



CALIBRATION CERTIFICATE

Date: 09/11/2022

This is to certify that **Mindray BS-240 PRO** Bio-chemistry analyzer (Sl. No. **BC7-23001933**) installed at **ANUBHAV LIFECARE** is calibrated as per the recommended procedures.

The system parameters as mentioned below were verified and necessary calibrations done as applicable.

System temperatures:

Temperature Sensor	Temperature (°C)	Operating range (°C)
Reaction Carousel Temperature	37.0	36.7 to 37.3
Cuvette Cleaning Fluid Temperature	44.1	39.0 to 49.0
Cuvette Wash Solution Temperature	44.6	39.0 to 49.0

Power Supply Units:

Power Supply	Measured (V&A)	Range (V&A)
+24Volts	24.03 V	20V to 30 V
+12Volts	11.98 V	11V to 14 V
AC Mains Input Voltage to the instrument	224 V	220V to 240V
Ground Voltage	1.2 V	<5 Volts



Photometer Check:

Wavelength (nm)	Absorbance	Remarks
340	8506	Well within range
380	8372	Well within range
412	8652	Well within range
450	8589	Well within range
505	7581	Well within range
546	7511	Well within range
570	7564	Well within range
605	7496	Well within range
660	7531	Well within range
700	7538	Well within range
740	7534	Well within range
800	7495	Well within range

The equipment is certified to be in good working condition and is ready for the intended use.

For,
Avantor Performance Materials India Limited.

Manas Kumar Ghosh
(Regional Service Manager)
Authorised Signatory



CALIBRATION CERTIFICATE

Date: 09.11.2022

This is to certify that the **Mindray BS-240 Pro Biochemistry Analyzer** (Sl. No. **BC7-23001933**) installed at **ANUBHAV LIFECARE** has been calibrated as per the recommended procedures. The system parameters are found to be within the specified ranges. The System has passed the performance tests. The system is ready for calibration of the Chemistries with the respective calibrators. The validation of the chemistry results must be done with multi levels of commercially available controls.

Calibration validity: 12 Months

Last Calibration Done on: 09/11/2022

Next Calibration Due on: 08/11/2023

For,
Avantor Performance Materials India Limited.

Manas Kumar Ghosh
(Regional Service Manager)
Authorised Signatory

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 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,

ANUBHAV LIFECARE

2/8 JESSORE ROAD, HRIDAYPUR, 24 PGS, BARASAT, KOLKATA

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. Manas Kumar Ghosh

Title: Regional Service Manager

Company: Avantor

Signature:

Customer Authorization:

ANUBHAV LIFECARE

2/8 JESSORE ROAD, HRIDAYPUR, 24 PGS,
BARASAT, KOLKATA

Signature:



CERTIFICATION OF INSTALLATION - REPORT

Analyzer Name: **BS 240 Pro**

Serial Number: **BC7-23001933**

CUSTOMER NAME & ADDRESS:

ANUBHAV LIFECARE

#2/8 JESSORE ROAD, HRIDAYPUR,
24 PGS, BARASAT, KOLKATA

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

Authorized Engineer,

Signature:

A handwritten signature in blue ink, appearing to read 'MK Ghosh', with a blue arrow pointing to the right.


Name: Mr. Manas Kumar Ghosh
Designation: Regional Service Manager
Company: **Avantor**

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

<p>Mr. Manas Kumar Ghosh</p> 	<p>Designation:</p> <p>(Signature)</p>
--	--



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. Manas Kumar Ghosh

Regional Service Manager

IVD-Automation

Company: **AVANTOR**

Customer Authorization:

ANUBHAV LIFECARE

2/8 JESSORE ROAD, HRIDAYPUR, 24 PGS,
BARASAT, KOLKATA

Authorized Engineer's Signature

Customer's Signature


Date:

Date:

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. Manas Kumar Ghosh</p> 	<p>Designation:</p> <p>(Signature)</p>
--	--



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: Ipsita Bhowmick
Title: Application
Specialist
IVD- Automation

Company: **AVANTOR**

Customer Authorization:

ANUBHAV LIFECARE
2/8 JESSORE ROAD, HRIDAYPUR, 24 PGS,
BARASAT, KOLKATA



Authorized Engineer's Signature


Date:

Customer's Signature

Date:

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.

 Ipsita Bhowmick Application Specialist IVD-Automation	Designation: Signature:
---	------------------------------------

Accuracy:

Equipment name & Serial No	BS-240 Pro & S. No: BC7-23001933
Validated during	09.11.22
Method	Photometry at 37°C
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co.,
Name of Laboratory/Hospital	ANUBHAV LIFECARE
Department	Biochemistry

TESTS VALIDATED – Glucose, Urea, Creatinine, Total Cholesterol, Triglyceride, Calcium AST, ALT, UA, Total Bilirubin, Direct Bilirubin, Total Protein, Albumin, ALP, Amylase, Lipase. Alkaline Phosphatase, Albumin, Total Protein, LDH.

Accuracy protocol:

The accuracy of BS-240 Pro- S. No: BC7-23001933 been verified by analyzing Multi-Sera Calibrator LOT No: 150122008.

S. No	Parameter	Value Obtained	Calibrator
1	Glucose (mg/dl)	190.6	195
2	Urea (mg/dL)	99.2	103
3	Creatinine (mg/dl)	3.97	4.06
4	TC (mg/dl)	152.5	158
5	TG (mg/dL)	134.8	136
6	AST (U/L)	115.3	113
7	ALT (U/L)	106.8	109
8	ALP (U/L)	192.5	203
9	Albumin (g/dl)	3.47	3.48
10	TP (g/dl)	5.36	5.52
11	Total Bilirubin (mg/dL)	4.90	5.11
12	Direct Bilirubin (mg/dL)	2.63	2.71
13	Amylase (U/L)	212.30	214.00
14	Lipase (U/L)	85.80	91.20
15	LDH	219	250
16	Calcium (mg/dL)	11.07	11.20
17	Uric Acid (mg/dl)	5.22	5.13

Conclusion: BC7-23001933 has been verified by analyzing the Multi-Sera Calibrator, the results obtained were satisfactory

Reported By



Application Specialist
IVD-Automation



Analyzer Model	BS 240 PRO
Serial Number	BC7-23001933
Method	Photometry
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Name of the Laboratory	ANUBHAV LIFECARE
Validation Date	09.11.2022

Parameters Validated: GLUCOSE, ALT, AST, UA, T-BIL, UREA, CREATININE, TG, TC, CA.

