

BS240Pro

Automated Clinical Chemistry Analyzer



Qualification Manual:

Installation Qualification/Operation Qualification/Performance Qualification

IQ/OQ/PQ-BS240 Pro



INSTALLATION QUALIFICATION

INSTRUCTIONS:

1. This document is to be completed at the time the system is unpacked and set up for operation.
2. An authorized Mindray representative will check out 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,

SUNSHINE PATH CARE PVT LTD
SAGAR

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.



CERTIFICATION OF INSTALLATION-REPORT

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:

**SUNSHINE PATH CARE PVT LTD
SAGAR**

Signatur





CERTIFICATION OF INSTALLATION-REPORT

Analyzer Name: **BS240Pro**

Serial Number: **BC-7-18001329**

CUSTOMER NAME & ADDRESS:

**SUNSHINE PATH CARE PVT LTD
SAGAR**

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

Authorized Engineer,

Signature: 



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

IQ/OQ/PQ-BS240 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. ALIGNMENT VERIFICATION	Success

<p>Mr. Amol Patil</p> 	<p>DR. SURYA DUBEY</p> <p>Designation: M.D PATHOLOGY</p> 
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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:

**SUNSHINE PATH CARE PVT LTD
SAGAR**

Authorized Engineer's Signature

Date: 08.06.2022



Customer's Signature

Date: 08.06.2022

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

<p>Mr. Amol Patil</p> 	<p>DR. SURYA DUBEY</p> <p>Designation: M.D PATHOLOGY</p> 
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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 – BS240 Pro*
2. *Service Manual – BS240 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:

**SUNSHINE PATH CARE PVT LTD
SAGAR**

Authorized Engineer's Signature

A handwritten signature in black ink, appearing to be 'E. C. ...', written over a light blue horizontal line.

Date 08.06.2022

IQ/OQ/PQ-BS240 Pro



Customer's Signature

A handwritten signature in black ink, appearing to be 'Sagar', written over a light blue horizontal line.

Date: 08.06.2022

PERFORMANCEQUALIFICATIONVERIFICATIONREPORT

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. SURYA DUBEY</p> <p>Designation: M.D PATHOLOGY</p> <p>Signature: </p>
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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	BS240Pro & BC-7-18001329
Date of Validation	08.06.2022
Method	Photometry
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Name of LABORATORIES	SUNSHINE PATH CARE PVT LTD
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 **BS240Pro**

Reported By 
 Name - Viraj
 Designation - Manager
 Technical Company - Avantor

Accuracy:

Equipmentname& SerialNo	BS-240Pro&S. No:BC-7-18001329
Validatedduring	08.06.2022
Method	Photometryat37°C
Manufacturer	ShenzhenMindrayBio-MedicalElectronicsCo., Ltd
NameofLaboratory/Hospital	SUNSHINE PATH CARE PVT LTD
Department	Laboratory

TESTSVALIDATED–Glucose,Urea,Creatinine,TotalCholesterol,Triglycerides,SGOT,SGPT,
Albumin, Total Protein, Albumin, Total Protein, Total Bilirubin,Direct
Bilirubin,Calcium

Accuracyprotocol:

The accuracy of **BS-240 Pro- S. No: BC-7-18001329**been verified by analyzing Multi-Sera Calibrator **LOT No:150121008**.

S. No	Parameter	ValueObtained	CalibratorConcentration
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-7-18001329has been verified by analyzing the Multi-Sera Calibrator the results obtainedwere satisfactory

