

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,

**S.S PATHLAB
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.

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:

S.S PATHLAB
SAGAR
SUNSHINE PATHCARE PVT. LTD.

Signature:

CERTIFICATION OF INSTALLATION – REPORT

Analyzer Name: **BS 240 Pro**

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

CUSTOMER NAME & ADDRESS:

S.S PATHLAB
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 -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:

S.S PATHLAB
SAGAR

SUNSHINE PATHCARE PVT. LTD.

Authorized Engineer's Signature

Customer's Signature


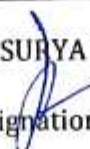

Date: 08.06.2022

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>  <p>(Signature)</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 –BS 240 Pro*
2. *Service Manual – 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:
S.S PATHLAB

SUNSHINE HEALTHCARE PVT. LTD.

Authorized Engineer's Signature

Date: 08.06.2022

Customer's Signature

Date: 08.06.2022

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. 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	BS 240 Pro & BC-7-18001329
Date of Validation	08.06.2022
Method	Photometry
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Name of LABORATORIES	S.S PATHLAB
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

Accuracy:

Equipment name & Serial No	BS-240 Pro & S. No: BC-7-18001329
Validated during	08.06.2022
Method	Photometry at 37°C
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Name of Laboratory/Hospital	S.S PATHLAB
Department	Laboratory

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

Accuracy protocol:

The accuracy of BS-240 Pro- S. No: BC-7-18001329 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-7-18001329 has been verified by analyzing the Multi-Sera Calibrator the results obtained were satisfactory

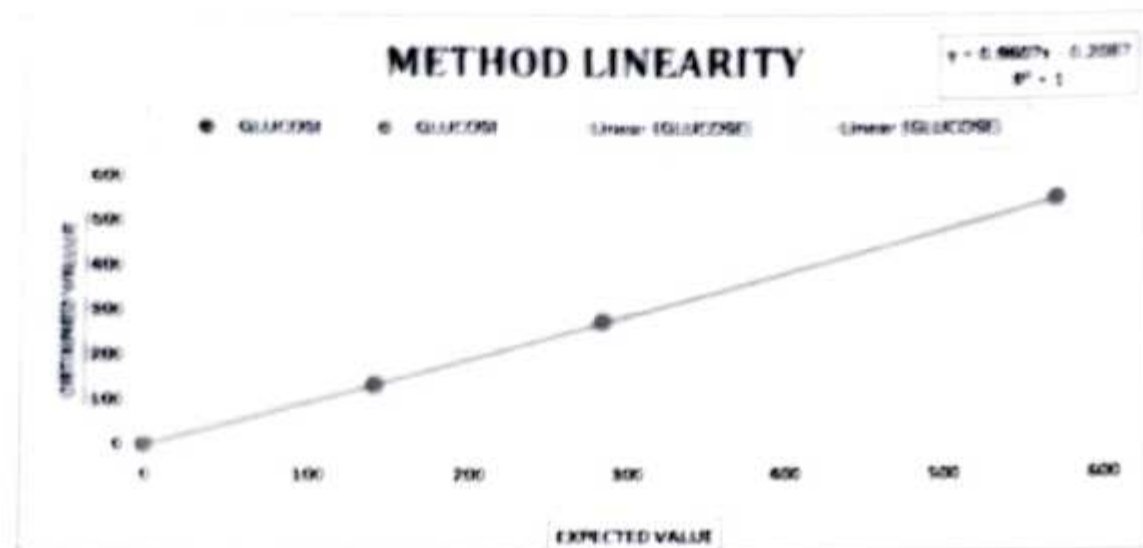
Reported By



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

LINEARITY ANALYSIS REPORT

Date of Analysis:	05.05.2023	Analyte:	GLUCOSE
Customer Site:	S. S. PATH, AB	Test Equip:	Mindray BS-240 PRO
Analyst:	Vinay Kulkarni	Serial Number:	BC-7-18001329

LINEARITY PLOT


LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	GLUCOSE
Customer Site:	S.S PATHLAB	Test Equip:	Mindray BS-240 PRO
Analyst:	Viraj Kale	Serial Number:	BC-7-18001329

