

First Line

Second Line

QC(Name-Lot)	Test	Target Value	SD Value	QC Range	Result	Test Date	State
PATHOLYTE--29249	GLUC	260	33	195 ~ 325	257	27-04-2023	
PATHOLYTE--29249	ALB	4.7	0.6	3.5 ~ 5.8	5.0	27-04-2023	
PATHOLYTE--29249	UREA	142	20	102 ~ 182	134	27-04-2023	
PATHOLYTE--29249	TP	8.20	1.10	6.00 ~ 10.40	7.50	27-04-2023	
PATHOLYTE--29249	SGPT	132	17	99 ~ 165	122	27-04-2023	
PATHOLYTE--29249	CREAT	4.10	0.64	2.82 ~ 5.38	4.09	27-04-2023	
PATHOLYTE--29249	SGOT	115	16	83 ~ 147	125	27-04-2023	
PATHOLYTE--29249	UA	8.1	1.3	5.6 ~ 10.6	7.5	27-04-2023	
PATHOLYTE--29249	HDL - D	59	8	44 ~ 74	55	27-04-2023	
PATHOLYTE--29249	GGT	90	12	67 ~ 113	83	27-04-2023	
PATHOLYTE--29249	ALP	346	11	324 ~ 368	331	27-04-2023	
PATHOLYTE--29249	CALCIUM	10.50	1.48	7.54 ~ 13.46	11.38	27-04-2023	
PATHOLYTE--29249	CHOL	190	18	154 ~ 226	182	27-04-2023	
PATHOLYTE--29249	PHOS	6.8	0.8	5.1 ~ 8.5	6.0	27-04-2023	
PATHOLYTE--29249	TGL	192	19	155 ~ 229	185	27-04-2023	
PATHOLYTE--29249	BIL D	1.38	0.26	0.86 ~ 1.90	1.75	27-04-2023	
PATHOLYTE--29249	TBIL	3.94	0.49	2.96 ~ 4.92	3.64	27-04-2023	
PATHOLYTE--29249	IRON	247.00	15.00	217.00 ~ 277.00	158.79	27-04-2023	1-2S 1-3S

# **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,

**RSD HOSPITAL & RESEARCH CENTER**  
**MORADABAD**

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:

**RSD HOSPITAL & RESEARCH CENTER  
MORADABAD**

Signatur





**CERTIFICATION OF INSTALLATION-REPORT**

Analyzer Name: **BS240Pro**

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

**CUSTOMER NAME & ADDRESS:**

**RSD HOSPITAL & RESEARCH CENTER  
MORADABAD**

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:

**RSD HOSPITAL & RESEARCH CENTER  
MORADABAD**

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.

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

**RSD HOSPITAL & RESEARCH CENTER  
MORADABAD**

Authorized Engineer's Signature

A handwritten signature in blue ink, appearing to read 'E. Chaudhary', is 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 a stylized name, is 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	<b>BS240Pro &amp; BC-7-18001329</b>
Date of Validation	<b>08.06.2022</b>
Method	<b>Photometry</b>
Manufacturer	<b>Shenzhen Mindray Bio-Medical Electronics Co., Ltd</b>
Name of LABORATORIES	<b>RSD HOSPITAL &amp; RESEARCH CENTER</b>
Department	<b>LABORATORY</b>

**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%	<b>1.1%</b>
2	Urea (mg/dl)	< /= 4.0%	<b>0.7%</b>
3	Creatinine (mg/dl)	< /= 3.0%	<b>0.9%</b>
4	Total Cholesterol (mg/dl)	< /= 3.0%	<b>0.0%</b>
5	Triglycerides (mg/dl)	< /= 3.0%	<b>0.6%</b>
6	Total Protein (g/dl)	< /= 3.0%	<b>0.8%</b>
7	Uric Acid (mg/dl)	< /= 3.0%	<b>0.3%</b>
8	SGPT (U/L)	< /= 3.5%	<b>0.9%</b>
9	SGOT (U/L)	< /= 3.5%	<b>0.5%</b>
10	Albumin (g/dl)	< /= 3.0%	<b>0.4%</b>
11	Total Bilirubin (mg/dl)	< /= 5.0%	<b>0.6%</b>
12	Direct Bilirubin (mg/dl)	< /= 4.0%	<b>0.8%</b>

**Conclusion:**

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

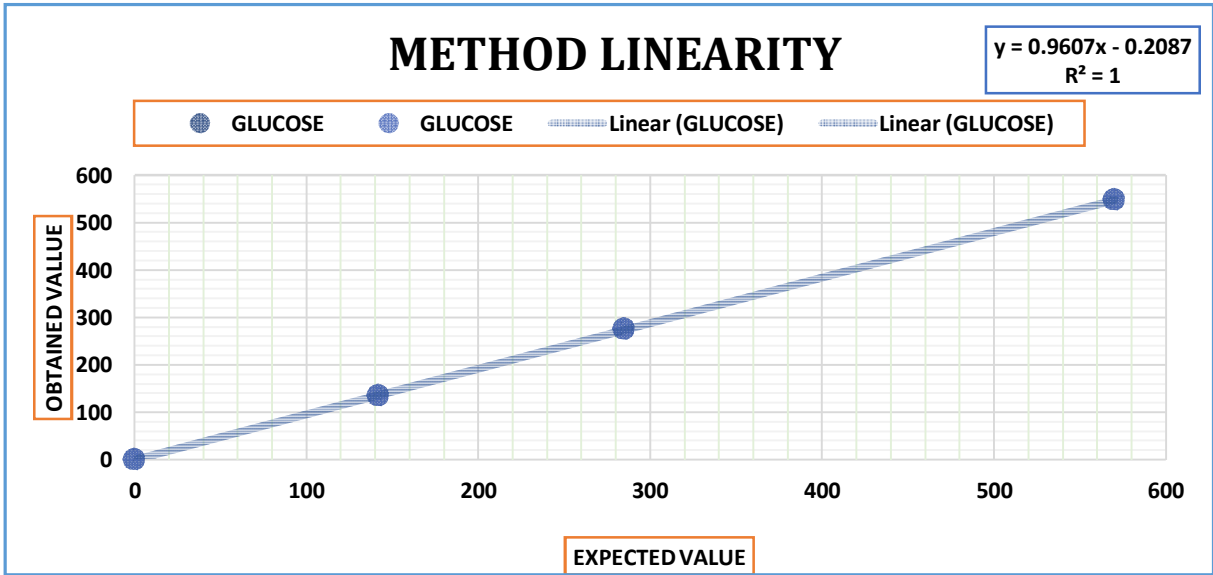
The Percentage coefficient variation (CV %) of all the parameters obtained are well within the acceptable limits (Manufacturer's CV%) on **BS240Pro**