ReportedBy

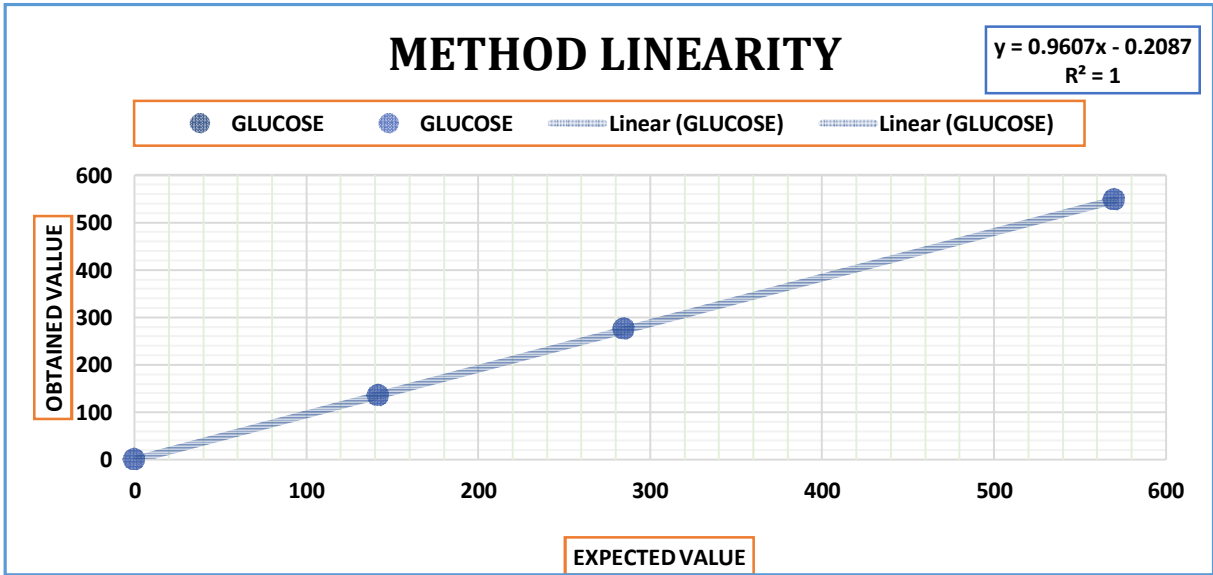


Viraj Kale
Manager-
TechnicalIVD-
Automation
+91-9930033581

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	GLUCOSE
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	Viraj Kale	Serial Number:	BC-7-18001329

LINEARITY PLOT





LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	GLUCOSE
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	Viraj Kale	Serial Number:	BC-7-18001329

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

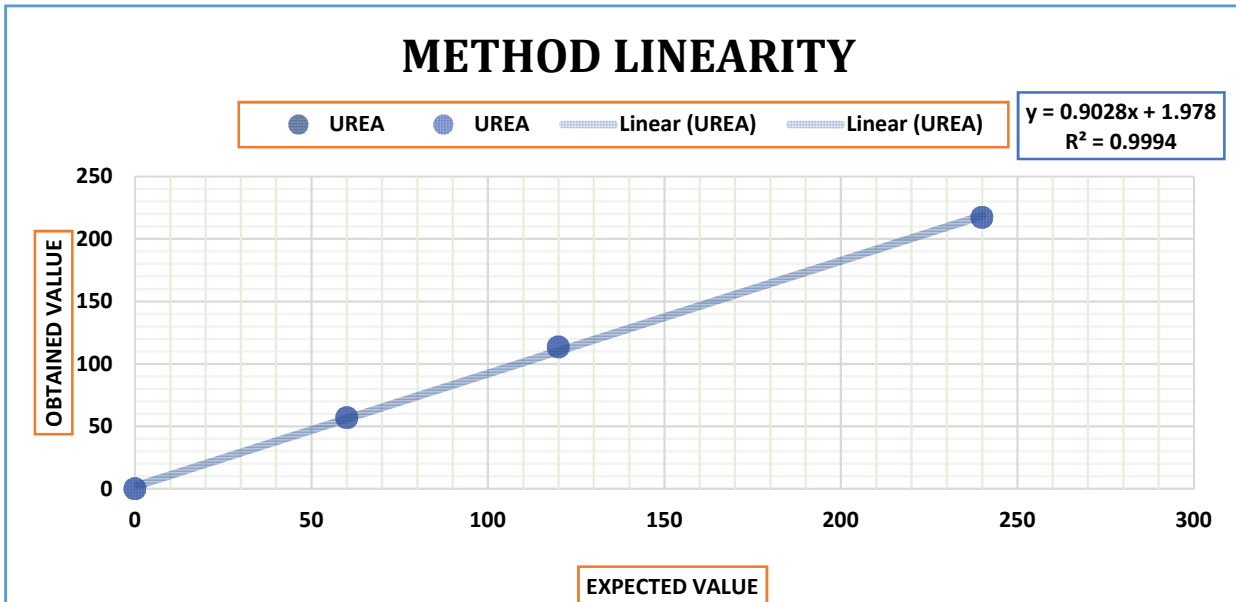
Linear Regression Statistics	
No. of Samples	4
Slope	0.9607
Y-Intercept	-0.21
Correlation (r)	1.0000

Linearity Report Generated for Akshay Laboratories

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	UREA
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	UREA
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