Within run precision report protocol:

10 replicates were performed on BS 240 PRO (S. No.BC7-23001933) continuously to verify the – **Within Run Precision**

Model: BS 240 PRO

Serial Number: BC7-23001933

	GLU	ALT	AST	T-BIL	Calcium	CREAT	TC	TG	UREA	UA
1	229.0	49.6	34.8	0.74	9.96	3.78	124.1	84.8	67.6	6.08
2	223.3	49.9	35.8	0.75	9.99	3.71	123.5	83.1	68.2	6.04
3	222.7	50.4	34.8	0.74	9.92	3.69	123.7	83.2	67.8	6.03
4	223.2	50.1	35.1	0.73	9.91	3.70	124.2	83.1	68.6	6.06
5	221.8	49.6	35.1	0.73	9.85	3.65	123.4	82.4	68.1	6.05
6	220.6	50.2	35.0	0.73	9.77	3.64	123.5	82.9	67.6	6.05
7	222.7	50.3	35.2	0.74	9.77	3.66	123.4	83.3	68.1	6.07
8	220.4	50.1	35.4	0.74	9.82	3.67	123.7	82.5	67.5	6.05
9	221.5	52.0	35.7	0.72	9.80	3.67	123.0	82.8	68.0	6.10
10	219.6	51.4	35.9	0.72	9.67	3.66	123.3	82.6	67.2	6.09
Mean	222.5	50.4	35.3	0.7	9.85	3.68	123.6	83.1	67.9	6.06
SD	2.61	0.77	0.40	0.01	0.10	0.04	0.36	0.68	0.41	0.02
CV%	1.17	1.52	1.14	1.32	1.01	1.10	0.29	0.82	0.60	0.37



Conclusion:

Within run precision of the tabulated parameters covering the methods of various reagents, sample volume & reaction time were completed. The percentage coefficient of variation for all the parameters is < 3% on BS 240 PRO bearing the serial number BC7-23001933.

Reported By

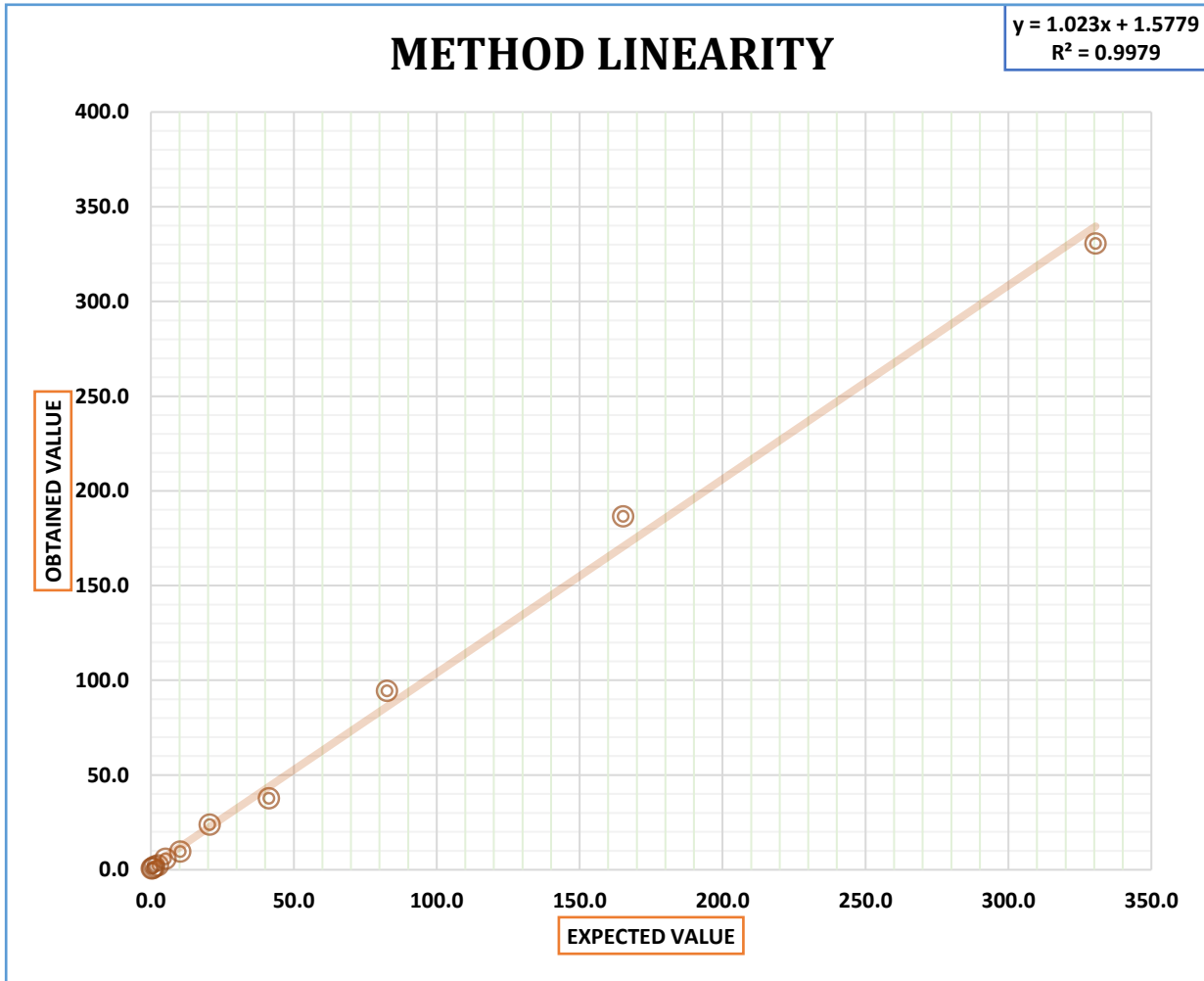
A handwritten signature in blue ink, appearing to be 'Ipsita Bhowmick'.

Ipsita Bhowmick
Application Specialist
IVD-Automation
Avantor

LINEARITY ANALYSIS REPORT

Date of Analysis:	9/11/2022	Analyte:	GLUCOSE
Customer Site:	ANUBHAV LIFECARE	Test Equip:	MINDRAY BS 240 PRO
Analyst:	Ipsita Bhowmick	Serial Number:	BC7-23001933

LINEARITY PLOT





LINEARITY ANALYSIS REPORT

Date of Analysis:	9/11/2022	Analyte:	GLUCOSE
Customer Site:	ANUBHAV LIFECARE	Test Equip:	MINDRAY BS 240 PRO
Analyst:	Ipsita Bhowmick	Serial Number:	BC7-23001933