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

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	GLUCOSE
Customer Site:	SD HOSPITAL & RESEARCH CENT	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:	RSD HOSPITAL & RESEARCH CENTER	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

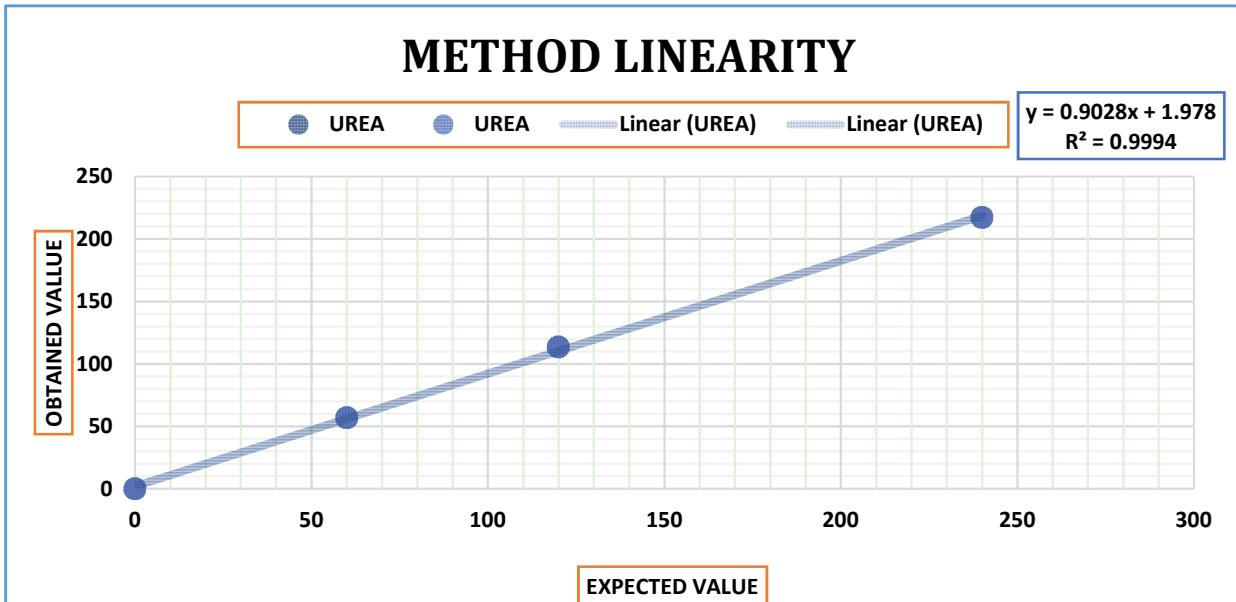
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Linearity Report Generated for Akshay Laboratories

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	UREA
Customer Site:	SD HOSPITAL & RESEARCH CENTE	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

**LINEARITY PLOT**



<b>LINEARITY ANALYSIS REPORT</b>
----------------------------------

<b>Date of Analysis:</b>	<b>08.06.2022</b>	<b>Analyte:</b>	<b>UREA</b>
<b>Customer Site:</b>	<b>RSD HOSPITAL &amp; RESEARCH CENTER</b>	<b>Test Equip:</b>	<b>Mindray BS-240 PRO</b>
<b>Analyst:</b>	<b>VIRAJ KALE</b>	<b>Serial Number:</b>	<b>BC-7-18001329</b>