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

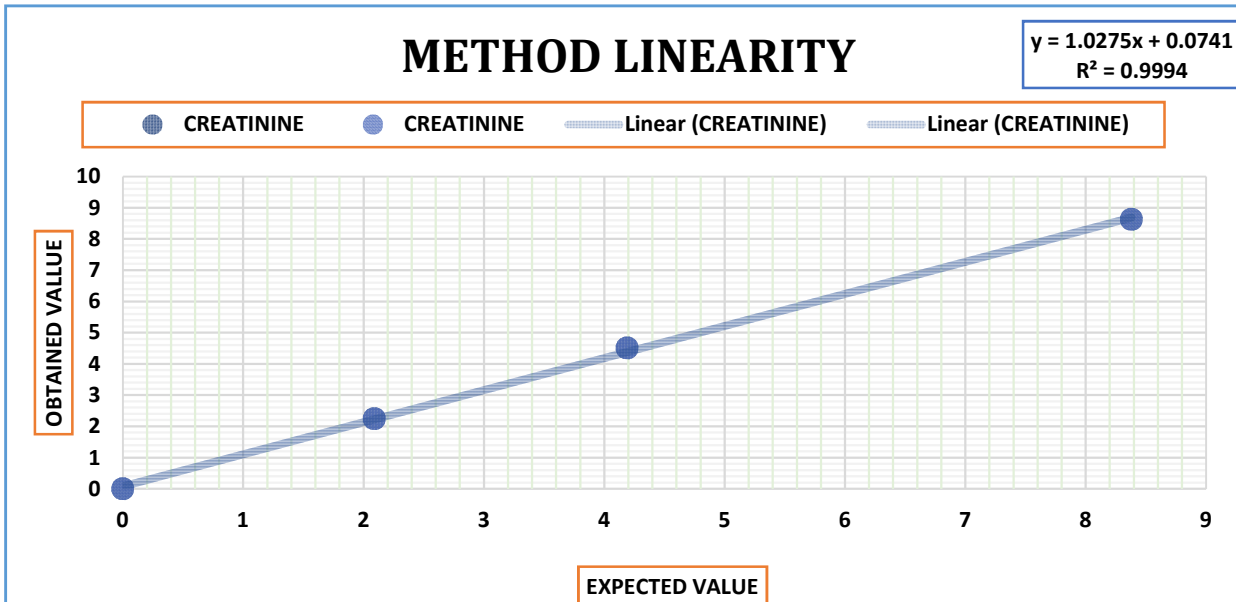
Linear Regression Statistics	
No. of Samples	4
Slope	0.9028
Y-Intercept	1.98
Correlation (r)	0.9997

Linearity Report Generated for AKSHAY LABORATORIES

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	CREATININE
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	CREATININE
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

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

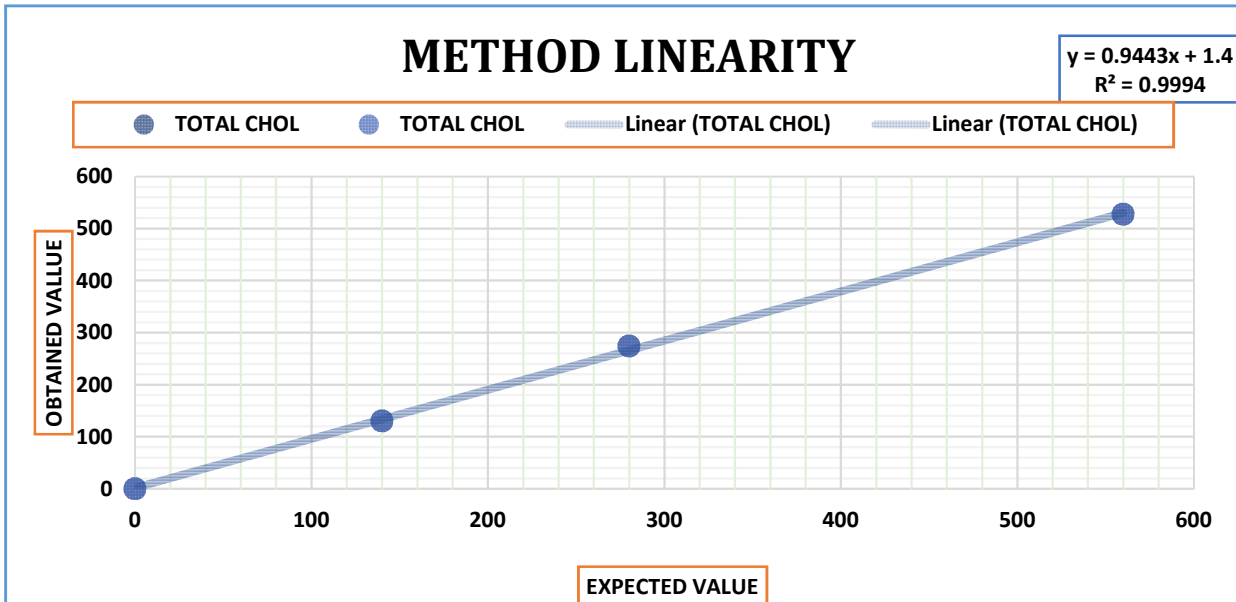
Linear Regression Statistics	
No. of Samples	4
Slope	1.0275
Y-Intercept	0.07
Correlation (r)	0.9997

Linearity Report Generated for AKSHAY LABORATORIES

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TOTAL CHOLESTEROL
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TOTAL CHOLESTEROL
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

