

# BS 240 Pro

## Automated Clinical Chemistry Analyzer



### Qualification Manual:

Installation Qualification / Operation Qualification / Performance Qualification

*IQ/OQ/PQ - BS 240 Pro*

## 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,

#### **DOC OPD LABS**

NOIDA

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 & appropriate course of action will be determined.

*IQ/OQ/PQ -BS 240 Pro*

**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: **AVANTOR REPRESENTATIVE**

Name: Mr.Amol Patil  
Title: Area Service Manager  
Company: Avantor

Signature: 

Customer Authorization:

**DOC OPD LABS**  
NOIDA

Signature: ..... 

*IQ/OQ/PQ -BS 240 Pro*

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CERTIFICATION OF INSTALLATION - REPORT

Analyzer Name: **BS 240 Pro**

Serial Number: **BC-8-88000013**

CUSTOMER NAME & ADDRESS:


**DOC OPD LABS**  
NOIDA

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

Authorized Engineer,

Autl

Signature: 

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Name: Mr. Amol Patil  
Designation: Area Service Manager  
Company: **Avantor**

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*IQ/OQ/PQ - BS 240 Pro*

Installation Qualification Notes & Attachments:

OPERATIONAL QUALIFICATION

SYSTEM CERTIFICATION:

Study date has determined that the system described in this document 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: AVANTOR REPRESENTATIVE

Name: Mr. Amol Patil  
Area Service Manager  
Company: AVANTOR

Customer Authorization:

**DOC OPD LABS**  
NOIDA

Authorized Engineer's Signature

Date: 08.06.2022

Customer's Signature

Date: 08.06.2022




*IQ/OQ/PQ -BS 240 Pro*

### 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	REMARK
A) Carton arrival	Checked
B) Spare and accessibility	Checked & Cleared
C) Electrical input	Checked & Passed
D) Ambient temperature and Humidity	Passed
E) Ventilation	Passed
F) Drainage	NA
2. UNPACKING & INSTALLING THE CONSOLE	Passed
3. INSTALLING THE ELECTRICAL CABLES	Checked & Passed
4. UNPACKING & INSTALLING THE ANALYTICAL UNIT	Passed
5. SETTING THE ANALYTICAL UNIT	Success
6. ALIGNMENTS VERIFICATION	Success

Mr. Amol Patil  	DR. ARUN KUMAR  Designation: M.D PATHOLOGY  (Signature)
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*IQ/OQ/PQ -BS 240 Pro*

### 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 240 Pro*
2. *Service Manual – BS 240 Pro*

*IQ/OQ/PQ - BS 240 Pro*

Operational Qualification Notes:

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: AVANTOR REPRESENTATIVE

Name: Viraj Kale  
Title: Manager-Technical  
IVD- Automation

Company: **AVANTOR**

Customer Authorization:

DOC OPD  
NOIDA

Authorized Engineer's Signature



Date: 08.06.2022



Date: 08.06.2022

*IQ/OQ/PQ -BS 240 Pro*



**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.


<p>Viraj Kale</p> <p>Manager-Technical IVD-Automation</p> 	<p>DR. ARUN KUMAR</p> <p>Designation: M.D PATHOLOGY</p>  <p>Signature:</p>
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**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.

OPERATIONAL QUALIFICATION PROTOCOL	REMARKS
1] CHECKING THE ANALYTICAL UNIT	
A] SOFTWARE BOOTING & INITIALIZATION	Success
B] BASIC SYSTEM CHECKS & VERIFICATION	Verified
2] IMPORTING & CALIBRATING THE CHEMISTRIES	Success
3] RUNNING CONTROLS	Success
4] TRAINING THE OPERATORS	Completed

Mr. Amol Patil	DR. ARUN KUMAR Designation: M.D PATHOLOGY  (Signature)
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## PERFORMANCE ANALYSIS

**Tests Validated** - Glucose, Urea, Creatinine, Total Cholesterol, Triglycerides, Total Protein, Uric Acid, SGPT, SGOT, Albumin, Total Bilirubin, Direct Bilirubin, Alkaline Phosphatase, LDH.

