



STAR BIOMED PVT. LTD.

AUTO CHEMISTRY ANALYZER

Mindray BS-240

**INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION
PERFORMANCE QUALIFICATION
(IQ/OQ/PQ)**

Sood Diagnostics

1/165, Sadar Bazaar, Delhi Cantt-110010,

BY:-
Star Biomed Pvt. Ltd



Date: - 24/04/2024

25-B/7, W.E.A. New Rohtak Road, Near Liberty Cinema, Karol Bagh, New Delhi-110005
Tel. : 9643207024, 20, 9810028448 • Email : starbiomed@rediffmail.com, info@starbiomed.com



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CERTIFICATE OF INSTALLATION

INSTRUMENT NAME : MINDRAY BS240 AUTO CHEMISTRY ANALYZER
SERIAL NUMBER : YX- 24005344
CUSTOMER NAME : Sood Diagnostics
ADDRESS : 1/165, Sadar Bazaar, Delhi Cantt-110010,

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

Engineer

Signature :



Name : Amit Thakur

Designation : Service Engineer

Company : Star Biomed Pvt. Ltd.,

Quality Manager

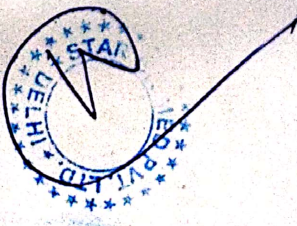
Signature :

Name : Ritesh Mishra

Designation : Quality Manager

Company : Star Biomed Pvt. Ltd.,

Date-24.04.2024



INSTALLATION REPORT

Customer Name : Sood Diagnostics
: 1/165, Sadar Bazar, Delhi Cantt-110010.

Place : Delhi

Department : Lab

Contact Person : Dr. Harish Sood

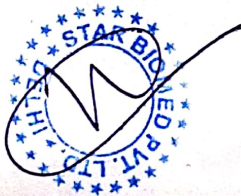
Instrument Name : Mindray BS-240

Serial Number : YX- 24005344

The Analyzer was installed along with the necessary standard accessories. All basic requirements and adjustments were checked and are found to be satisfactory. The preliminary standardization of the analyzer and the training were provided to the complete satisfaction of the customer. The analyzer is found to be working satisfactorily.

For *Star Biomed Pvt. Ltd*

Service Engineer



INSTALLATION QUALIFICATION/IO PROTOCOL

1. *System Unpacking*
2. *System Checking For any Damages*
3. *All accessories as per check List verification*
4. *Space Requirement*
5. *Power Requirement*
6. *Reagents, Control, Calibrators verification.*

1. SYSTEM UNPACKING & 2. SYSTEM CHECKING

Unpack Bs-240 instrument carefully and check for any physical Damages.

3. ACCESSORIES CHECK-

Check all accessories as per check List

4. SPACE REQUIREMENT –

- Checked site for proper space allocation. At least 100 CM on each side and enough room on below the countertop to accommodate the reagents & pneumatic unit and waste containers.

DIMENSIONS		
PARAMETER	Analyzer OV	Pneumatic Unit
Width mm	690	650
Depth mm	570	520
Height mm	595	520
Weight Kg	100	75

5. POWER REQUIREMENT –

<i>Requirement</i>	<i>Acceptable Range</i>	<i>Observed Ranged</i>
Input Voltage	220 +/- 10 V	225 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C – 30 C	23

7. Reagents , Calibrators Check-

REAGENT CALIBRATION CHECK		
NAME	Auto Cal value	Remark
Glucose Mindray	218	OK
ALP Mindray	465	OK
TP Mindray	7.36	OK
CHO Mindray	265	OK
TG Mindray	252	OK
UREA Mindray	46.5	OK
CRE Mindray	4.70	OK
UA Mindray	10.5	OK
ALB Mindray	5.48	OK
SGOT Mindray	130	OK
SGPT Mindray	134	OK
CALCIUM Mindray	13.0	OK
T BILL Mindray	4.0	OK
D BILL Mindray	3.0	OK

PRE-INSTALLTION VERIFICATION REPORT :-

PRE-INSTALLATION VERIFICATION REPORT		
S/N	PARAMETER	REMARK
1	Unpacking Instrument	OK
2	System Checking for damages	OK
3	Accessories check	OK
4	SPACE CHECK	OK
5	Power Check	OK
6	Reagents Check	OK

OPERATIONAL QUALIFICATION

The Operational Qualification procedure specifies the methodology for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

OO PROTOCOL

1. System Connections
2. Reagent & Waste Connections
3. Customizing the Analyzer Software
4. System Booting , Initialization & Check
5. Maintenance procedures.
6. Customer Training – Operation & Maintenance.