LINEARITY VALUES

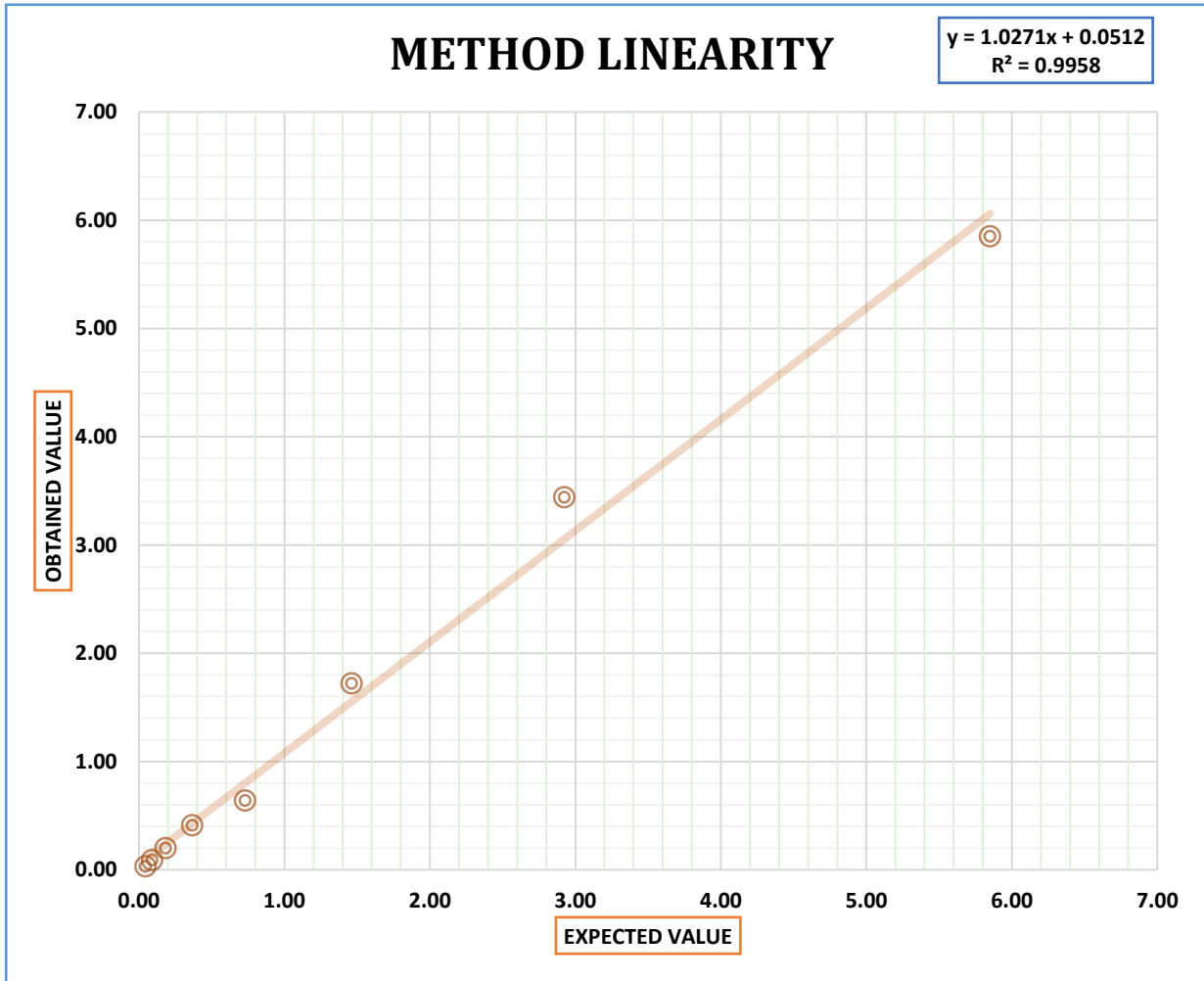
Linearity Samples (Values in mg/dL)		
Sample	Expected	Obtained mean
Lin 1	330.5	330.5
Lin 2	165.3	186.5
Lin 3	82.6	94.3
Lin 4	41.3	37.7
Lin 5	20.7	23.8
Lin 6	10.3	9.5
Lin 7	5.2	5.7
Lin 8	2.6	2.2
Lin 9	1.3	1.6
Lin 10	0.6	0.8
Lin 11	0.3	0.6

Linear Regression Statistics	
No. of Samples	11
Slope	1.0230
Y-Intercept	1.58
Correlation (r)	0.9979

LINEARITY ANALYSIS REPORT

Date of Analysis:	9/11/2022	Analyte:	CREATININE
Customer Site:	ANUBHAV LIFECARE	Test Equip:	MINDRAY BS 240 PRO
Analyst:	Ipsita Bhowmick	Serial Number:	BC7-23001933

LINEARITY PLOT





LINEARITY ANALYSIS REPORT

Date of Analysis:	9/11/2022	Analyte:	CREATININE
Customer Site:	ANUBHAV LIFECARE	Test Equip:	MINDRAY BS 240 PRO
Analyst:	Ipsita Bhowmick	Serial Number:	BC7-23001933

LINEARITY VALUES

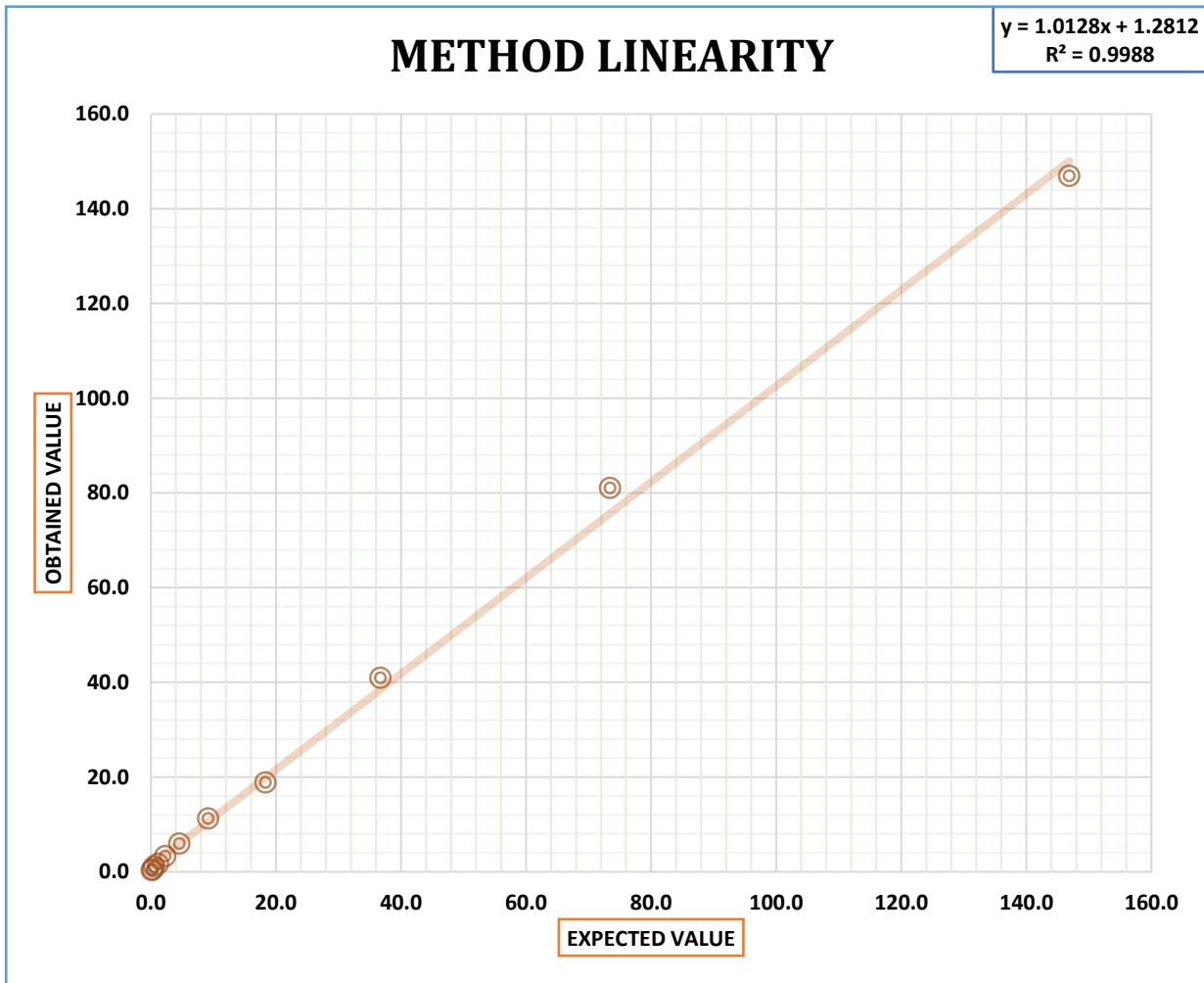
Linearity Samples (Values in mg/dL)		
Sample	Expected	Obtained mean
Lin 1	5.85	5.85
Lin 2	2.93	3.44
Lin 3	1.46	1.72
Lin 4	0.73	0.64
Lin 5	0.37	0.41
Lin 6	0.18	0.20
Lin 7	0.09	0.09
Lin 8	0.05	0.03