LINEARITY VALUES

Sample	Expected	Obtained
0.0%	0	0
25.0%	142	135
50.0%	285	275
100.0%	570	547

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

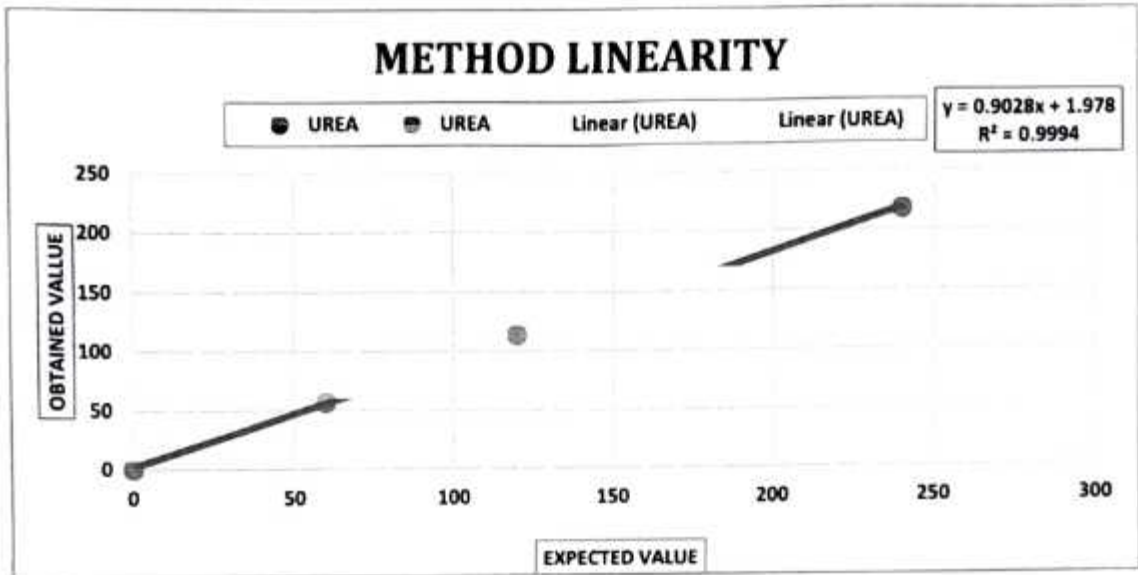
Linearity Report Generated for Akshay Laboratories



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	UREA
Customer Site:	S.S PATHLAB	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:	S.S PATHLAB	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

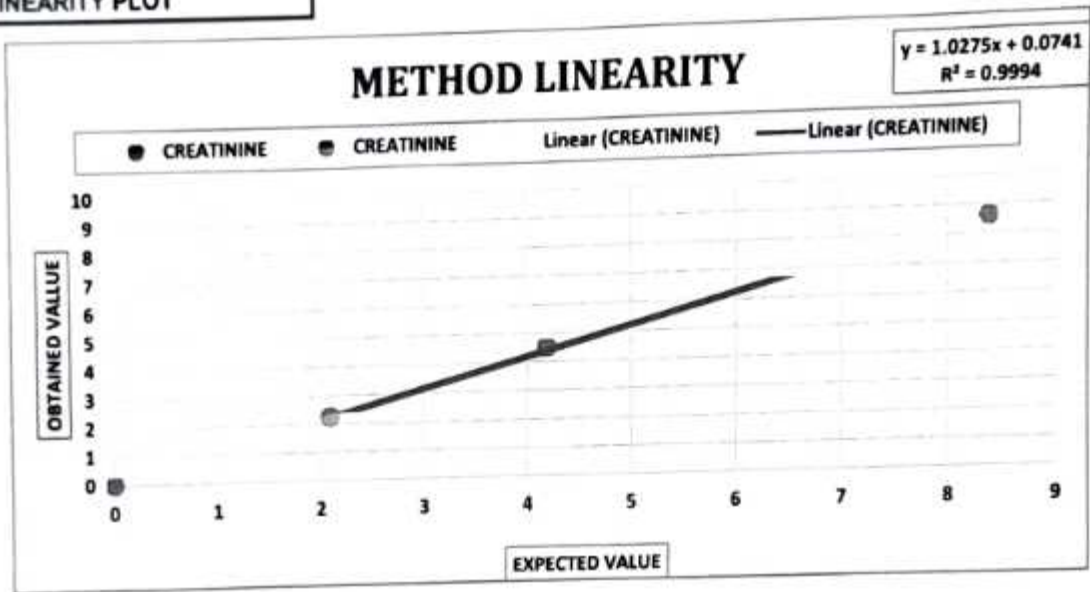
Linearity Report Generated for AKSHAY LABORATORIES