Analyzer Model & Serial No	BS 240 Pro & BC-8-88000013
Date of Validation	08.06.2022
Method	Photometry
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Name of LABORATORIES	DOC OPD LABS
Department	LABORATORY

### Within run precision report protocol:

20 replicates each of Randox chemistry control Level 3 analyzed on **BS 240 Pro** bearing the serial number **BC7-18001355** continuously to verify the precision

### Summary:

S. No	Parameter	Manufacturer's CV%	Observed CV%
1	Glucose (mg/dl)	</=3.0%	1.1%
2	Urea (mg/dl)	</=4.0%	0.7%
3	Creatinine (mg/dl)	</=3.0%	0.9%
4	Total Cholesterol (mg/dl)	</=3.0%	0.0%
5	Triglycerides (mg/dl)	</=3.0%	0.6%
6	Total Protein (g/dl)	</=3.0%	0.8%
7	Uric Acid (mg/dl)	</=3.0%	0.3%
8	SGPT (U/L)	</=3.5%	0.9%
9	SGOT (U/L)	</=3.5%	0.5%
10	Albumin (g/dl)	</=3.0%	0.4%
11	Total Bilirubin (mg/dl)	</=5.0%	0.6%
12	Direct Bilirubin (mg/dl)	</=4.0%	0.8%

### Conclusion:

Within run precision of the parameters involving the modes, endpoint & fixed-time kinetic with various sample volume, reagent volume, wavelengths were completed & tabulated.

The Percentage coefficient variation (CV %) of all the parameters obtained are well within the acceptable limits (Manufacturer's CV%) on **BS 240 Pro**

Reported By  
Name  
Designation  
Company

  
- Viraj Kale  
- Manager Technical  
- Avantor

*IQ/OQ/PQ -BS 240 Pro*

**Accuracy:**

Equipment name & Serial No	BS-240 Pro & S. No: BC-8-88000013
Validated during	08.06.2022
Method	Photometry at 37°C
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Name of Laboratory/Hospital	DDC OPD LABS
Department	Laboratory

**TESTS VALIDATED** – Glucose, Urea, Creatinine, Total Cholesterol, Triglycerides, SGOT, SGPT, Albumin, Total Protein, Albumin, Total Protein, Total Bilirubin, Direct Bilirubin, Calcium

**Accuracy protocol:**

The accuracy of BS-240 Pro- S. No: BC-8-88000013 been verified by analyzing Multi-Sera Calibrator LOT No:150121008.

S. No	Parameter	Value Obtained	Calibrator Concentration
1	Glucose (mg/dl)	191	190
2	Urea (mg/dl)	102	102
3	Creatinine (mg/dl)	4.05	4.53
4	TC (mg/dl)	160	164
5	TGL (mg/dl)	132	131
6	SGOT (U/L)	108	110
7	SGPT (U/L)	103	103
8	Ca (mg/dl)	11	10.57
9	UA(mg/dl)	5.80	5.76
10	Albumin (g/dl)	3.6	3.68
11	TP (g/dl)	5.70	5.82
12	T.BILI (mg/dl)	4.88	4.72
13	D.BILI(mg/dl)	2.57	2.75

**Conclusion**

BC-8-88000013 has been verified by analyzing the Multi-Sera Calibrator the results obtained were satisfactory