Linear Regression Statistics	
No. of Samples	8
Slope	1.0271
Y-Intercept	0.05
Correlation (r)	0.9958

LINEARITY ANALYSIS REPORT

Date of Analysis:	9/11/2022	Analyte:	UREA
Customer Site:	ANUBHAV LIFECARE	Test Equip:	MINDRAY BS 240 PRO
Analyst:	Ipsita Bhowmick	Serial Number:	BC7-23001933

LINEARITY PLOT





LINEARITY ANALYSIS REPORT

Date of Analysis:	9/11/2022	Analyte:	UREA
Customer Site:	ANUBHAV LIFECARE	Test Equip:	MINDRAY BS 240 PRO
Analyst:	Ipsita Bhowmick	Serial Number:	BC7-23001933

LINEARITY VALUES

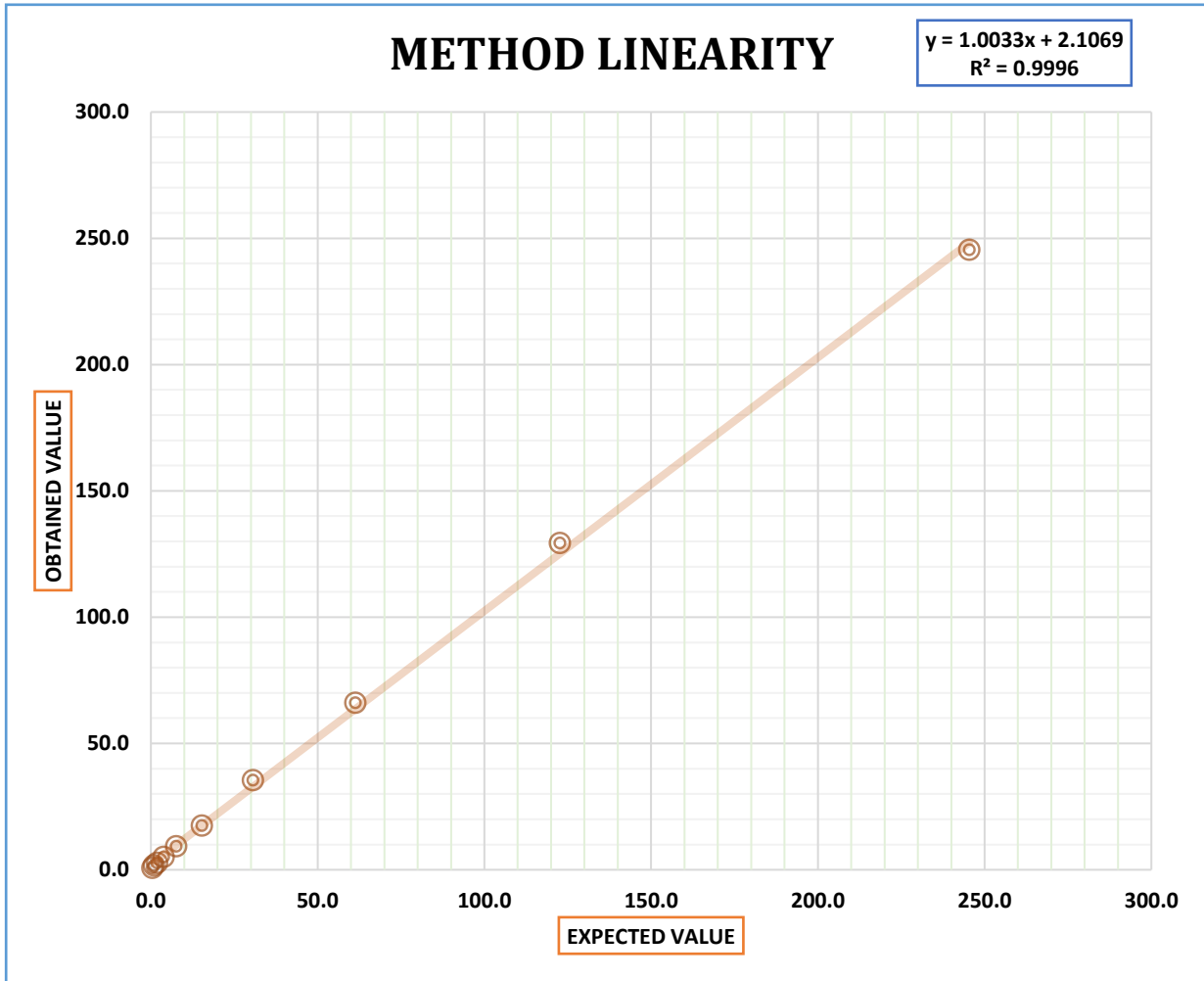
Linearity Samples (Values in mg/dL)		
Sample	Expected	Obtained mean
Lin 1	146.9	146.9
Lin 2	73.5	81.0
Lin 3	36.7	40.9
Lin 4	18.4	18.8
Lin 5	9.2	11.2
Lin 6	4.6	5.9
Lin 7	2.3	3.3
Lin 8	1.1	1.6
Lin 9	0.6	1.1
Lin 10	0.3	0.5
Lin 11	0.1	0.3