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	CREATININE
Customer Site:	S.S PATHLAB	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:	S.S PATHLAB	Test Equip:	Mindray BS-240 PRO
Analyt:	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

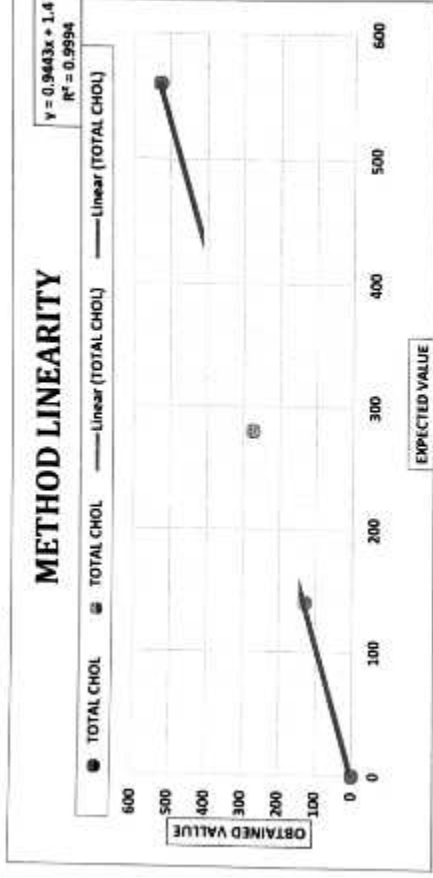
Linear Regression Statistics	
No. of Samples	4
Slope	1.0275
Y-Intercept	0.07
Correlation (r)	0.9997

Linearity Report Generated for AKSHAY LABORATORIES

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TOTAL CHOLESTEROL
Customer Site:	S-S PATHLAB	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:	S.S PATHLAB	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:	S.S PATHLAB	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

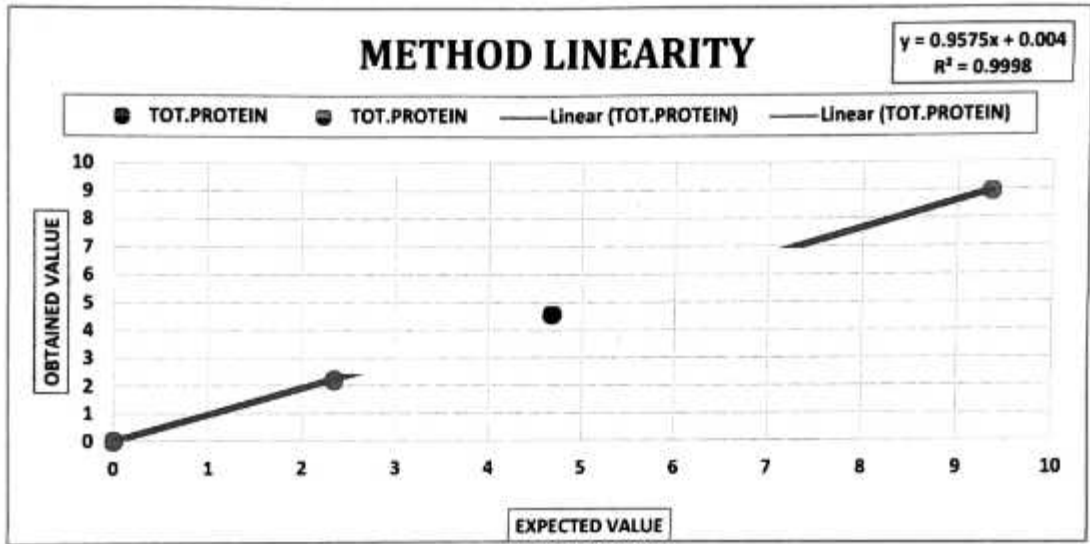
Linearity Report Generated for AKSHAY LABORATORIES