<b>LINEARITY VALUES</b>
-------------------------

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

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

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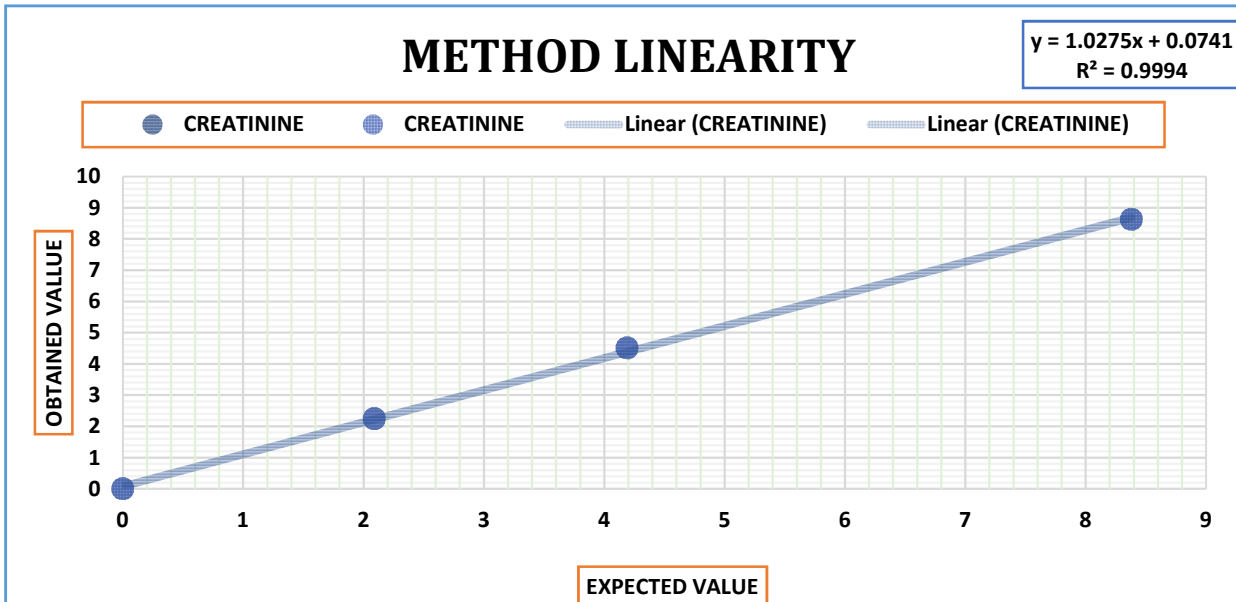
Linearity Report Generated for AKSHAY LABORATORIES



**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	CREATININE
Customer Site:	SD HOSPITAL & RESEARCH CENTE	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

**LINEARITY PLOT**



<b>LINEARITY ANALYSIS REPORT</b>
----------------------------------

Date of Analysis:	08.06.2022	Analyte:	CREATININE
Customer Site:	RSD HOSPITAL & RESEARCH CENTER	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

<b>LINEARITY VALUES</b>
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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

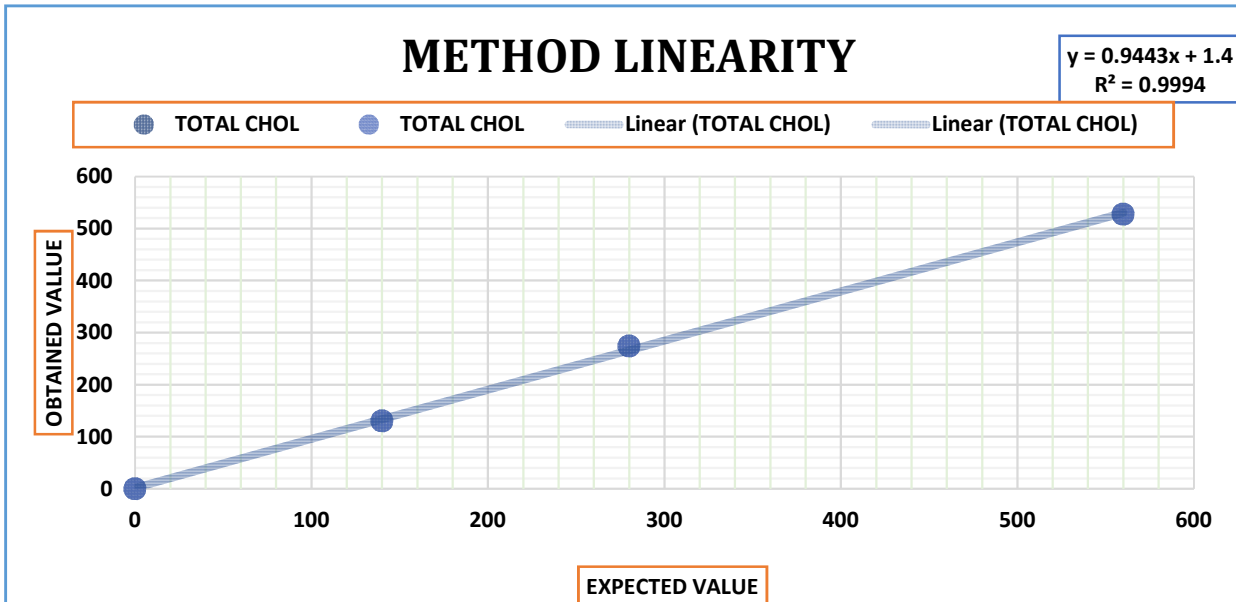
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Linearity Report Generated for AKSHAY LABORATORIES

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	TOTAL CHOLESTEROL
Customer Site:	SD HOSPITAL & RESEARCH CENTE	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