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

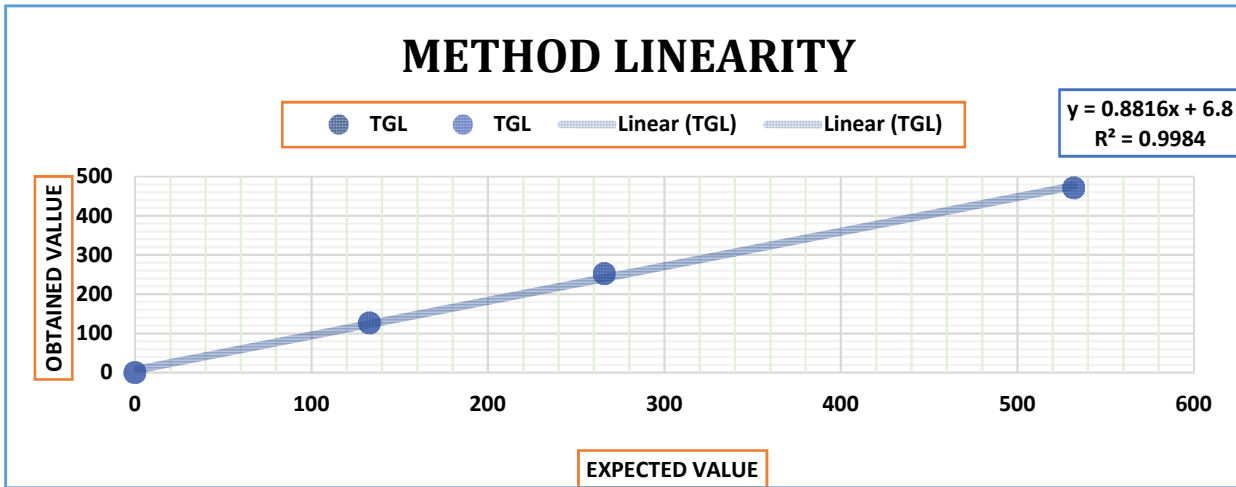
Linear Regression Statistics	
No. of Samples	4
Slope	0.9443
Y-Intercept	1.40
Correlation (r)	0.9997

Linearity Report Generated for AKSHAY LABORATORIES

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TRIGLYCERIDES
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TRIGLYCERIDES
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY VALUES

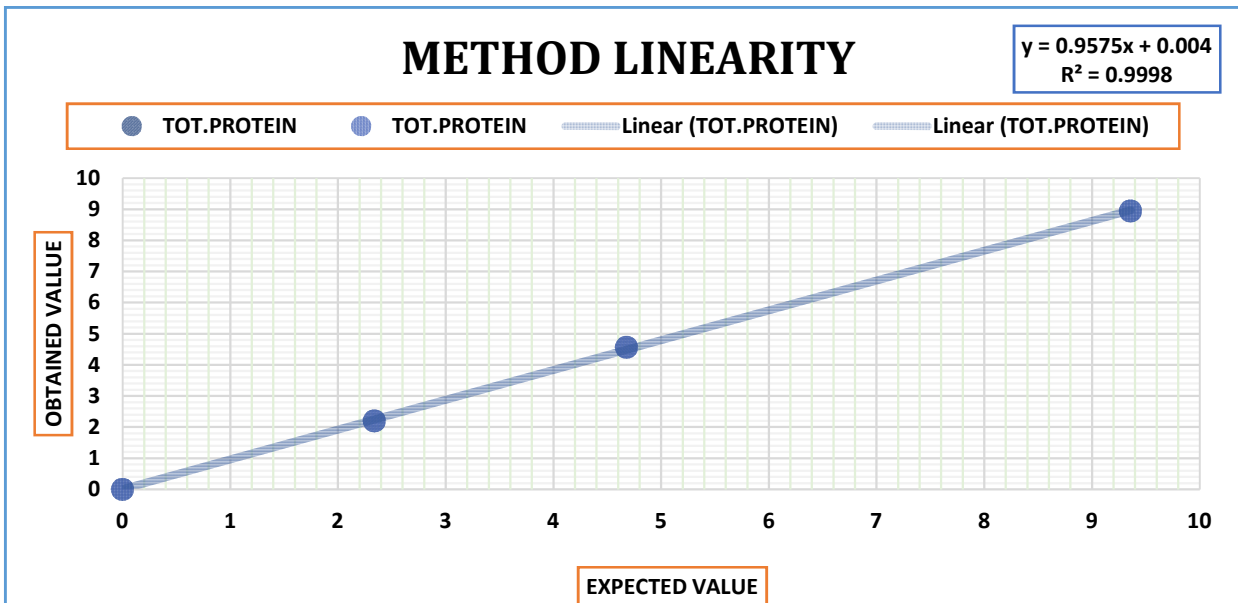
Linearity Samples (Values in mg/dl)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	133	126
50.0%	266	252
100.0%	532	470.00

Linear Regression Statistics	
No. of Samples	4
Slope	0.8816
Y-Intercept	6.80
Correlation (r)	0.9992

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TOTAL PROTEIN
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TOTAL PROTEIN
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY VALUES

Linearity Samples (Values in g/dl)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	2.34	2.2
50.0%	4.68	4.56
100.0%	9.36	8.94