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TOTAL PROTEIN
Customer Site:	S.S PATHLAB	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:	S.S PATHLAB	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

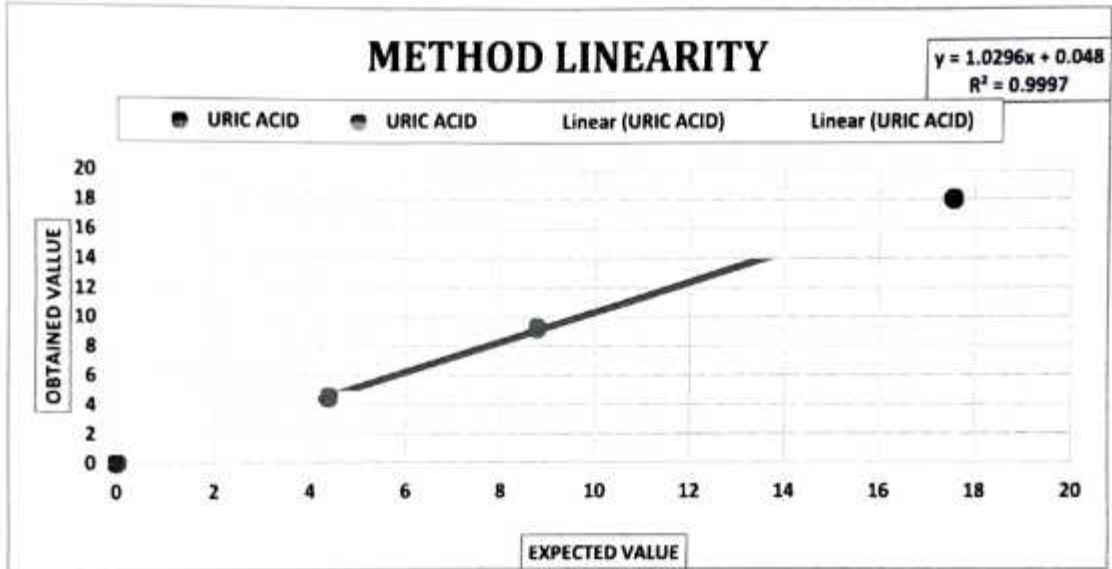
Linearity Report Generated for AKSHAY LABORATORIES



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	URIC ACID
Customer Site:	S.S PATHLAB	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:	S.S PATHLAB	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

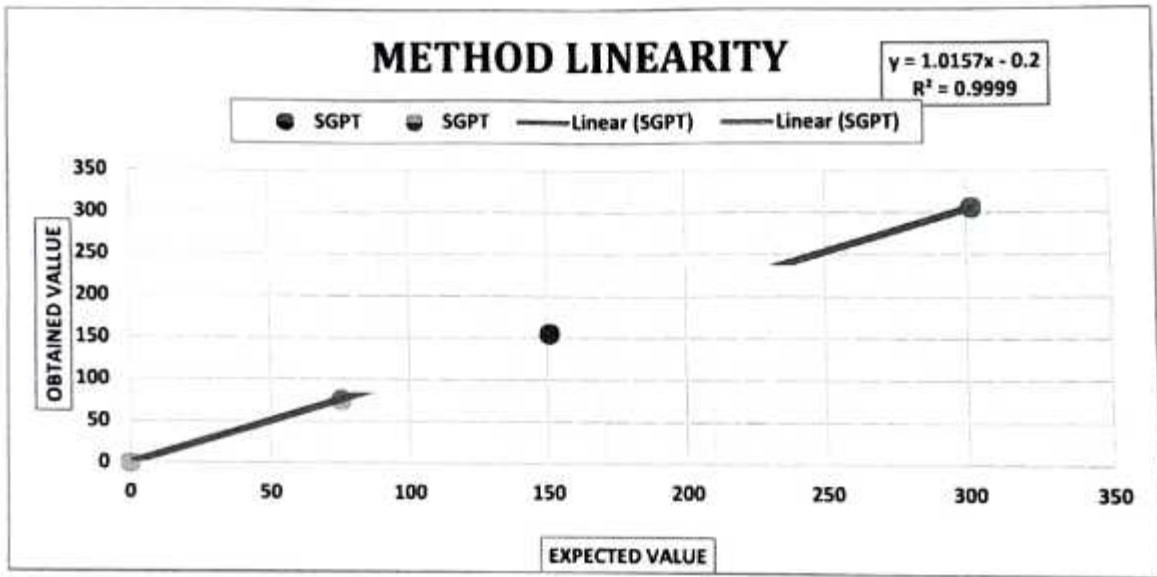
Linearity Report Generated for AKSHAY LABORATORIES