**LINEARITY PLOT**



<b>LINEARITY ANALYSIS REPORT</b>
----------------------------------

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

<b>LINEARITY VALUES</b>
-------------------------

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

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

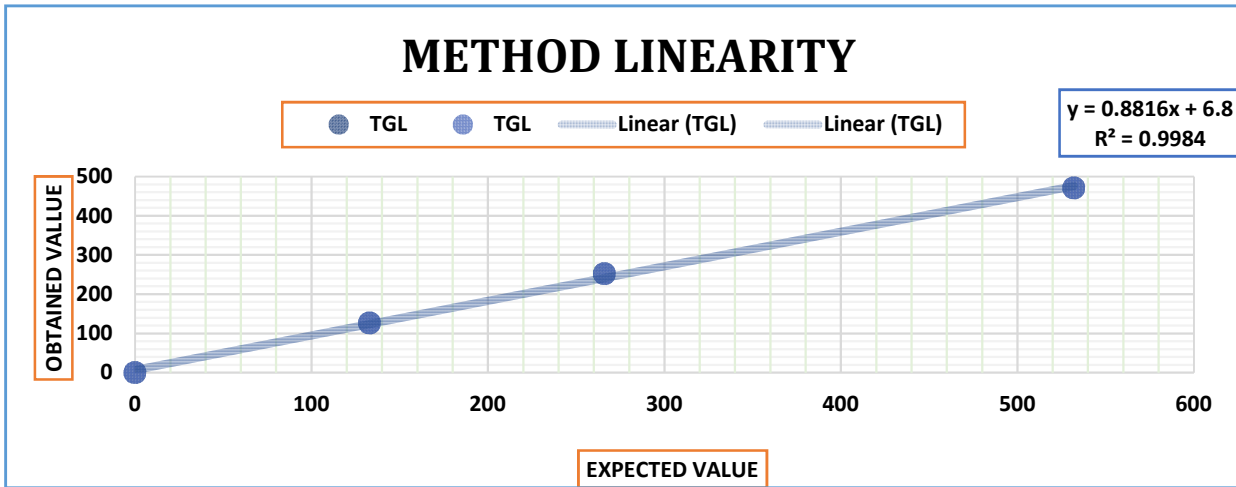
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Linearity Report Generated for AKSHAY LABORATORIES

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	TRIGLYCERIDES
Customer Site:	SD HOSPITAL & RESEARCH CENTE	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

**LINEARITY PLOT**



<b>LINEARITY ANALYSIS REPORT</b>
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<b>Date of Analysis:</b>	<b>08.06.2022</b>	<b>Analyte:</b>	<b>TRIGLYCERIDES</b>
<b>Customer Site:</b>	<b>RSD HOSPITAL &amp; RESEARCH CENTER</b>	<b>Test Equip:</b>	<b>Mindray BS-240 PRO</b>
<b>Analyst:</b>	<b>VIRAJ KALE</b>	<b>Serial Number:</b>	<b>BC-7-18001329</b>

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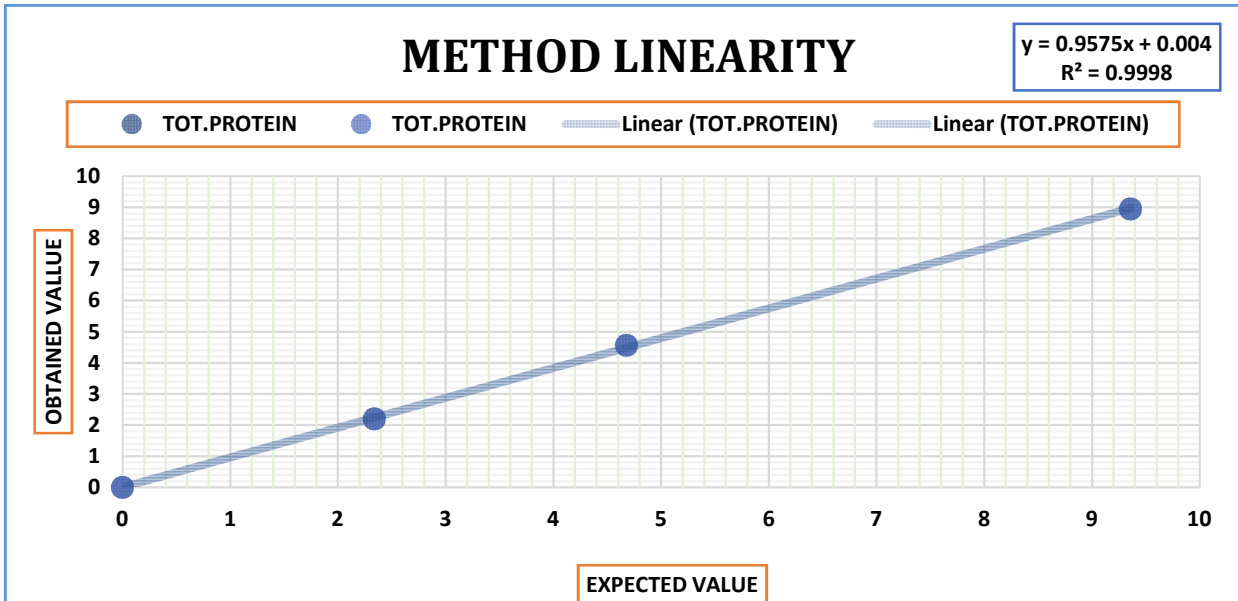
<b>Linearity Samples (Values in mg/dl)</b>		
<b>Sample</b>	<b>Expected</b>	<b>Obtained</b>
<b>0.0%</b>	0	0
<b>25.0%</b>	133	126
<b>50.0%</b>	266	252
<b>100.0%</b>	532	470.00

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

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	TOTAL PROTEIN
Customer Site:	SD HOSPITAL & RESEARCH CENTE	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

**LINEARITY PLOT**



<b>LINEARITY ANALYSIS REPORT</b>
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<b>Date of Analysis:</b>	<b>08.06.2022</b>	<b>Analyte:</b>	<b>TOTAL PROTEIN</b>
<b>Customer Site:</b>	<b>RSD HOSPITAL &amp; RESEARCH CENTER</b>	<b>Test Equip:</b>	<b>Mindray BS-240 PRO</b>
<b>Analyst:</b>	<b>VIRAJ KALE</b>	<b>Serial Number:</b>	<b>BC-7-18001329</b>