Linear Regression Statistics	
No. of Samples	11
Slope	1.0128
Y-Intercept	1.28
Correlation (r)	0.9988

LINEARITY ANALYSIS REPORT

Date of Analysis:	9/11/2022	Analyte:	ALT
Customer Site:	ANUBHAV LIFECARE	Test Equip:	MINDRAY BS 240 PRO
Analyst:	Ipsita Bhowmick	Serial Number:	BC7-23001933

LINEARITY PLOT





LINEARITY ANALYSIS REPORT

Date of Analysis:	9/11/2022	Analyte:	ALT
Customer Site:	ANUBHAV LIFECARE	Test Equip:	MINDRAY BS 240 PRO
Analyst:	Ipsita Bhowmick	Serial Number:	BC7-23001933

LINEARITY VALUES

Linearity Samples (Values in U/L)		
Sample	Expected	Obtained mean
Lin 1	245.4	245.4
Lin 2	122.7	129.3
Lin 3	61.4	66.1
Lin 4	30.7	35.4
Lin 5	15.3	17.4
Lin 6	7.7	9.2
Lin 7	3.8	5.1
Lin 8	1.9	2.7
Lin 9	1.0	1.7
Lin 10	0.5	0.7

Linear Regression Statistics	
No. of Samples	10
Slope	1.0033
Y-Intercept	2.11
Correlation (r)	0.9996

Value sheet of Mindray BS Measurement System



Русский : Таблица результатов для системы BS компании Mindray
 Português : Planilha de valores do Sistema de Medição BS da Mindray
 Español : Hoja de valores del sistema de medición Mindray BS
 Italiano : Scheda dei valori del sistema di misurazione BS di Mindray
 Türkçe : Mindray BS Ölçüm Sistemi'nin değer sayfası

This Lot is the new version Bil-D reagent, the updated calibrator value sheet is inside the box. Please select the corresponding value and update.

The data of each group is same.

Русский : Данные совпадают во всех группах.

Português : A dados de cada grupo é a mesma.

Español : la datos de cada grupo es la misma.

Italiano : la dati di ogni gruppo è la stessa.

Türkçe : her grubun veri aynıdır.

1. **BS-120**: BS-120, BS-130;

10. **BS-360E**: BS-360E, BS-370E, BS-350S, BS-360S,

2. **BS-180**: BS-180, BS-190;

BS-330E(V35.00)(Serial Number starts with "W8-"
and software version starts with "35.00"),
BS-350E(V35.00) (Serial Number starts with "W9-"
and software version starts with "35.00");

3. **BS-200**: BS-200, BS-220;

11. **BS-380**: BS-380, BS-390;

4. **BS-200E**: BS-200E, BS-220E;

12. **BS-400**: BS-400, BS-420;

5. **BS-230**: BS-230, BS-240, BS-240VET;

13. **BS-430**: BS-430, BS-450, BS-460;

6. **BS-240E**: BS240E, BS240Pro;

14. **BS-480**: BS-480, BS-490;

7. **BS-300**: BS-300, BS-320;

15. **BS-600**: BS-600, BS-620;

8. **BS-330**: BS-330, BS-350;

16. **BS-600M**: BS-600M;

17. **BS-620M**: BS-620M;

9. **BS-330E**: **BS-330E**(Serial Number starts with "XQ-"),

18. **BS-800**: BS-800, BS-820, BS-800M, BS-820M,
BS-1800, BS-1800plus;

19. **BS-2000**: BS-2000, BS-2200, BS-2000M, BS-2200M;

BS-350E(Serial Number starts with "XS-");

20. **BS-2800M**: BS-2600M.

LOT : 150122008

⌚ : 2023-10-31

Abbreviated name	Unit	Calibration Value									
		BS-120 ¹	BS-180 ²	BS-200 ³	BS-200E ⁴	BS-230 ⁵	BS-240E ⁶	BS-300 ⁷	BS-330 ⁸	BS-330E ⁹	BS-360E ¹⁰
ALB II	g/L	34.8	34.8	34.8	34.8	34.8	34.8	34.8	34.8	34.8	34.8
	μmol/L	529	529	529	529	529	529	529	529	529	529
ALP	U/L	203	203	203	203	203	203	203	203	203	203
	μkat/L	3.39	3.39	3.39	3.39	3.39	3.39	3.39	3.39	3.39	3.39
ALT	U/L	109	109	109	109	109	109	109	109	109	109
	μkat/L	1.82	1.82	1.82	1.82	1.82	1.82	1.82	1.82	1.82	1.82
α-AMY	U/L	214	214	214	214	214	214	214	214	214	214
	μkat/L	3.57	3.57	3.57	3.57	3.57	3.57	3.57	3.57	3.57	3.57
AST	U/L	113	113	113	113	113	113	113	113	113	113
	μkat/L	1.89	1.89	1.89	1.89	1.89	1.89	1.89	1.89	1.89	1.89
Bil-D(DSA) II	μmol/L	46.4	46.4	46.4	46.4	46.4	46.4	46.4	46.4	46.4	46.4
	mg/dL	2.71	2.71	2.71	2.71	2.71	2.71	2.71	2.71	2.71	2.71
Bil-D(VOX) (after 21004)	μmol/L	40.9	40.9	40.9	40.9	41.7	40.9	40.9	40.9	40.9	40.9
	mg/dL	2.39	2.39	2.39	2.39	2.44	2.39	2.39	2.39	2.39	2.39
Bil-D(VOX) (before 21003)	μmol/L	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7
	mg/dL	2.73	2.73	2.73	2.73	2.73	2.73	2.73	2.73	2.73	2.73
*Note: "after 21004" means this reference value is only applicable to 140721004 and subsequent batch Bil-D(VOX) reagents, "before 21003" means this reference value is only applicable to 140721004 and before batch Bil-D(VOX) reagents.											
Bil-T(DSA) II	μmol/L	87.3	87.3	87.3	87.3	87.3	87.3	87.3	87.3	87.3	87.3
	mg/dL	5.11	5.11	5.11	5.11	5.11	5.11	5.11	5.11	5.11	5.11