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	SGPT
Customer Site:	S.S PATHLAB	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:	S.S PATHLAB	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

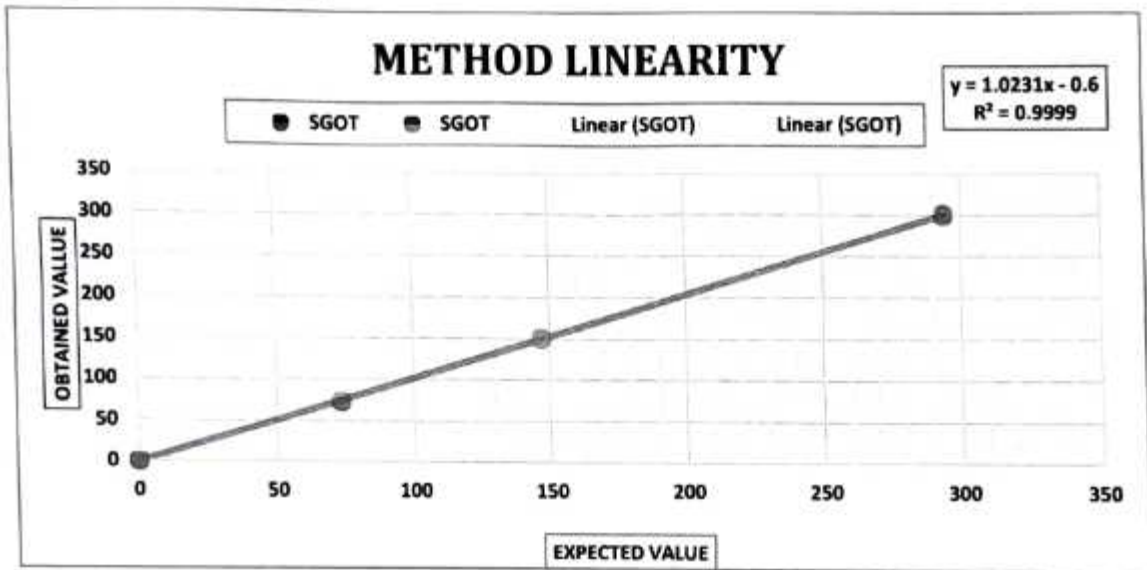
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LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	SGOT
Customer Site:	S.S PATHLAB	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT



Linearity Report Generated for AKSHAY LABORATORIES



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	SGOT
Customer Site:	S.S PATHLAB	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

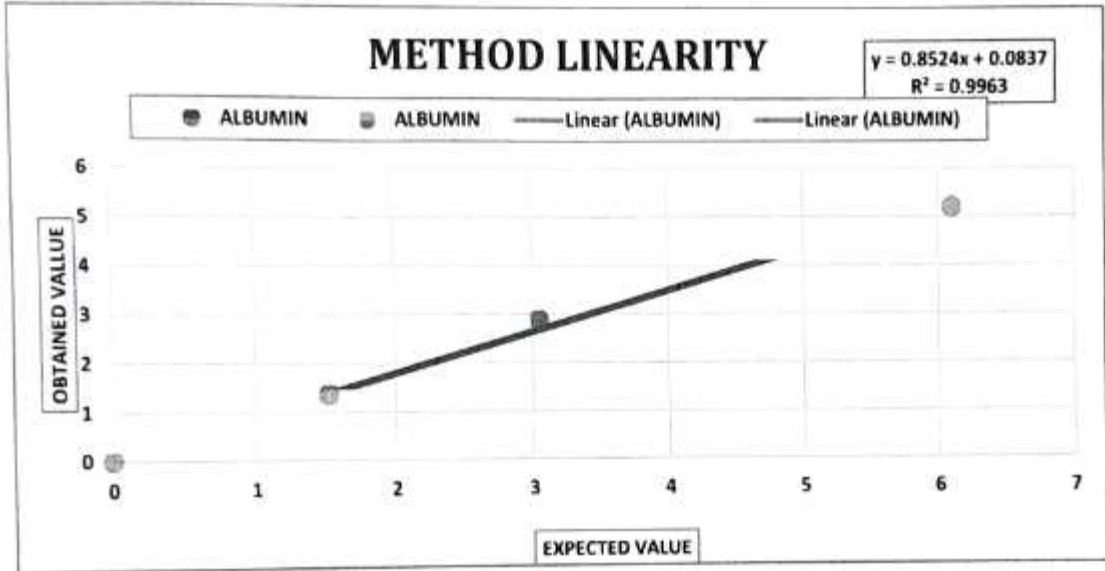
Linearity Report Generated for AKSHAY LABORATORIES




LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	ALBUMIN
Customer Site:	S.S PATHLAB	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT



Linearity Report Generated for AKSHAY LABORATORIES





LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	ALBUMIN
Customer Site:	S.S PATHLAB	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

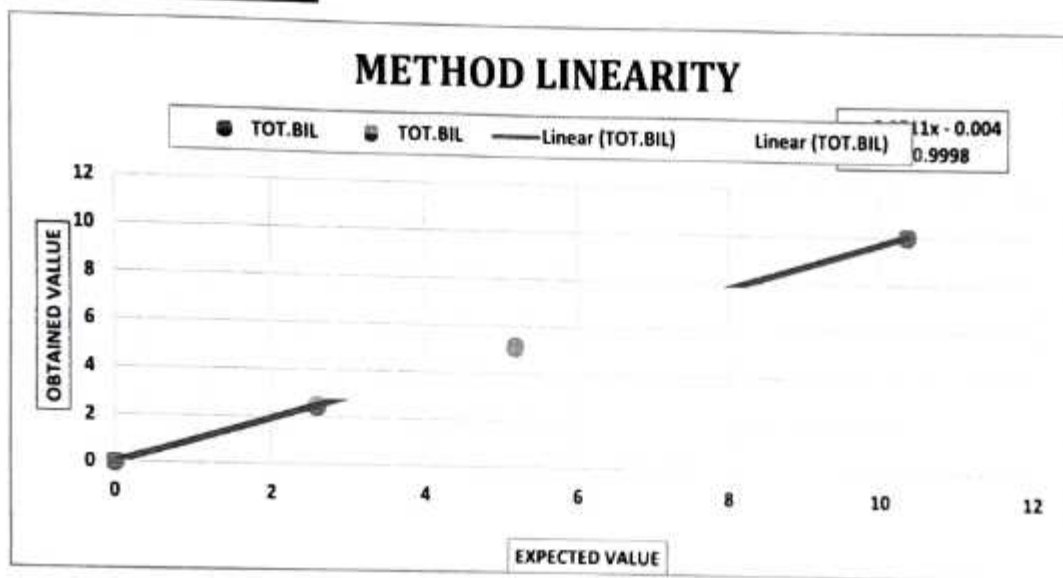
Linear Regression Statistics	
No. of Samples	4
Slope	0.8524
Y-Intercept	0.08
Correlation (r)	0.9982

 Linearity Report Generated for AKSHAY LABORATORIES
 

LINEARITY ANALYSIS REPORT

Date of Analysis:	08.06.2022	Analyte:	TOTAL BILIRUBIN
Customer Site:	S.S PATHLAB	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:	S.S PATHLAB	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