1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/N	NAME	Check	Remark
1	Pneumatic Unit	Yes	OK
2	Input Power supply	Yes	OK
4	Printer Connection	No	

2. REAGENT & WASTE CONNECTIONS -

REAGENT CONNECTION CHECK		
NAME	CHECK	Remark
Glucose Mindray	YES	Ok
ALP Mindray	YES	Ok
TP Mindray	YES	Ok
TCHO Mindray	YES	Ok
TG Mindray	YES	Ok
UREA Mindray	YES	Ok
CRE Mindray	YES	Ok
UA Mindray	YES	Ok
ALB Mindray	YES	Ok
SGOT Mindray	YES	Ok
SGPT Mindray	YES	Ok
CALCIUM MINDRAY	YES	Ok
T BILL Mindray	YES	Ok
D BILL Mindray	YES	Ok

3. CUSTOMIZING ANALYZER SOFTWARE –

CUSTOMIZING ANALYZER SOFTWARE			
S/N	Parameters	Check	Remark
1	Date & Time	Operating Manual 5.2.1	OK
2	Reagents	Operating Manual 5.2.1	OK
3	Reference Ranges	Operating Manual 5.3.1	OK
4	Reference Units	Operating Manual 5.3.1	OK
5	Printing format	Operating Manual 5.3.1	OK
6	Creating New User	Operating Manual 5.3.2	OK

4. SYSTEM BOOTING, INITIALIZATION & Check -

Power ON System and check instrument Initialization successfully.
Check following Parameters.

TEMPERATURES & PRESSURES				
S/N	Parameters	Actual °C	Range °C	Remark
1	Preheat Bath	40	30 to 50	Ok
2	Reaction Bath	36.9	30 to 45	Ok
3	Ambience	25.4	15 to 35	Ok
4	Laser Diode	35.9	15 to 45	Ok

MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Yes	Ok
2	Replacing Priming Reagents	Yes	Ok
3	Cleaning	Yes	Ok
4	Maintenance	Yes	Ok
5	Overall Maintenance	Yes	Ok
6	Version Information	Yes	Ok
7	Temperature & Pressure	Yes	Ok
8	Touch Screen Calibration	Yes	Ok
9	Cleaning SRV Manually	Yes	Ok

ADJUSTMENT			
S/N	Parameters	Check	Remark
1	Vacuum & Pressure	Yes	Ok
2	Error Messages & Recommendations	Yes	Ok

PERFORMANCE QUALIFICATION-

Multi Control Level 1			
TEST	Mean conc.	SD (Calc)	
Glucose Human	88.3	13.9	
ALP Mindray	238	55.5	
TP MINDRAY	6.37	0.53	
UREA Mindray	33.1	7.3	
CRE MINDRAY	2.50	0.202	
ALB Mindray	3.80	0.67	
SGOT Mindray	35.5	6.1	
SGPT Mindray	32.8	7.5	
CALCIUM MINDRAY	9.49	0.706	
PHOS Mindray	3.77	0.68	
Multi control Level-Plus			
TEST	Mean conc.	SD (Calc)	
Glucose Mindray	223	36.0	
ALP Mindray	475	119.0	
TP Mindray	6.52	0.71	
CHO Mindray	264	37.0	
TG Mindray	186	33.5	
UREA Mindray	46.2	10.05	
CRE Mindray	5.59	0.506	
UA Mindray	10.9	1.52	
ALB H Mindray	4.47	1.03	
SGOT Mindray	135	30.5	
SGPT Mindray	13.5	31.0	
CALCIUM MINDRAY	12.15	0.81	
PHOS Human	8.45	1.52	

For *Star Biomed Pvt. Ltd*

Service Engineer

Date: 25/04/2024



mindray

Precision Study

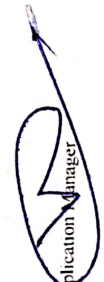
Customer Name **Sood Diagnostics**
 Department **Biochemistry-Laboratory**
 Address **Sadar Bazaar**