**Reported By**

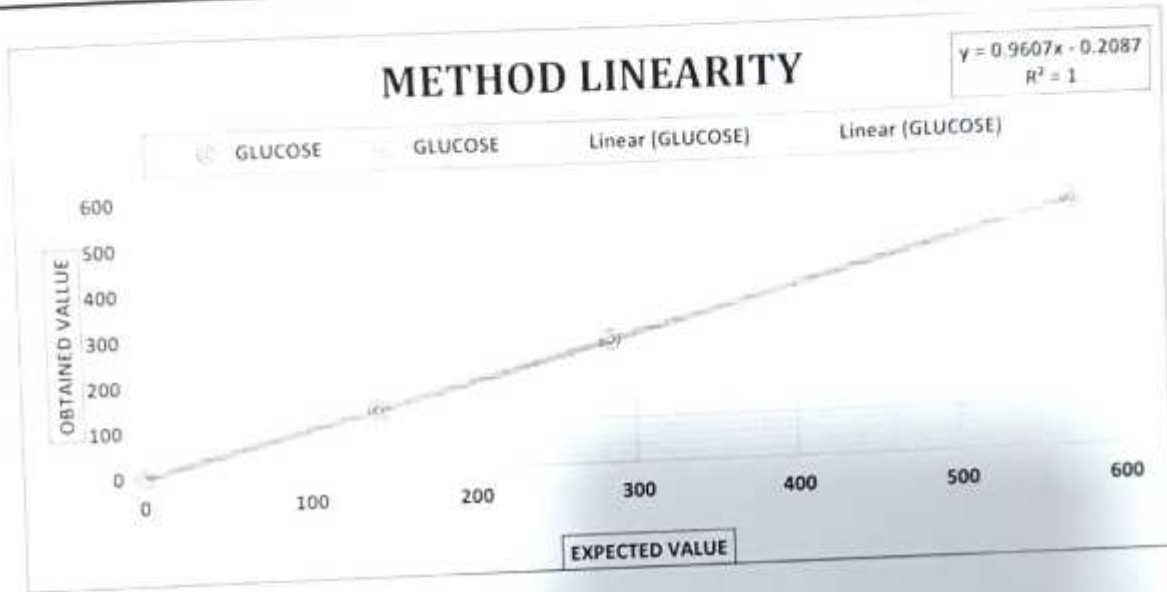


Viraj Kale  
 Manager- Technical  
 IVD-Automation  
 +91-9930033581

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	GLUCOSE
Customer Site:	DOCOPD LABS	Test Equip:	Mindray BS-240 PRO
Analyst:	Viraj Kale	Serial Number:	BC-8-88000013

LINEARITY PLOT



Linearity Report Generated for Akshay Laboratories

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	GLUCOSE
Customer Site:	DOCOPD LABS	Test Equip:	Mindray BS-240 PRO
Analyst:	Viraj Kale	Serial Number:	BC-8-88000013

**LINEARITY VALUES**

Linearity Samples (Values in mg/dl)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	142	135
50.0%	285	275
100.0%	570	547

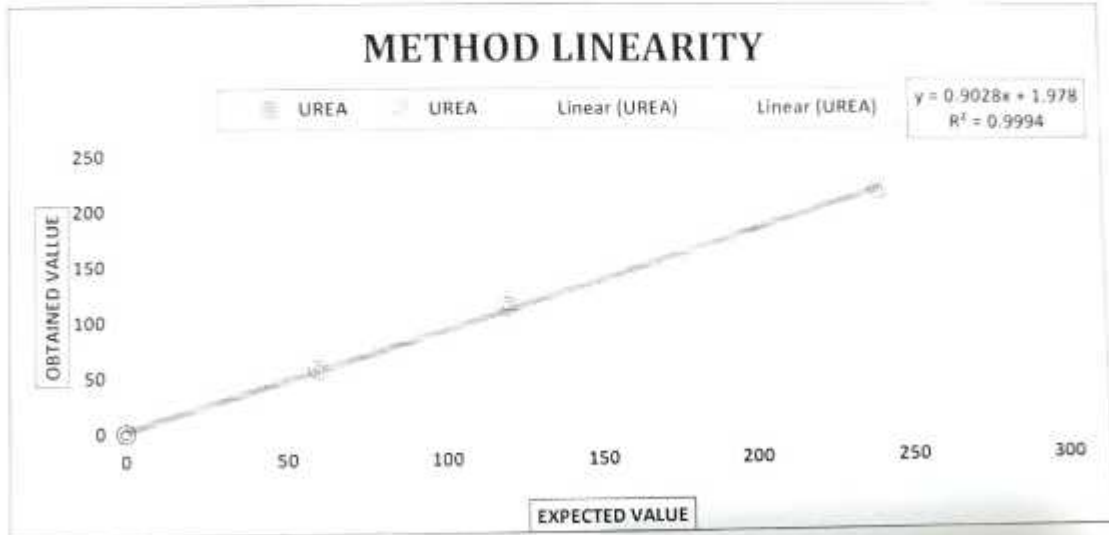
Linear Regression Statistics	
No. of Samples	4
Slope	0.9607
Y-Intercept	-0.21
Correlation (r)	1.0000