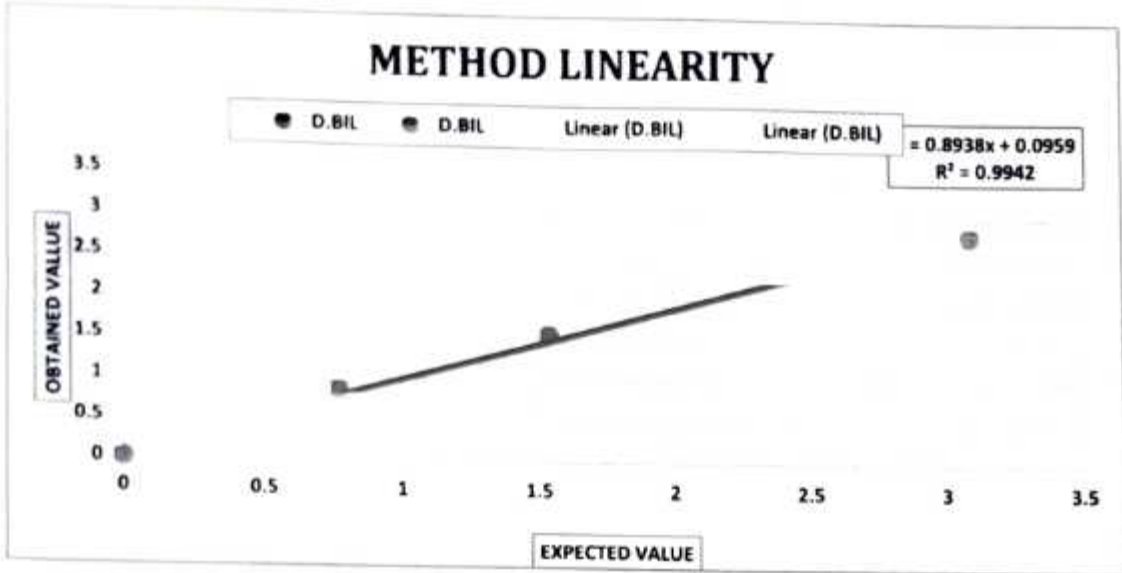
Linearity Report Generated for AKSHAY LABORATORIES



LINEARITY ANALYSIS REPORT

Date of Analysis:	08.11.2021	Analyte:	DIRECT BILIRUBIN
Customer Site:	S.S PATHLAB	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

LINEARITY PLOT




LINEARITY ANALYSIS REPORT

Date of Analysis:	08.11.2021	Analyte:	DIRECT BILIRUBIN
Customer Site:	S.S PATHLAB	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

Linearity Report Generated for AKSHAY LABORATORIES



Control	Lot No.	Chemistry	Lot No.	Unit	Measured Result	Set		Flag	Run Date/Time
						Mean	SD		
CONL2	1550UN	GLUR		mg/dL	116	111	8.3		04-12-2022 10:30:31
CONL2	1550UN	CHOLR		mg/dL	173	157	10	3.0s	04-12-2022 10:25:46
CONL2	1550UN	CHOLR		mg/dL	160	157	10		04-12-2022 11:07:01
CONL2	1550UN	TGR		mg/dL	97	96.5	7.65		04-12-2022 10:26:16
CONL2	1550UN	SGOTR		U/L	37.0	36	3.5		04-12-2022 10:29:31
CONL2	1550UN	SGPTR		U/L	43.6	41	4		04-12-2022 10:29:46
CONL2	1550UN	CREATH		mg/dL	1.51	1.47	0.15		04-12-2022 10:28:31
CONL2	1550UN	ALBR		g/dL	4.14	4.06	0.31		04-12-2022 10:27:16
CONL2	1550UN	ALPR		U/L	218.7	203	15		04-12-2022 10:31:31
CONL2	1550UN	CAR		mg/dL	9.3	8.74	0.42		04-12-2022 10:27:46
CONL2	1550UN	TPR		g/dL	5.4	5.74	0.58		04-12-2022 10:33:17
CONL2	1550UN	UREAR		mg/dL	42.4	43.9	3.3		04-12-2022 10:32:16
CONL2	1550UN	UAR		mg/dL	5.65	5.75	0.37		04-12-2022 10:28:31
CONL2	1550UN	HDLR		mg/dL	49.8	50.6	3.9		04-12-2022 10:36:47
CONL2	1550UN	D-BILIH		mg/dL	1.15	1.12	0.12		04-12-2022 10:29:01
CONL2	1550UN	T-BILIH		mg/dL	1.66	1.68	0.14		04-12-2022 10:26:31
CONL2	1550UN	LDL		mg/dL	96.1	85	10		04-12-2022 10:35:32
CONL2	1550UN	IRON B		µg/dL	108.2	104	9.3		04-12-2022 10:35:17