Abbreviated name	Unit	Calibration Value									
		BS-120 ¹	BS-180 ²	BS-200 ³	BS-200E ⁴	BS-230 ⁵	BS-240E ⁶	BS-300 ⁷	BS-330 ⁸	BS-330E ⁹	BS-360E ¹⁰
Bil-T(VOX)	μmol/L	78.2	78.2	78.2	78.2	78.2	78.2	78.2	78.2	78.2	78.2
	mg/dL	4.57	4.57	4.57	4.57	4.57	4.57	4.57	4.57	4.57	4.57
Ca	mmol/L	2.79	2.79	2.79	2.79	2.79	2.79	2.68	2.79	2.79	2.79
	mg/dL	11.2	11.2	11.2	11.2	11.2	11.2	10.7	11.2	11.2	11.2
TC	mmol/L	4.02	4.02	4.02	4.02	4.02	4.02	4.02	4.02	4.02	4.02
	mg/dL	155	155	155	155	155	155	155	155	155	155
CK	U/L	349	349	349	349	349	349	349	349	349	349
	μkat/L	5.83	5.83	5.83	5.83	5.83	5.83	5.83	5.83	5.83	5.83
Crea(SOX)	μmol/L	359	359	359	357	359	359	357	359	357	359
	mg/dL	4.06	4.06	4.06	4.04	4.06	4.06	4.04	4.06	4.04	4.06
GLU(GOD)	mmol/L	10.8	10.8	10.8	10.8	10.8	10.8	10.8	10.8	10.8	10.8
	mg/dL	195	195	195	195	195	195	195	195	195	195
GLU(HK)	mmol/L	10.9	10.9	10.9	10.9	10.9	10.7	10.9	10.9	10.9	10.7
	mg/dL	196	196	196	196	196	193	196	196	196	193
GGT	U/L	143	143	143	143	143	143	143	143	143	143
	μkat/L	2.39	2.39	2.39	2.39	2.39	2.39	2.39	2.39	2.39	2.39
α-HBDH	U/L	278	278	278	278	278	278	278	278	278	278
	μkat/L	4.64	4.64	4.64	4.64	4.64	4.64	4.64	4.64	4.64	4.64
LDH	U/L	250	250	250	250	250	250	250	250	250	250
	μkat/L	4.18	4.18	4.18	4.18	4.18	4.18	4.18	4.18	4.18	4.18
Mg II	mmol/L	1.19	1.19	1.19	1.19	1.19	1.17	1.17	1.19	1.19	1.19
	mg/dL	2.89	2.89	2.89	2.89	2.89	2.84	2.84	2.89	2.89	2.89
P	mmol/L	1.60	1.60	1.60	1.60	1.60	1.60	1.60	1.60	1.60	1.60
	mg/dL	4.96	4.96	4.96	4.96	4.96	4.96	4.96	4.96	4.96	4.96
TP	g/L	55.2	55.2	55.2	55.2	55.2	55.2	55.2	55.2	55.2	55.2
P II	mmol/L	1.70	1.70	1.70	1.70	1.70	1.70	1.70	1.70	1.70	1.70
	mg/dL	5.27	5.27	5.27	5.27	5.27	5.27	5.27	5.27	5.27	5.27
TP II	g/L	53.1	53.1	53.1	53.1	53.1	53.1	53.1	53.1	53.1	53.1
TG	mmol/L	1.54	1.54	1.54	1.54	1.54	1.54	1.54	1.54	1.54	1.54
	mg/dL	136	136	136	136	136	136	136	136	136	136
UA	μmol/L	305	305	305	305	305	305	305	305	305	305
	mg/dL	5.13	5.13	5.13	5.13	5.13	5.13	5.13	5.13	5.13	5.13
Urea	mmol/L	17.1	17.1	17.1	17.1	17.1	17.1	17.1	17.1	17.1	17.1
	mg/dL	103	103	103	103	103	103	103	103	103	103
LIP	U/L	91.2	/	91.2	91.2	91.2	91.2	91.2	/	91.2	91.2
	μkat/L	1.52	/	1.52	1.52	1.52	1.52	1.52	/	1.52	1.52
CHE	U/L	/	/	5190	5190	5190	5190	5190	/	5190	5190
	μkat/L	/	/	86.7	86.7	86.7	86.7	86.7	/	86.7	86.7

Abbreviated name	Unit	Calibration Value									
		BS-380 ¹¹	BS-400 ¹²	BS-430 ¹³	BS-480 ¹⁴	BS-600 ¹⁵	BS-600M ¹⁶	BS-620M ¹⁷	BS-800 ¹⁸	BS-2000 ¹⁹	BS-2800M ²⁰
ALB II	g/L	34.8	34.8	34.8	35.7	34.8	35.5	35.5	34.8	35.0	35.5
	μmol/L	529	529	529	543	529	540	540	529	532	540
ALP	U/L	203	203	203	203	203	205	205	203	204	205
	μkat/L	3.39	3.39	3.39	3.39	3.39	3.42	3.42	3.39	3.41	3.42
ALT	U/L	109	109	109	109	109	111	111	109	110	111
	μkat/L	1.82	1.82	1.82	1.82	1.82	1.85	1.85	1.82	1.84	1.85
α-AMY	U/L	214	214	214	214	214	217	217	214	217	217
	μkat/L	3.57	3.57	3.57	3.57	3.57	3.62	3.62	3.57	3.62	3.62
AST	U/L	113	113	113	113	113	112	112	113	112	112
	μkat/L	1.89	1.89	1.89	1.89	1.89	1.87	1.87	1.89	1.87	1.87
Bil-D(DSA) II	μmol/L	46.4	46.4	46.4	46.4	46.4	46.4	46.4	46.4	46.3	46.6
	mg/dL	2.71	2.71	2.71	2.71	2.71	2.71	2.71	2.71	2.71	2.73
Bil-D(VOX) (after 21004)	μmol/L	41.3	41.3	41.3	40.9	41.3	41.4	41.4	40.9	40.9	41.4
	mg/dL	2.42	2.42	2.42	2.39	2.42	2.42	2.42	2.39	2.39	2.42
Bil-D(VOX) (before 21003)	μmol/L	46.7	46.7	46.7	46.7	46.7	47.2	47.2	46.7	46.9	47.2
	mg/dL	2.73	2.73	2.73	2.73	2.73	2.76	2.76	2.73	2.74	2.76
*Note: "after 21004" means this reference value is only applicable to 140721004 and subsequent batch Bil-D(VOX) reagents, "before 21003" means this reference value is only applicable to 140721004 and before batch Bil-D(VOX) reagents.											
Bil-T(DSA) II	μmol/L	87.3	87.3	87.3	87.3	87.3	87.8	87.8	87.3	87.3	87.8
	mg/dL	5.11	5.11	5.11	5.11	5.11	5.13	5.13	5.11	5.11	5.13
Bil-T(VOX)	μmol/L	78.2	78.2	78.2	78.2	78.2	78.7	78.7	78.2	78.6	78.7
	mg/dL	4.57	4.57	4.57	4.57	4.57	4.60	4.60	4.57	4.60	4.60
Ca	mmol/L	2.79	2.79	2.79	2.79	2.79	2.77	2.77	2.79	2.81	2.77
	mg/dL	11.2	11.2	11.2	11.2	11.2	11.1	11.1	11.2	11.3	11.1
TC	mmol/L	4.02	4.02	4.02	4.02	4.02	4.02	4.02	4.02	4.00	3.99
	mg/dL	155	155	155	155	155	155	155	155	155	154
CK	U/L	349	349	349	349	349	351	351	349	349	351
	μkat/L	5.83	5.83	5.83	5.83	5.83	5.86	5.86	5.83	5.83	5.86
Crea(SOX)	μmol/L	357	359	359	359	359	359	339	339	340	339
	mg/dL	4.04	4.06	4.06	4.06	4.06	4.06	3.83	3.83	3.85	3.83
GLU(GOD)	mmol/L	10.8	10.8	10.8	10.8	10.8	10.7	10.7	10.6	10.8	10.9
	mg/dL	195	195	195	195	195	193	193	191	195	196
GLU(HK)	mmol/L	10.9	10.9	10.7	10.7	10.7	10.8	10.8	10.7	10.9	10.9
	mg/dL	196	196	193	193	193	195	195	193	196	196
GGT	U/L	143	143	143	143	143	143	143	143	142	143
	μkat/L	2.39	2.39	2.39	2.39	2.39	2.39	2.39	2.39	2.37	2.39
α-HBDH	U/L	278	278	278	278	278	279	279	278	282	279
	μkat/L	4.64	4.64	4.64	4.64	4.64	4.66	4.66	4.64	4.71	4.66
LDH	U/L	250	250	250	250	250	252	252	250	251	252
	μkat/L	4.18	4.18	4.18	4.18	4.18	4.21	4.21	4.18	4.19	4.21
Mg II	mmol/L	1.17	1.17	1.17	1.17	1.17	1.18	1.18	1.17	1.18	1.18
	mg/dL	2.84	2.84	2.84	2.84	2.84	2.87	2.87	2.84	2.87	2.87
P	mmol/L	1.60	1.60	1.60	1.60	1.60	1.60	1.60	1.60	1.61	/
	mg/dL	4.96	4.96	4.96	4.96	4.96	4.96	4.96	4.96	4.99	/
TP	g/L	55.2	55.2	55.2	55.2	55.2	55.2	55.2	55.2	55.7	/
P II	mmol/L	1.70	1.70	1.70	1.70	1.70	1.73	1.73	1.70	1.73	1.73
	mg/dL	5.27	5.27	5.27	5.27	5.27	5.36	5.36	5.27	5.36	5.36
TP II	g/L	53.1	53.1	53.1	53.1	53.1	53.6	53.6	53.1	53.2	53.6
TG	mmol/L	1.54	1.54	1.54	1.54	1.54	1.59	1.59	1.54	1.57	1.59
	mg/dL	136	136	136	136	136	141	141	136	139	141
UA	μmol/L	305	305	305	305	305	311	311	305	306	311
	mg/dL	5.13	5.13	5.13	5.13	5.13	5.23	5.23	5.13	5.14	5.23
Urea	mmol/L	17.1	17.1	17.1	17.1	17.1	17.0	17.0	17.1	17.2	17.0
	mg/dL	103	103	103	103	103	102	102	103	103	102
LIP	U/L	91.2	91.2	91.2	91.2	91.2	92.2	92.2	91.2	91.4	92.2
	μkat/L	1.52	1.52	1.52	1.52	1.52	1.54	1.54	1.52	1.53	1.54
CHE	U/L	5190	5190	5190	5190	5190	5245	5245	5190	5251	5245
	μkat/L	86.7	86.7	86.7	86.7	86.7	87.6	87.6	86.7	87.7	87.6