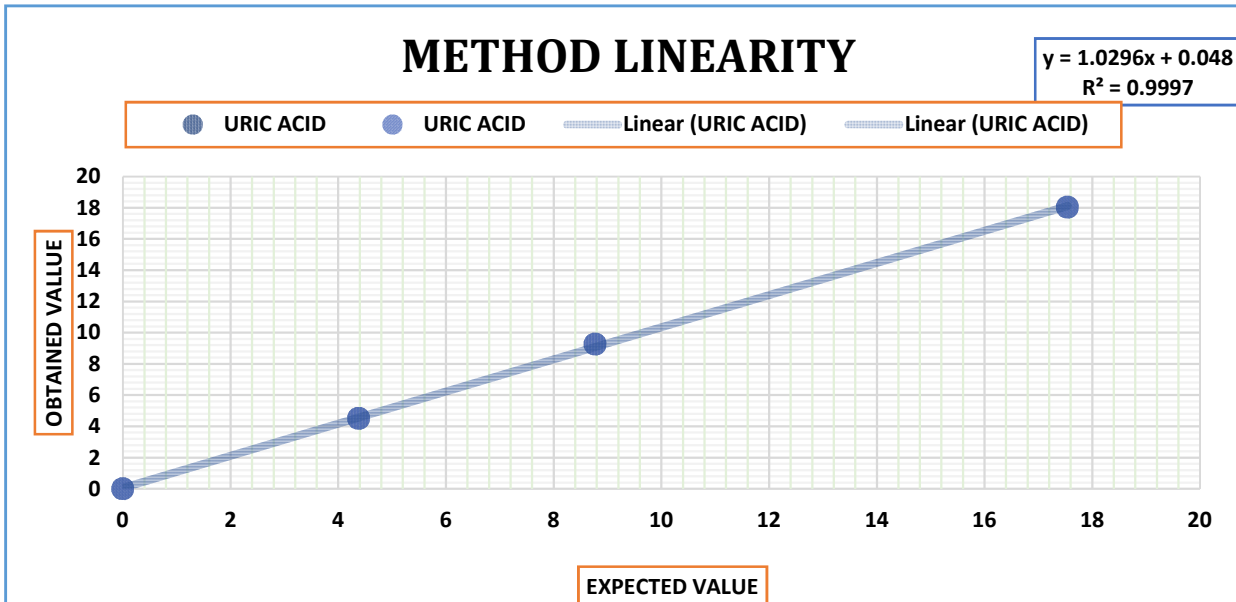
Linear Regression Statistics	
No. of Samples	4
Slope	0.9575
Y-Intercept	0.00
Correlation (r)	0.9999

Linearity Report Generated for AKSHAY LABORATORIES

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	URIC ACID
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	URIC ACID
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY VALUES

Linearity Samples (Values in mg/dl)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	4.38	4.5
50.0%	8.77	9.26
100.0%	17.54	18.03

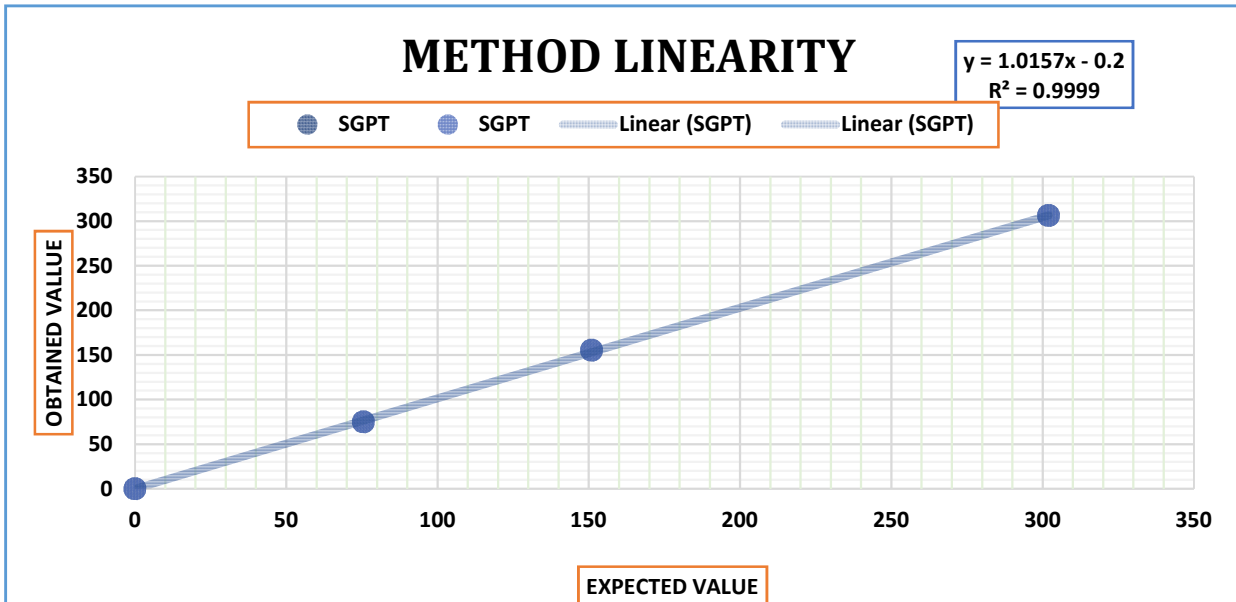
Linear Regression Statistics	
No. of Samples	4
Slope	1.0296
Y-Intercept	0.05
Correlation (r)	0.9999