Linearity Report Generated for Akshay Laboratories

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	UREA
Customer Site:	DOC OPD LABS	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-8-88000013

**LINEARITY PLOT**



Linearity Report Generated for AKSHAY LABORATORIES

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	UREA
Customer Site:	DOC OPD LABS	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-8-88000013

**LINEARITY VALUES**

Linearity Samples (Values in mg/dl)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	60	56.81
50.0%	120	113.27
100.0%	240	217

Linear Regression Statistics	
No. of Samples	4
Slope	0.9028
Y-Intercept	1.98
Correlation (r)	0.9997

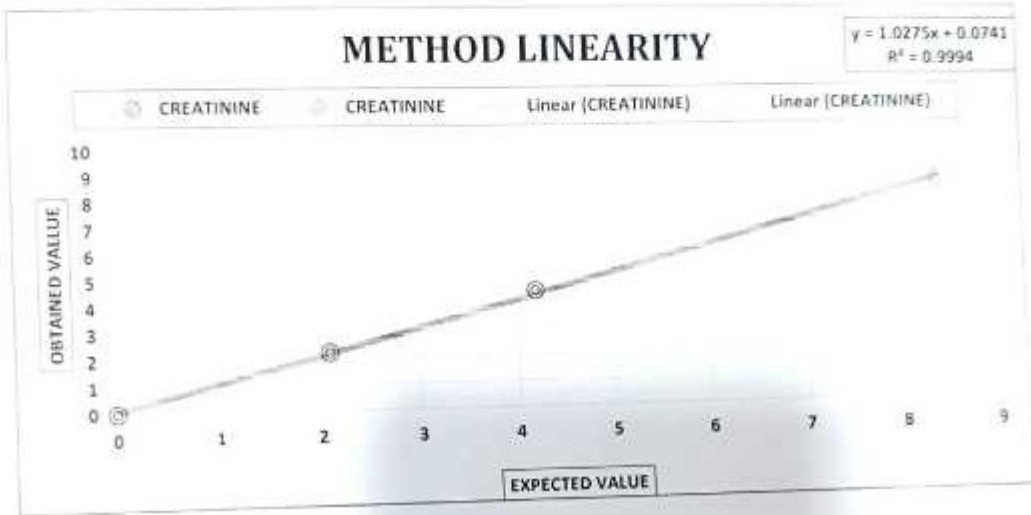
Linearity Report Generated for AKSHAY LABORATORIES



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	CREATININE
Customer Site:	DOC OPD LABS	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-8-88000013

LINEARITY PLOT



Linearity Report Generated for AKSHAY LABORATORIES

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	CREATININE
Customer Site:	DOC OPD LABS	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-8-88000013

**LINEARITY VALUES**

Linearity Samples (Values in mg/dl)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	2.09	2.24
50.0%	4.19	4.5
100.0%	8.38	8.62