<b>LINEARITY VALUES</b>
-------------------------

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

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

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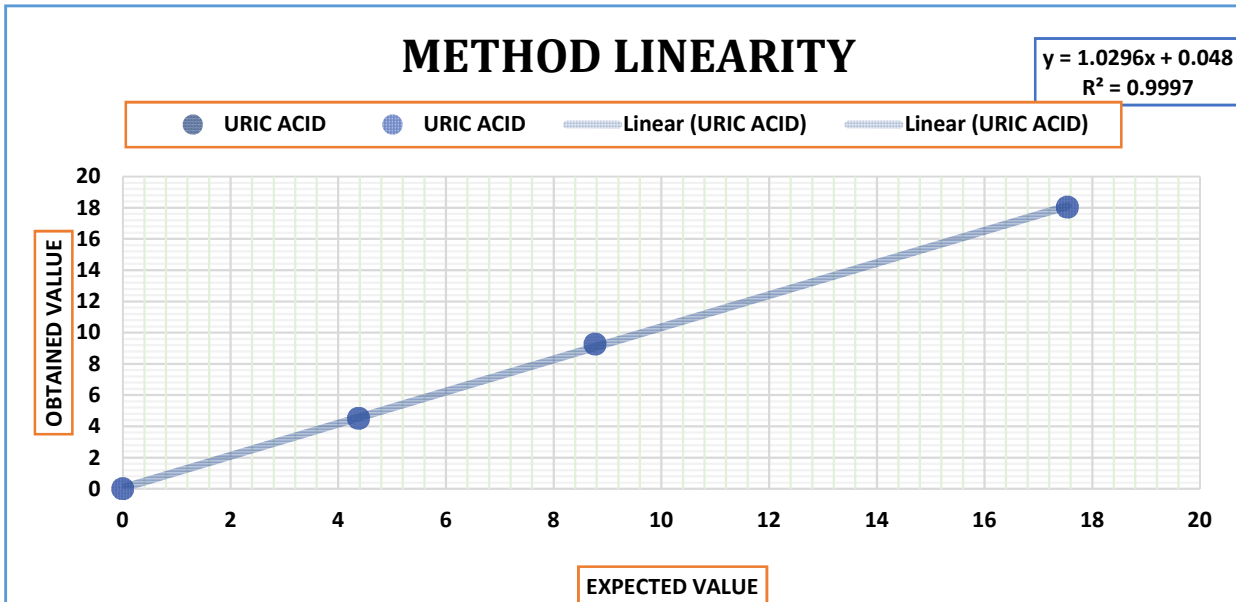
Linearity Report Generated for AKSHAY LABORATORIES



**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	URIC ACID
Customer Site:	SD HOSPITAL & RESEARCH CENTE	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

**LINEARITY PLOT**



<b>LINEARITY ANALYSIS REPORT</b>
----------------------------------

<b>Date of Analysis:</b>	<b>08.06.2022</b>	<b>Analyte:</b>	<b>URIC ACID</b>
<b>Customer Site:</b>	<b>RSD HOSPITAL &amp; RESEARCH CENTER</b>	<b>Test Equip:</b>	<b>Mindray BS-240 PRO</b>
<b>Analyst:</b>	<b>VIRAJ KALE</b>	<b>Serial Number:</b>	<b>BC-7-18001329</b>

<b>LINEARITY VALUES</b>
-------------------------

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

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

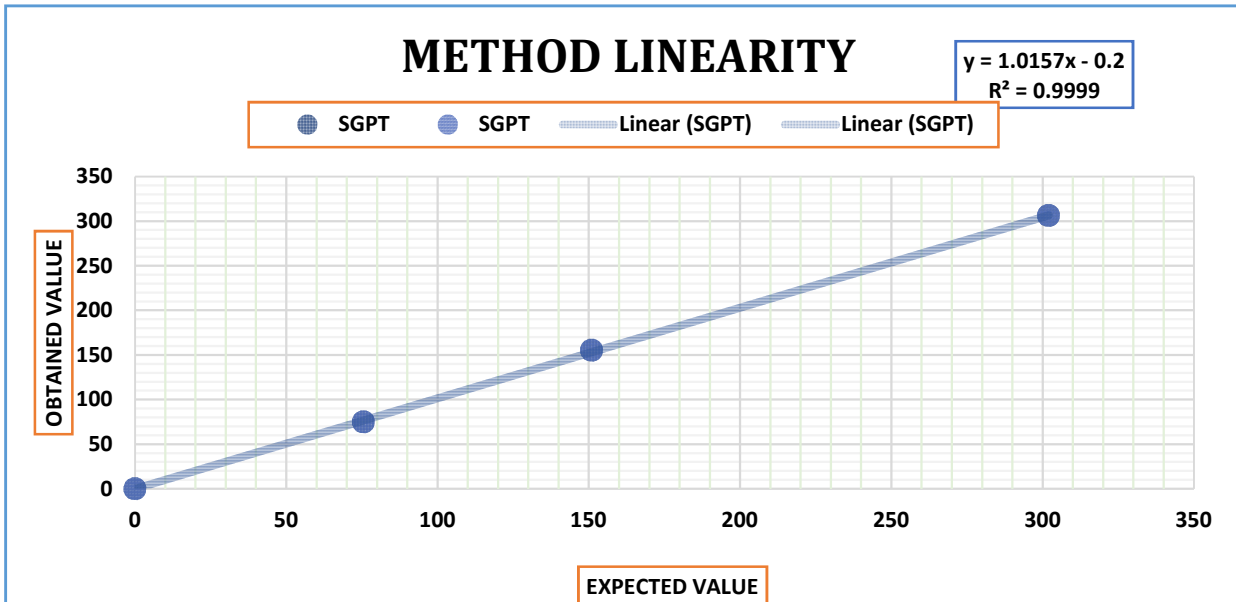
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Linearity Report Generated for AKSHAY LABORATORIES