Linearity Report Generated for AKSHAY LABORATORIES

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	SGPT
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT





LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	SGPT
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY VALUES

Linearity Samples (Values in IU/L)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	75.5	75
50.0%	151	155
100.0%	302	306

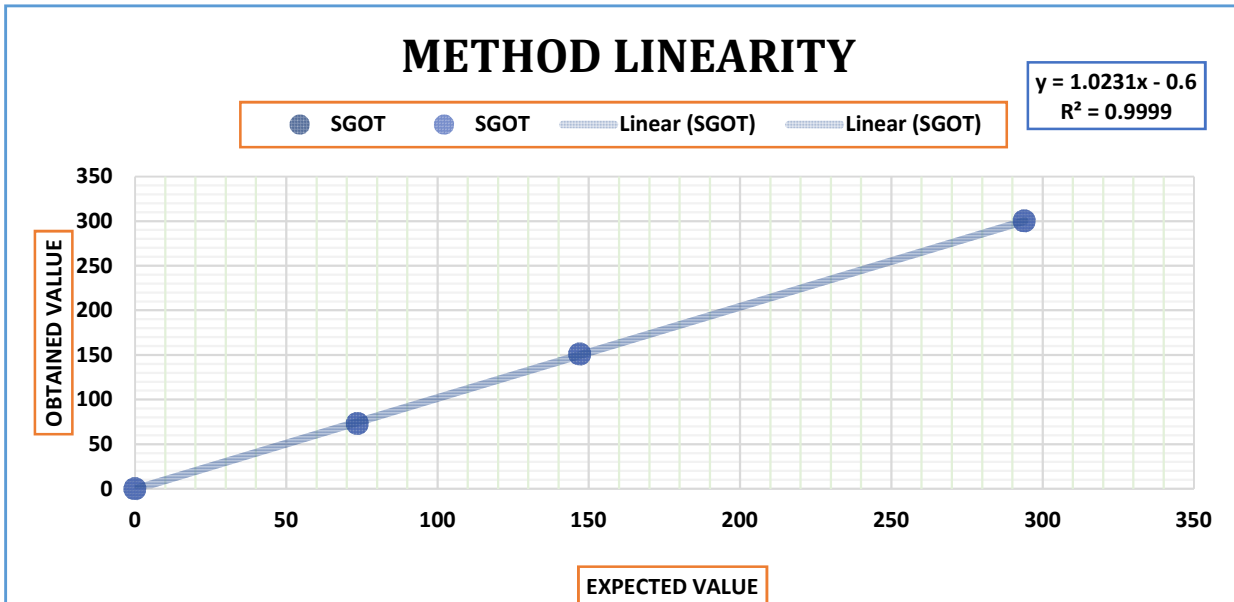
Linear Regression Statistics	
No. of Samples	4
Slope	1.0157
Y-Intercept	-0.20
Correlation (r)	0.9999

Linearity Report Generated for AKSHAY LABORATORIES

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	SGOT
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT





LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	SGOT
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY VALUES

Linearity Samples (Values in IU/L)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	73.5	73
50.0%	147	151
100.0%	294	300