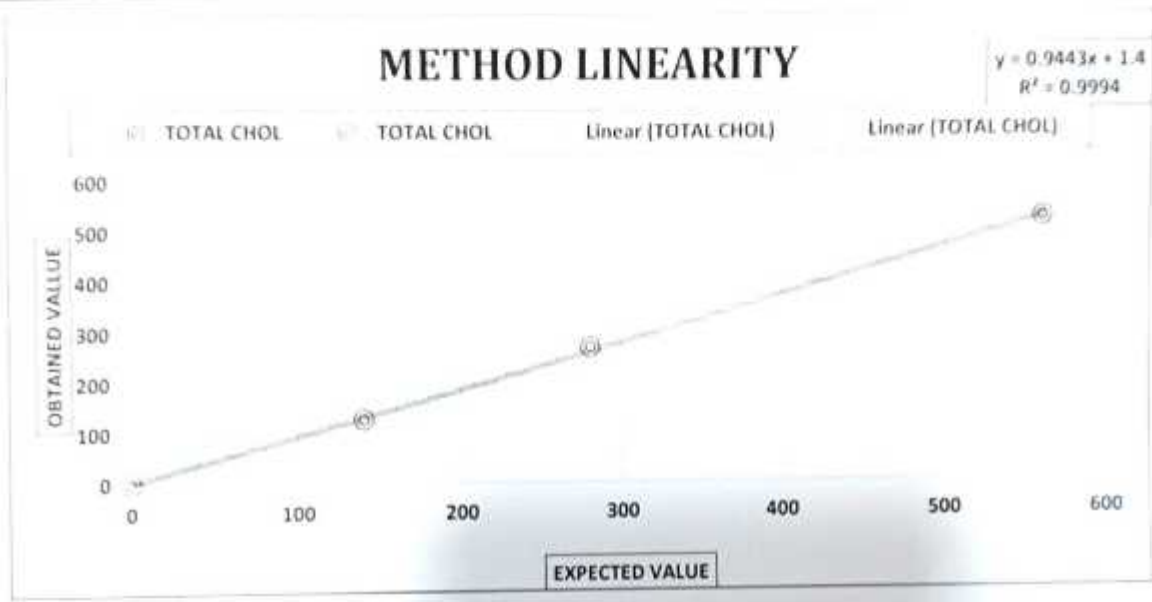
Linear Regression Statistics	
No. of Samples	4
Slope	1.0275
Y-Intercept	0.07
Correlation (r)	0.9997

Linearity Report Generated for **AKSHAY LABORATORIES**

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	TOTAL CHOLESTEROL
Customer Site:	DOC OPD LABS	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-8-88000013

**LINEARITY PLOT**



Linearity Report Generated for AKSHAY LABORATORIES

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TOTAL CHOLESTEROL
Customer Site:	DOC OPD LABS	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-8-88000013

LINEARITY VALUES

Linearity Samples (Values in mg/dl)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	140	130
50.0%	280	274
100.0%	560	527

Linear Regression Statistics	
No. of Samples	4
Slope	0.9443
Y-Intercept	1.40
Correlation (r)	0.9997

Linearity Report Generated for AKSHAY LABORATORIES

Control

- RANDOX L2
- RANDOX L2
- RANDOX L2
- RANDOX L2
- RANDOX L2
- RANDOX L1
- RANDOX L1
- RANDOX L1
- RANDOX L1
- RANDOX L1
- RANDOX I
- RANDOX
- RANDOX
- RANDOX
- RANDOX