English	Abbreviated name	Unit	Calibration Rule
Русский	сокращенное наименование	Прибор	Принцип калибровки
Português	Nome abreviado	Unidade	Regra de calibração
Español	nombre abreviado	Unidad	Regla de calibración
Italiano	abbreviazione	Unità	Regola di calibrazione
Türkçe	kısaltılmış ad	Ünite	Kalibrasyon Kuralı

	ALB	ALP	ALT	α-AMY
English	Albumin	Alkaline Phosphatase	Alanine Aminotransferase	α-Amylase
Русский	Альбумин	Щелочная фосфатаза	Аланинаминотрансфераза	α-амилаза
Português	Albumina	Fosfatase Alcalina	Alanina Aminotransferase	α-Amilase
Español	Albumina	Fosfatasa alcalina	Alanina aminotransferasa	α-amilasa
Italiano	Albumina	Fosfatasi alcalina	Alanina aminotransferasi	α-amilasi
Türkçe	Albumin	Alkalin fosfataz	Alanin Aminotransferaz	α-Amilaz

	AST	Bil-D	Bil-T	Ca
English	Aspartate Aminotransferase	Direct Bilirubin	Total Bilirubin	Calcium
Русский	Аспаратаминотрансфераза	Прямой билирубин	Общий билирубин	Кальций
Português	Aspartato aminotransferase	Bilirrubina Direta	Bilirrubina Total	Cálcio
Español	Aspartato aminotransferasa	Bilirrubina directa	Bilirrubina total	Calcio
Italiano	Aspartato aminotransferasi	Bilirubina diretta	Bilirubina totale	Calcio
Türkçe	Aspartat Aminotransferaz	Direkt Bilirubin	Toplam Bilirubin	Kalsiyum

	TC	CK	Crea	GLU	GGT
English	Total Cholesterol	Creatine Kinase	Creatinine	Glucose	Gamma-Glutamyltransferase
Русский	Общий холестерин	Креатинкиназа	Креатинин	Глюкоза	Гамма-глутамилтрансфераза
Português	Colesterol Total	Creatina Quinase	Creatinina	Glicose	Gama Glutamyl Transferase
Español	Colesterol total	Creatina quinasa	Creatinina	Glucosa	Gamma-Glutamiltransferasa
Italiano	Colesterolo totale	Creatina chinasi	Creatinina	Glucosio	Gamma-glutamyltransferasi
Türkçe	Toplam Kolesterol	Kreatin Kinaz	Kreatinin	Glikoz	Gama-Glutamiltransferaz

	α-HBDH	LDH	Mg	P
English	α-Hydroxybutyrate Dehydrogenase	Lactate Dehydrogenase	Magnesium	Phosphorus
Русский	α-гидроксипутиратдегидрогеназа	Лактатдегидрогеназа	Магний	Фосфор
Português	α-Hidroxi butirato Desidrogenase	Lactato Desidrogenase	Magnésio	Fósforo
Español	α-hidroxi butirato deshidrogenasa	lactato deshidrogenasa	Magnesio	Fósforo
Italiano	α-idrossibutirrato deidrogenasi	Lattato deidrogenasi	Magnesio	Fosforo
Türkçe	α-Hidroksibutirat Dehidrojenaz	Laktat Dehidrojenaz	Magnezyum	Fosfor

	TP	TG	UA	Urea	LIP	CHE
English	Total Protein	Triglycerides	Uric Acid	Urea	Lipase	Cholinesterase
Русский	Общий белок	Триглицериды	Мочевая кислота	Мочевина	Липаза	Холинэстераза
Português	Proteína Total	Triglicéridos	Ácido Úrico	Ureia	Lipase	Colinesterase
Español	Proteínas totales	Triglicéridos	Ácido úrico	Urea	Lipasa	Colinesterasa
Italiano	Proteina totale	Trigliceridi	Acido urico	Urea	lipasi	colinesterasi
Türkçe	Toplam Protein	Trigliserit	Ürik Asit	Üre	lipasi	Kolinesteraz

Declaration

Dear Mr. / Ms,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** hereby declare that Mindray chemistry parameters can be traceable to internationally accepted reference method and materials or be traceable to manufacture measurement procedures.