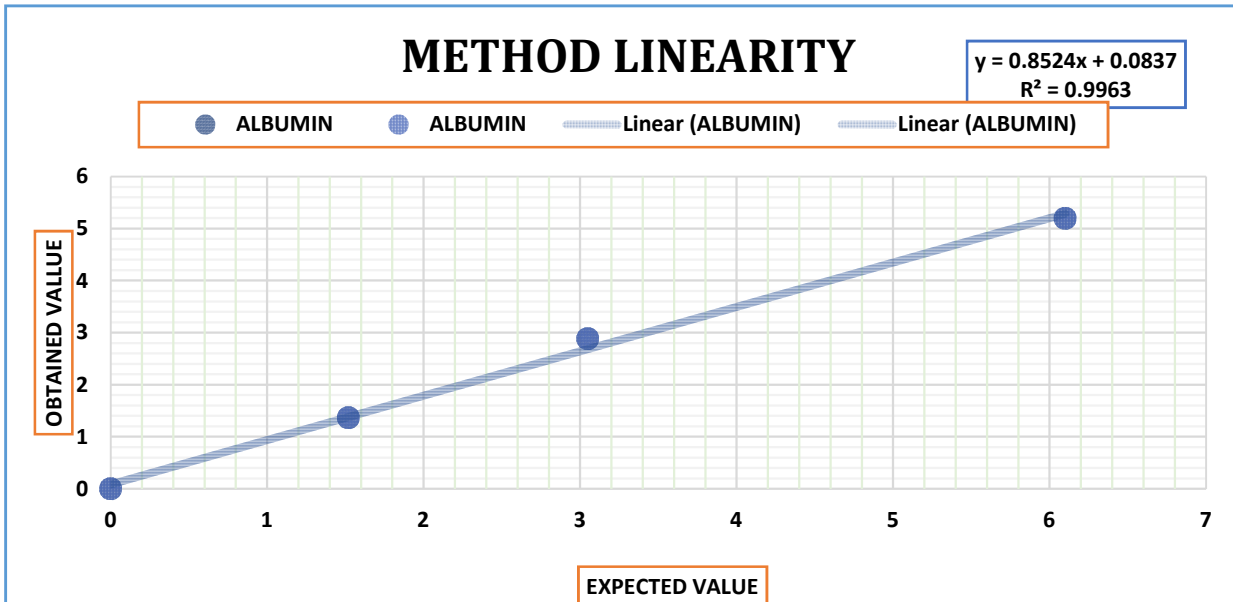
Linear Regression Statistics	
No. of Samples	4
Slope	1.0231
Y-Intercept	-0.60
Correlation (r)	1.0000

Linearity Report Generated for AKSHAY LABORATORIES

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	ALBUMIN
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	ALBUMIN
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY VALUES

Linearity Samples (Values in g/dl)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	1.52	1.36
50.0%	3.05	2.88
100.0%	6.1	5.19

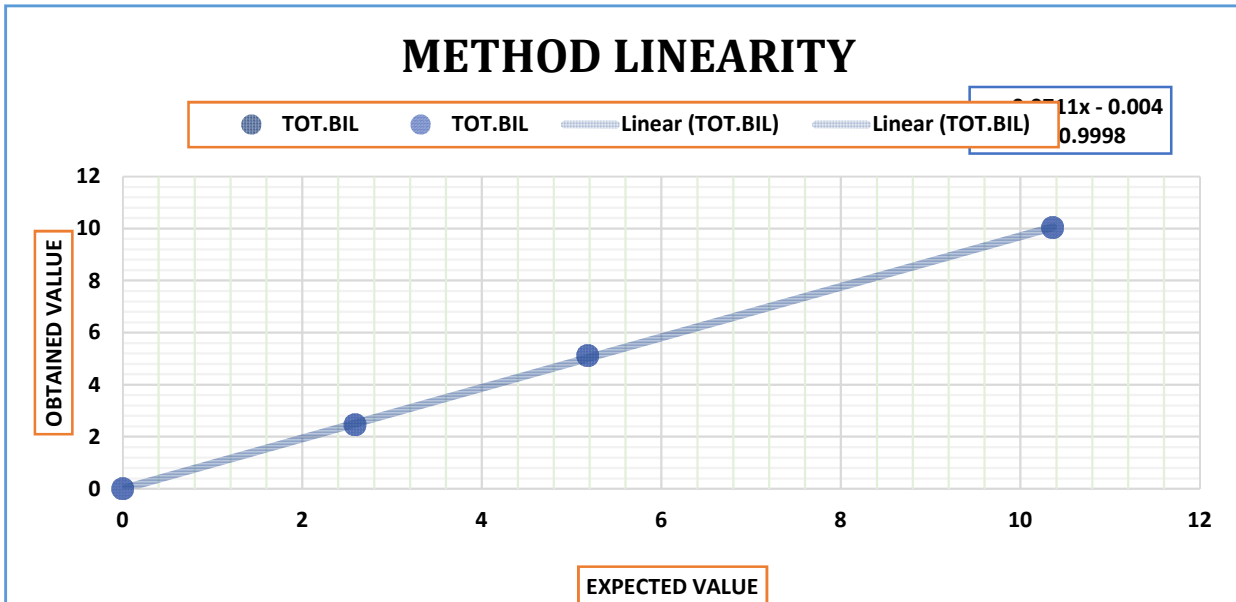
Linear Regression Statistics	
No. of Samples	4
Slope	0.8524
Y-Intercept	0.08
Correlation (r)	0.9982

Linearity Report Generated for AKSHAY LABORATORIES

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TOTAL BILIRUBIN
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TOTAL BILIRUBIN
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY VALUES