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	SGPT
Customer Site:	SD HOSPITAL & RESEARCH CENTE	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

**LINEARITY PLOT**



<b>LINEARITY ANALYSIS REPORT</b>
----------------------------------

<b>Date of Analysis:</b>	<b>08.06.2022</b>	<b>Analyte:</b>	<b>SGPT</b>
<b>Customer Site:</b>	<b>RSD HOSPITAL &amp; RESEARCH CENTER</b>	<b>Test Equip:</b>	<b>Mindray BS-240 PRO</b>
<b>Analyst:</b>	<b>VIRAJ KALE</b>	<b>Serial Number:</b>	<b>BC-7-18001329</b>

<b>LINEARITY VALUES</b>
-------------------------

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

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

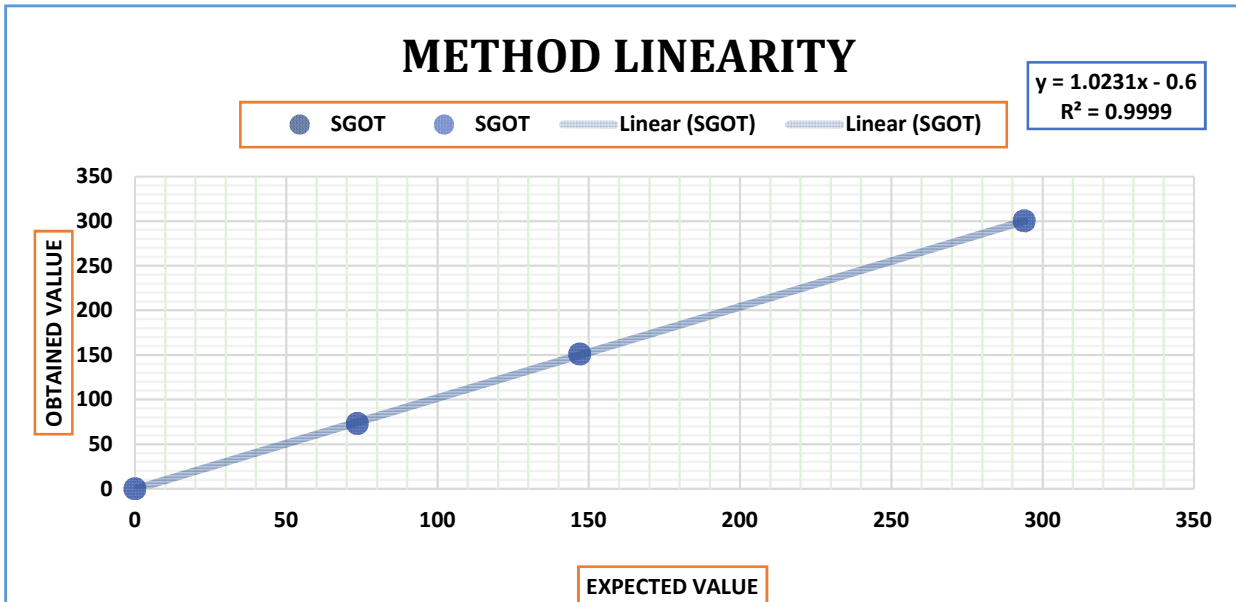
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Linearity Report Generated for AKSHAY LABORATORIES

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	SGOT
Customer Site:	SD HOSPITAL & RESEARCH CENTE	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

**LINEARITY PLOT**



<b>LINEARITY ANALYSIS REPORT</b>
----------------------------------

<b>Date of Analysis:</b>	<b>08.06.2022</b>	<b>Analyte:</b>	<b>SGOT</b>
<b>Customer Site:</b>	<b>RSD HOSPITAL &amp; RESEARCH CENTER</b>	<b>Test Equip:</b>	<b>Mindray BS-240 PRO</b>
<b>Analyst:</b>	<b>VIRAJ KALE</b>	<b>Serial Number:</b>	<b>BC-7-18001329</b>

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

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

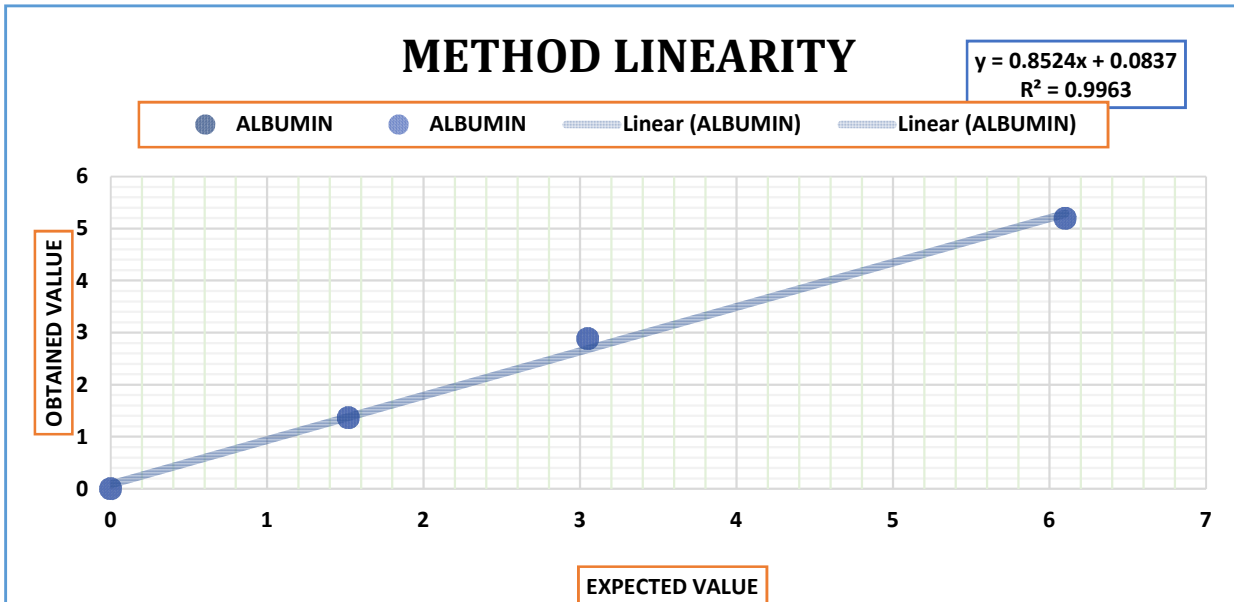
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Linearity Report Generated for AKSHAY LABORATORIES