The detail traceability information is shown in the below table:

No.	Parameter	Reference Measurement Procedure	Reference Material
1	ALB	/	ERM-DA 470K
2	ALP	IFCC Reference Measurement Procedure(37°C)for ALP,manual measurement	/
3	ALT	WS/T 352-2011 Reference procedure for the measurement of catalytic activity concentration of alanine aminotransferase (No pyridoxal-5'-phosphoric acid)	/
4	α -AMY	IFCC Reference Measurement Procedure(37°C)for AMY,manual measurement	ERM-AD 456/IFCC
5	AST	WS/T 353-2011 Reference procedure for the measurement of catalytic activity concentration of aspartate aminotransferase (No pyridoxal-5'-phosphoric acid)	/
6	Bil-D-DSA	Manufacturer's Selected Measurement Procedure	/
7	Bil-D-VOX	Manufacturer's Selected Measurement Procedure	/
8	Bil-T-DSA	Doumas Reference Method,manual measurement	NIST SRM 916a
9	Bil-T-VOX	Doumas Reference Method,manual measurement	NIST SRM 916a
10	Ca	NIST/CDC/AACC Flame Atomic Absorption method	NIST SRM 915b,SRM 956b
11	TC	NIST definitive method of ID-GC/MS	NIST SRM 911c,SRM 909b,SRM 1951b
12	CREA-J	NIST definitive method of ID-GC/MS	NIST SRM 914a,NIST SRM 967
13	CREA-S	NIST definitive method of ID-GC/MS	NIST SRM 914a,NIST SRM 967
14	γ -GT	IFCC Reference Measurement Procedure (37°C)for GGT,manual measurement	ERM-AD452/IFCC
15	Glu-HK	NIST definitive method ID-LC/MS/MS,CDC HK method	NIST SRM 965a,SRM 917c

**SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.**

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 81888998
Fax: +86 755 26582680
Website: www.mindray.com

16	Glu-O	NIST definitive method ID-LC/MS/MS,CDC HK method	NIST SRM 965a,SRM 917c
17	α -HBDH	Manufacturer's Selected Measurement Procedure	/
18	LDH	IFCC Reference Measurement Procedure(37°C) for LDH, manual measurement	ERM-AD453/IFCC
19	Mg	AAS reference method	SRM 929a, SRM 956b
20	P	Manufacturer's Selected Measurement Procedure	/
21	TG	NIST definitive method of ID-GC/MS	GBW09149,NIST SRM 909b,SRM 1951b
22	TP	Doumas reference method	NIST SRM 927d
23	UA	NIST definitive method of ID-LC/MS/MS	NIST SRM 913a, SRM 909b
24	UREA	CDC reference method	NIST SRM 912a, SRM 909b
25	CK	IFCC Reference Measurement Procedure(37°C)for CK,manual measurement	ERM-AD455/IFCC
26	CK-MB	Manufacturer's Selected Measurement Procedure	/
27	HDL-C	Ultracentrifugation-HPLC, CDC beta-quantification	NIST 911c,SRM1951b
28	LDL-C	Ultracentrifugation-HPLC, CDC beta-quantification	NIST 911c,SRM1951b
29	TBA	Manufacturer's Selected Measurement Procedure	/
30	ApoA1	/	WHO SP1-01
31	ApoB	/	WHO SP3-07
32	C3	/	ERM-DA470K
33	C4	/	ERM-DA470K
34	CRP	/	ERM-DA472
35	IgA	/	ERM-DA470K
36	IgG	/	ERM-DA470K
37	IgM	/	ERM-DA470K
38	PA	/	ERM-DA470K
39	Lp(a)	Manufacturer's Selected Measurement Procedure	/
40	Fe	/	SRM937
41	FUN	Manufacturer's Selected Measurement Procedure	/
42	5'-NT	Manufacturer's Selected Measurement Procedure	/
43	ADA	Manufacturer's Selected Measurement Procedure	/

**SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.**

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 81888998
Fax: +86 755 26582680
Website: www.mindray.com



44	β 2-mG	/	WHO B2M
45	CysC	/	ERM-DA471/IFCC
46	HS-CRP	/	ERM-DA472
47	LIP	Manufacturer's Selected Measurement Procedure	/
48	AFU	Manufacturer's Selected Measurement Procedure	/
49	CHE	Manufacturer's Selected Measurement Procedure	/
50	CO2	/	SRM 351a
51	HbA1c	DCCT	JCCRM 423,JCCRM411
52	UIBC	/	SRM937
53	TRF	/	ERM-DA470k
54	FER	/	WHO Standard 94/572
55	MALB	/	ERM DA470K
56	IgE	/	WHO Standard 75/502
57	β -HB	Manufacturer's Selected Measurement Procedure	/
58	G6PD	Manufacturer's Selected Measurement Procedure	/
59	D-Dimer	Manufacturer's Selected Measurement Procedure	/
60	ACE	Manufacturer's Selected Measurement Procedure	/
61	RBP	Manufacturer's Selected Measurement Procedure	/
62	MYO	Manufacturer's Selected Measurement Procedure	/
63	ASO II	Manufacturer's Selected Measurement Procedure	/
64	RF II	Manufacturer's Selected Measurement Procedure	/
65	FR-CRP	/	ERM-DA472
66	CysC II	/	ERM-DA471/IFCC
67	β 2-MG II	/	WHO B2M
68	Sodium	/	SRM956
69	Potassium	/	SRM956

**SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.**

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China

Tel: +86 755 81888998

Fax: +86 755 26582680

Website: www.mindray.com

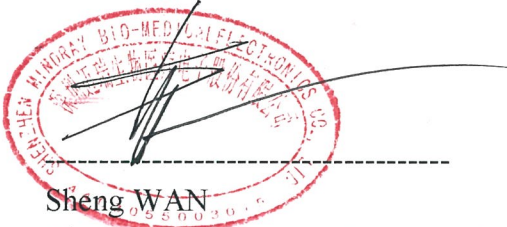
90303

90303

70	Chloride	/	SRM956
71	T-Bil-D II	Dumas Reference Method, manual measurement	NIST SRM 916a
72	D-Bil-D II	Manufacturer's Selected Measurement Procedure	/
73	TPUC	/	NIST SRM 927d
74	HCY II	/	SRM1955

We declared the given information on the above statement is true and correct.

Sincerely,



Sheng WAN

Director of International Sales & Marketing, In-Vitro Diagnostic Division

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Date: Aug. 15th, 2019



**SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.**

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 81888998
Fax: +86 755 26582680
Website: www.mindray.com