0.92		
0012	Serum	PRECISION CHECK	0.90		
0013	Serum	PRECISION CHECK	0.93		
0014	Serum	PRECISION CHECK	0.91		
0015	Serum	PRECISION CHECK	0.90		
0016	Serum	PRECISION CHECK	0.92		
0017	Serum	PRECISION CHECK	0.91		
0018	Serum	PRECISION CHECK	0.89		
0019	Serum	PRECISION CHECK	0.88		

Edit

Detail Information

Routine

# Sample Manager

Sample

IRB: CAL/06

Main

Sample

Test

03/26/2022 07:07

Reaction Monitor

Test Name 5:GLUC

Sample No.	Type	Sample ID	Result	Time	Data Flags	
0002	Serum	9000704529	95.41			Nirgundaji Maharaj
0004	Serum	9000704594	127.36			Sourabh Shukla
0010	Serum	PRECISION CHECK	105.71			
0011	Serum	PRECISION CHECK	104.53			
0012	Serum	PRECISION CHECK	104.29			
0013	Serum	PRECISION CHECK	104.41			
0014	Serum	PRECISION CHECK	103.70			
0015	Serum	PRECISION CHECK	104.05			
0016	Serum	PRECISION CHECK	103.29			
0017	Serum	PRECISION CHECK	102.14			
0018	Serum	PRECISION CHECK	102.60			
0019	Serum	PRECISION CHECK	101.08			

Edit

Detail Information

Routine

Sample Manager

Sample

RB/CAL/00

Main

Sample

Test

Index 03/26/2022 07:07

Reaction Monitor

Test Name 10.PHOS



Sample No.	Type	Sample ID	Result	Data Flags	
0009	Serum	9000704657	3.00		Natural
0010	Serum	PRECISION CHECK	2.89		
0011	Serum	PRECISION CHECK	2.54		
0012	Serum	PRECISION CHECK	2.56		
0013	Serum	PRECISION CHECK	2.55		
0014	Serum	PRECISION CHECK	2.60		
0015	Serum	PRECISION CHECK	2.57		
0016	Serum	PRECISION CHECK	2.58		
0017	Serum	PRECISION CHECK	2.54		
0018	Serum	PRECISION CHECK	2.56		
0019	Serum	PRECISION CHECK	2.46		

Edit

Detail Information



Sample ID	Type	Sample ID	Result	Data Flags	
0003	Serum	RAJAT 07859	1.99		
1	Serum	PRECISION CHECK	2.42		
0011	Serum	PRECISION CHECK	2.40		
0012	Serum	PRECISION CHECK	2.38		
0013	Serum	PRECISION CHECK	2.39		
0014	Serum	PRECISION CHECK	2.33		
0015	Serum	PRECISION CHECK	0.07	u	G
0016	Serum	PRECISION CHECK	0.09	u	G
0017	Serum	PRECISION CHECK	0.04	u	G
0018	Serum	PRECISION CHECK	0.00	u	G
0019	Serum	PRECISION CHECK	0.00	u	G

Edit

Detail  
Information

Code	Sample Type	Sample ID	Value	Unit	Reference Range	Remarks
0002	Serum	9000704520	6.54			Muzundaji Maharaj
000F	Serum	9000704759	6.99			Manoj Kumar Bunker
00L	Serum	9000704789	7.07			Nishikumar Patel
0010	Serum	PRECISION CHECK	7.03			
0011	Serum	PRECISION CHECK	6.99			
0012	Serum	PRECISION CHECK	7.00			
0013	Serum	PRECISION CHECK	6.99			
0014	Serum	PRECISION CHECK	7.05			
0015	Serum	PRECISION CHECK	7.00			
0016	Serum	PRECISION CHECK	7.06			
0017	Serum	PRECISION CHECK	7.01			
0018	Serum	PRECISION CHECK	7.07			
0019	Serum	PRECISION CHECK	4.05			

Edit

Detail Information



Main Sample Test

ax 03/26/2022 07:07

Reaction Monitor

Test Name 21.ALB

Sample No.	Type	Sample ID	Result	Data Flags	
0002	Serum	9000704529	4.11		Nirgundasi Maheraj
0006	Serum	9000704759	3.97		Manoj Kumar Bunker
0009	Serum	9000704789	3.90		Nishitkumar Patel
0010	Serum	PRECISION CHECK	3.88		
0011	Serum	PRECISION CHECK	3.85		
0012	Serum	PRECISION CHECK	3.88		
0013	Serum	PRECISION CHECK	3.85		
0014	Serum	PRECISION CHECK	3.85		
0015	Serum	PRECISION CHECK	3.86		
0016	Serum	PRECISION CHECK	3.86		
0017	Serum	PRECISION CHECK	3.80		
0018	Serum	PRECISION CHECK	4.08		
0019	Serum	PRECISION CHECK	0.00	G	