# QC Result

DOC OPD LABS

Control	Lot No.	Chemistry	Lot No.	Unit	Measured	Set		Flag	Run Date/Time
					Result	Mean	SD		
RANDOX L2	1417UN (HN Ca		1001	mg/dL	9.10	9.06	0.88		11-11-2022 15:50:28
RANDOX L2	1417UN (HN Glu-G		1002	mg/dL	110.4	117	17.5		11-11-2022 15:58:34
RANDOX L2	1417UN (HN ALT		1002	U/L	30.7	40	8		11-11-2022 15:57:22
RANDOX L2	1417UN (HN AST		1001	U/L	33.8	38	7		11-11-2022 15:57:40
RANDOX L2	1417UN (HN ALP		1001	U/L	189.9	176	26		11-11-2022 15:54:04
RANDOX L2	1417UN (HN TP		1002	g/dL	5.15	6.1	1.22		11-11-2022 15:59:10
RANDOX L2	1417UN (HN TC		1002	mg/dL	160.7	159	21		11-11-2022 15:54:40
RANDOX L2	1417UN (HN UA		1002	mg/dL	5.59	5.58	0.72		11-11-2022 16:00:22
RANDOX L2	1417UN (HN UREA		1002	mg/dL	45.66	44.8	6.7		11-11-2022 15:55:52
RANDOX L2	1417UN (HN CREAT OPT			mg/dL	0.48	1.57	0.32		11-11-2022 15:58:34
RANDOX L2	1417UN (HN HDL (C)			mg/dL	50.13	51.7	7.7		11-11-2022 16:01:34
RANDOX L2	1417UN (HN D-bil-D II		1002	mg/dL	1.29	1.29	0.27		11-11-2022 16:01:52
RANDOX L2	1417UN (HN ALB II		1001	g/dL	4.26	4.12	0.62		11-11-2022 15:56:46
RANDOX L2	1417UN (HN T-bil-D II		1006	μmol/L	1.70	1.84	0.39		11-11-2022 16:02:28
RANDOX L2	1417UN (HN TG -AGAPPE			mg/dL	90.83	92.9	14.7		11-11-2022 16:21:39

# QC Result

Doc opd labs

Control	Lot No.	Chemistry	Lot No.	Unit	Measured Result	Set		Flag	Run Date/Time
						Mean	SD		
RANDOX L3	1174UE (HE1 Ca		1001	mg/dL	11.99	12.7	1.2		11-11-2022 15:54:58
RANDOX L3	1174UE (HE1 Glu-G		1002	mg/dL	284.7	285	44		11-11-2022 16:03:22
RANDOX L3	1174UE (HE1 ALT		1002	U/L	160.5	151	30		11-11-2022 16:02:10
RANDOX L3	1174UE (HE1 AST		1001	U/L	155.7	147	30		11-11-2022 16:03:22
RANDOX L3	1174UE (HE1 ALP		1001	U/L	341.0	325	48		11-11-2022 16:00:40
RANDOX L3	1174UE (HE1 TP		1002	g/dL	4.19	4.68	0.93		11-11-2022 16:05:46
RANDOX L3	1174UE (HE1 TC		1002	mg/dL	278.4	280	36		11-11-2022 16:02:46
RANDOX L3	1174UE (HE1 UA		1002	mg/dL	8.82	8.77	1.14		11-11-2022 16:08:28
RANDOX L3	1174UE (HE1 UREA		1002	mg/dL	118.05	120	18		11-11-2022 16:04:34
RANDOX L3	1174UE (HE1 CREAT OPT			mg/dL	1.30	3.98	0.79		11-11-2022 16:06:57
RANDOX L3	1174UE (HE1 HDL (C)			mg/dL	85.57	93.4	13.9		11-11-2022 16:09:57
RANDOX L3	1174UE (HE1 D-bil-D II		1002	mg/dL	1.54	1.54	0.32		11-11-2022 16:10:33
RANDOX L3	1174UE (HE1 ALB II		1001	g/dL	3.02	3.05	0.46		11-11-2022 16:05:27
RANDOX L3	1174UE (HE1 T-bil-D II		1006	μmol/L	5.29	5.18	1.08		11-11-2022 16:11:10
RANDOX L3	1174UE (HE1 TG -AGAPPE			mg/dL	255.88	266	43		11-11-2022 16:21:21

*[Handwritten signature]*