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	ALBUMIN
Customer Site:	SD HOSPITAL & RESEARCH CENTE	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

**LINEARITY PLOT**



<b>LINEARITY ANALYSIS REPORT</b>
----------------------------------

<b>Date of Analysis:</b>	<b>08.06.2022</b>	<b>Analyte:</b>	<b>ALBUMIN</b>
<b>Customer Site:</b>	<b>RSD HOSPITAL &amp; RESEARCH CENTER</b>	<b>Test Equip:</b>	<b>Mindray BS-240 PRO</b>
<b>Analyst:</b>	<b>VIRAJ KALE</b>	<b>Serial Number:</b>	<b>BC-7-18001329</b>

<b>LINEARITY VALUES</b>
-------------------------

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

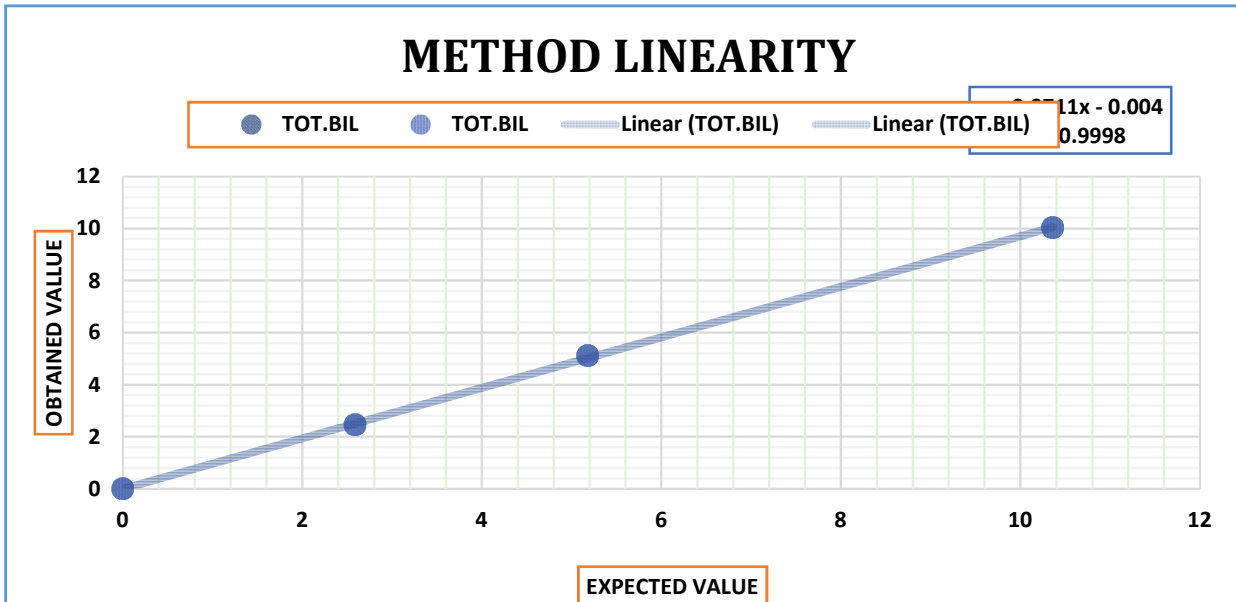
<b>Linear Regression Statistics</b>	
<b>No. of Samples</b>	<b>4</b>
<b>Slope</b>	<b>0.8524</b>
<b>Y-Intercept</b>	<b>0.08</b>
<b>Correlation (r)</b>	<b>0.9982</b>



**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	TOTAL BILIRUBIN
Customer Site:	SD HOSPITAL & RESEARCH CENTE	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

**LINEARITY PLOT**



<b>LINEARITY ANALYSIS REPORT</b>
----------------------------------

<b>Date of Analysis:</b>	<b>08.06.2022</b>	<b>Analyte:</b>	<b>TOTAL BILIRUBIN</b>
<b>Customer Site:</b>	<b>RSD HOSPITAL &amp; RESEARCH CENTER</b>	<b>Test Equip:</b>	<b>Mindray BS-240 PRO</b>
<b>Analyst:</b>	<b>VIRAJ KALE</b>	<b>Serial Number:</b>	<b>BC-7-18001329</b>