Edit

Detail Information

Sample

RB/CAL/QC

Main

Sample

Test

Reaction Monitor

Index 03/26/2022 07:07

Test Name 28.ALT



Sample No.	Type	Sample ID	Result	Data Flags	
0002	Serum	9000704529			Nirgunclaji Maharaj
0006	Serum	9000704799	31.66	r	Manoj Kumar Bunker
0009	Serum	9000704789	28.42	r	Nishikumar Patel
0010	Serum	PRECISION CHECK	25.08		
0011	Serum	PRECISION CHECK	25.49		
0012	Serum	PRECISION CHECK	25.57		
0013	Serum	PRECISION CHECK	25.22		
0014	Serum	PRECISION CHECK	25.06		
0015	Serum	PRECISION CHECK	25.68		
0016	Serum	PRECISION CHECK	25.06		
0017	Serum	PRECISION CHECK	25.59		
0018	Serum	PRECISION CHECK	25.00		
0019	Serum	PRECISION CHECK	0.62	G	

Edit

Detail Information



03/26/2022 07:07

Test Name

82.GLB



Sample No.	Type	Sample ID	Result	Data/Flag	
0002	Serum	9000704529	2.93	D	Nirgundaji Mahara
0006	Serum	9000704759	3.60	r	Manoj Kumar Bunker
0009	Serum	9000704789	3.17	P	Nishankumar Patel
0010	Serum	PRECISION CHECK	3.15		
0011	Serum	PRECISION CHECK	3.14		
0012	Serum	PRECISION CHECK	3.12		
0013	Serum	PRECISION CHECK	3.14		
0014	Serum	PRECISION CHECK	3.21		
0015	Serum	PRECISION CHECK	3.14		
0016	Serum	PRECISION CHECK	3.20		
0017	Serum	PRECISION CHECK	3.21		
0018	Serum	PRECISION CHECK	2.99		
0019	Serum	PRECISION CHECK	4.05	G	

Sample

RB/CAL/QC

Main

Sample

Test

Reaction Monitor

Index

03/26/2022 07:07

Test Name

97.Na

Sample No.	Type	Sample ID	Result	Data Flags	
0001	Serum	9000704496	134.32	r	Mahesh Parmar
0002	Serum	9000704529	139.11	r	Nirgundasji Maharaj
0008	Serum	9000704657	137.29	r	Nathu Lal
0010	Serum	PRECISION CHECK	136.01		
0011	Serum	PRECISION CHECK	136.45		
0012	Serum	PRECISION CHECK	135.93		
0013	Serum	PRECISION CHECK	135.62		
0014	Serum	PRECISION CHECK	135.84		
0015	Serum	PRECISION CHECK	136.41		
0016	Serum	PRECISION CHECK	136.15		
0017	Serum	PRECISION CHECK	135.53		
0018	Serum	PRECISION CHECK	134.75		
0019	Serum	PRECISION CHECK	133.58		

Edit

Detail Information

Test Name 98.K  

Sample No.	Type	Sample ID	Result	Data Flag	
0001	Serum	9000704496	3.91	r	Mahesh Parmar
0002	Serum	9000704529	3.90	r	Nirgunidasji Maharaj
0007	Serum	9000704606	3.80	r	Chandra Prakash Mee
0008	Serum	9000704657	3.53	r	Nuthu Lal
0010	Serum	PRECISION CHECK	3.94		
0011	Serum	PRECISION CHECK	3.94		
0012	Serum	PRECISION CHECK	3.93		
0013	Serum	PRECISION CHECK	3.92		
0014	Serum	PRECISION CHECK	3.92		
0015	Serum	PRECISION CHECK	3.94		
0016	Serum	PRECISION CHECK	3.93		
0017	Serum	PRECISION CHECK	3.91		
0018	Serum	PRECISION CHECK	3.89		
0019	Serum	PRECISION CHECK	3.86		

Edit

Detail Information

Main

Sample

Test

Reaction Monitor

Index: 03/26/2022 07:07

Test Name: 3.CRE



Sample No.	Type	Sample ID	Result	Data Flags	
0003	Serum	RA1A1 07859	3.14	n	
0005	Serum	9000704732	0.99	r	Henil Patel
0007	Serum	9000704606	1.03	r	Chandra Prakash Mee
0008	Serum	9000704657	3.76	r	Nathu Lal
0010	Serum	PRECISION CHECK	0.92		
0011	Serum	PRECISION CHECK	0.92		
0012	Serum	PRECISION CHECK	0.90		
0013	Serum	PRECISION CHECK	0.92		
0014	Serum	PRECISION CHECK	0.91		
0015	Serum	PRECISION CHECK	0.90		
0016	Serum	PRECISION CHECK	0.92		
0017	Serum	PRECISION CHECK	0.91		
0018	Serum	PRECISION CHECK	0.89		
0019	Serum	PRECISION CHECK	0.88		

Edit

Detail Information