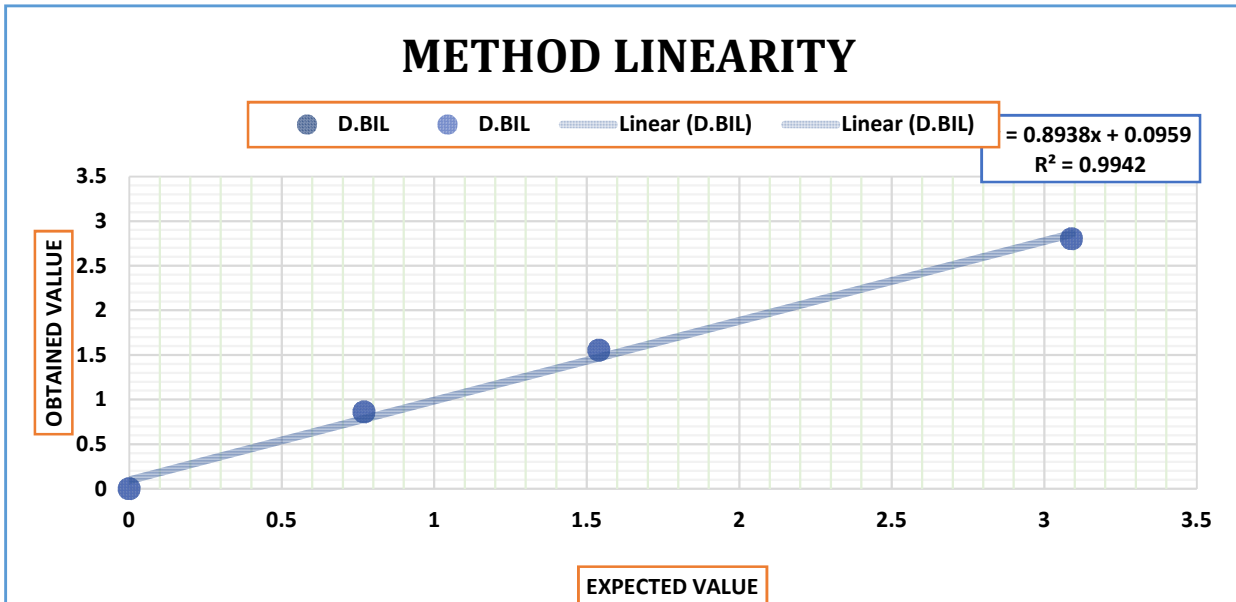
Linearity Samples (Values in mg/dl)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	2.59	2.45
50.0%	5.18	5.11
100.0%	10.36	10.03

Linear Regression Statistics	
No. of Samples	4
Slope	0.9711
Y-Intercept	0.00
Correlation (r)	0.9999

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	DIRECT BILIRUBIN
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	DIRECT BILIRUBIN
Customer Site:	SUNSHINE PATH CARE PVT LTD	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY VALUES

Linearity Samples (Values in mg/dl)		
Sample	Expected	Obtained
0.0%	0	0
25.0%	0.77	0.86
50.0%	1.54	1.55
100.0%	3.09	2.8

Linear Regression Statistics	
No. of Samples	4
Slope	0.8938
Y-Intercept	0.10
Correlation (r)	0.9971

QC Result

Control	Lot No.	Chemistry	Lot No.	Unit	Measured	Set		Flag	Run Date/Time
					Result	Mean	SD		
CONL2	1550UN	GLUR		mg/dL	109	111	8.3		24-11-2022 10:31:13
CONL2	1550UN	CHOLR		mg/dL	161	157	10		24-11-2022 10:26:28
CONL2	1550UN	TGR		mg/dL	89	96.5	7.65		24-11-2022 10:26:58
CONL2	1550UN	SGOTR		U/L	32.1	36	3.5		24-11-2022 10:30:13
CONL2	1550UN	SGPTR		U/L	39.2	41	4		24-11-2022 10:30:28
CONL2	1550UN	CREATH		mg/dL	1.21	1.47	0.15		24-11-2022 10:29:13
CONL2	1550UN	ALBR		g/dL	3.98	4.06	0.31		24-11-2022 10:27:58
CONL2	1550UN	ALPR		U/L	204.5	203	15		24-11-2022 10:32:13
CONL2	1550UN	CAR		mg/dL	8.3	8.74	0.42		24-11-2022 10:28:28
CONL2	1550UN	TPR		g/dL	5.3	5.74	0.58		24-11-2022 10:33:59
CONL2	1550UN	UREAR		mg/dL	40.4	43.9	3.3		24-11-2022 10:32:58
CONL2	1550UN	UAR		mg/dL	5.43	5.75	0.37		24-11-2022 10:29:13
CONL2	1550UN	HDLR		mg/dL	46.4	50.6	3.9		24-11-2022 10:37:29
CONL2	1550UN	D-BILIH		mg/dL	1.01	1.12	0.12		24-11-2022 10:29:43
CONL2	1550UN	T-BILIH		mg/dL	1.56	1.68	0.14		24-11-2022 10:27:13
CONL2	1550UN	LDL		mg/dL	93.8	85	10		24-11-2022 10:36:14
CONL2	1550UN	IRON B		µg/dL	84.1	104	9.3		24-11-2022 10:35:59