<b>LINEARITY VALUES</b>
-------------------------

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

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

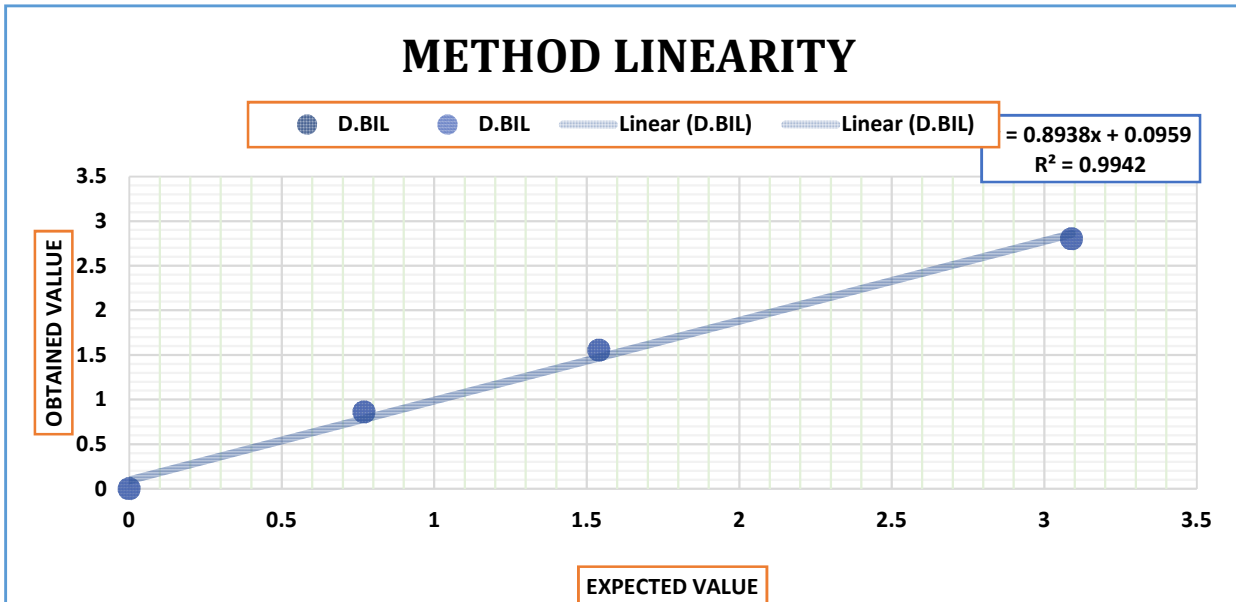
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Linearity Report Generated for AKSHAY LABORATORIES

**LINEARITY ANALYSIS REPORT**

Date of Analysis:	08.06.2022	Analyte:	DIRECT BILIRUBIN
Customer Site:	SD HOSPITAL & RESEARCH CENTE	Test Equip:	Mindray BS-240 PRO
Analyst:	VIRAJ KALE	Serial Number:	BC-7-18001329

**LINEARITY PLOT**



<b>LINEARITY ANALYSIS REPORT</b>
----------------------------------

<b>Date of Analysis:</b>	<b>08.06.2022</b>	<b>Analyte:</b>	<b>DIRECT BILIRUBIN</b>
<b>Customer Site:</b>	<b>RSD HOSPITAL &amp; RESEARCH CENTER</b>	<b>Test Equip:</b>	<b>Mindray BS-240 PRO</b>
<b>Analyst:</b>	<b>VIRAJ KALE</b>	<b>Serial Number:</b>	<b>BC-7-18001329</b>

<b>LINEARITY VALUES</b>
-------------------------

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

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

Date: 12/06/2023

**CALIBRATION CERTIFICATE OF Bs240**

CUSTOMER NAME – R.S.D. HOSPITAL AND RESEARCH CENTRE

Serial Number = : BC-7-18001329

User Software = V 5.4.2

Initialization Motor

Vertical Motors – S /R1 /R2 in Home

Polar Motors – S /R1 /R2 in Home

Reaction Rotor in home

Sample /Reagent rotor in Home

Ceramic Dispensing pump – S/ R1 /R2 in Home

Optics Initialization: Ok

Auto adjustment of the probe is done

Peltier cells and drivers test

Rotor Peltier/ Reagent Rotor peltier driver test: Ok

Temperature system initialized

LED test: ok

Hardware completely initialized

Parameters	Current value	Minimum	Maximum
Reading reference Position - Well 1	7896	7860	7905
Washing Solution Tank 0	0	-5	5
Washing Solution Tank 50	46	40	60
Washing Solution Tank 100	98	95	105
Waste Tank 0	-1	-5	5
Waste Tank 50	43	40	60
Waste Tank 100	100	95	105
Thermal adjustment of reaction rotor	37.0	36.0	39.0
Thermal adjustment of Wash station	44.9	44	50
Thermal adjustment of reagent tip 1	37.0	36	39

Thermal adjustment of reagent tip 2	37.0	36	39
Photometric Dark Current Adjustment	3885	3941	4500
Main Photo Diode Counts 340NM	8,82,490	2,16,086	950000
Main Photo Diode Counts 405NM	8,99,288	7,40,174	950000
Main Photo Diode Counts 505NM	9,01,338	7,03,853	950000
Main Photo Diode Counts 535NM	8,89,214	5,97,627	950000
Main Photo Diode Counts 560NM	8,99,482	7,10,590	950000
Main Photo Diode Counts 600NM	9,01,891	5,82,890	950000
Main Photo Diode Counts 635NM	9,00,649	5,91,854	950000
Main Photo Diode Counts 670NM	8,99,062	7,39,773	950000

Next calibration due on: 12/06/2024

FOR AVANTOR DIAGNOSTICS PVT. LTD.,

KRUNAL  
GORDHANBHAI  
MADHU

Digitally signed by KRUNAL  
GORDHANBHAI MADHU

DN: cn=KRUNAL GORDHANBHAI  
MADHU, c=IN, o=PERSONAL,  
email=krunalmadhu@biosystems.in  
Date: 2023.05.25 16:50:33 +0530'

Authorized Signatory