Instrument **BS 240**
 Serial Number **YX-24005344**

Replication No.	T.P	T.BIL	T-G	CRE	ALP	T.BILL	TP	TG	CREA	UA	ALB	CHO
1	5.5	118	113.7	1.02	212.7	118	5.5	113.7	1.02	5.22	3.3	111.27
2	5.4	115	114.4	1.03	214.4	115	5.4	114.4	1.03	5.22	3.3	107.17
3	5.4	120	116.5	1.03	213.4	120	5.4	116.5	1.03	5.28	3.3	108.74
4	5.4	118	115.9	1.04	214.3	118	5.4	115.9	1.04	5.3	3.3	107.59
5	5.5	118	117.6	1.04	212.4	116	5.5	117.6	1.04	5.27	3.2	107.03
6	5.4	116	115.4	1.02	213.9	116	5.4	115.4	1.02	5.28	3.3	106.91
7	5.4	116	115.2	1.03	213.9	121	5.4	115.2	1.03	5.19	3.3	105.75
8	5.3	121	114.4	1.02	215.4	117	5.3	114.4	1.02	5.18	3.3	107.83
9	5.4	117	116	1.02	213.9	117	5.4	116	1.02	5.27	3.4	106.82
10	5.3	117	116	1.04	215.2	122	5.3	116	1.04	5.28	3.3	105.72
11	5.5	122	116.2	1.01	213.5	115	5.5	116.2	1.01	5.2	3.3	106.48
12	5.3	115	117.1	1.03	215.0	114	5.3	117.1	1.03	5.29	3.4	105.35
13	5.4	114	113.7	1.01	212.0	116	5.4	113.7	1.01	5.24	3.3	105.55
14	5.4	116	115.6	1.01	214.0	119	5.4	115.6	1.01	5.31	3.4	106.57
15	5.5	119	116.7	1.03	212.3	121	5.5	116.7	1.03	5.29	3.3	106.92
16	5.4	121	115.9	1.02	214.7	121	5.4	115.9	1.02	5.24	3.3	105.51
17	5.5	121	115.7	1.03	214.4	119	5.5	115.7	1.03	5.24	3.3	106.15
18	5.3	119	116.2	1.05	214.8	117	5.3	116.2	1.05	5.2	3.3	107.27
19	5.3	117	115.2	1.17	213.4	119	5.3	115.2	1.17	5.29	3.3	104.97
20	5.4	119	116.9	1.01	214.5	120	5.3	116.9	1.01	5.27	3.3	104.78
Mean	5.40	118	115.72	1.03	213.91	118	5.40	115.72	1.03	5.26	3.31	106.72
SD	0.07	0.02	1.06	0.03	0.98	0.02	0.08	1.06	0.03	0.04	0.04	1.48
CV%	1.3	1.9	0.9	3.3	0.5	2.0	1.4	0.9	3.3	0.8	1.4	1.4
Limit(%)	≤3.0	≤4.0	≤5.0	≤3.5	≤3.0	≤5.0	≤5.0	≤5.0	≤5.0	≤5.0	≤5.0	≤5.0
Result	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Accepted By: 
 Date:

Star Bioned Pvt. Ltd.

Asst Application Manager 

Carry over experiment	
Instrument	Bs 240
Test Name	GLU

Srl No	sample	mg/dL
1	High1	206.4
2	High2	206.3
3	High3	205.5
4	Low1	11.7
5	Low2	11.2
6	Low3	11.2

CARRYOVER % 0.005

Carry over experiment	
Instrument	Bs 240
Test Name	T-Bill

Srl No	sample	mg/dL
1	High1	4.1
2	High2	4.07
3	High3	4.04
4	Low1	0.29
5	Low2	0.25
6	Low3	0.22

CARRYOVER % 0.261

Carry over experiment	
Instrument	Bs 240
Test Name	TP

Srl No	sample	g/dl
1	High1	8.8
2	High2	8.7
3	High3	8.8
4	Low1	0.5
5	Low2	0.4
6	Low3	0.4

CARRYOVER %

0.119

Carry over experiment	
Instrument	Bs 240
Test Name	TG

Srl No	sample	mg/dL
1	High1	220.2
2	High2	219.9
3	High3	221.5
4	Low1	11.6
5	Low2	11.6
6	Low3	11.2

CARRYOVER %

0.005

Carry over experiment	
Instrument	Bs 240
Test Name	CREA

Srl No	sample	mg/dL
1	High1	4.71
2	High2	4.77
3	High3	4.75
4	Low1	0.24
5	Low2	0.24
6	Low3	0.24

CARRYOVER %

0.219

Carry over experiment	
Instrument	Bs 240
Test Name	UA

Srl No	sample	mg/dL
1	High1	9.65
2	High2	9.49
3	High3	9.73
4	Low1	0.52
5	Low2	0.49
6	Low3	0.49

CARRYOVER % 0.110

Carry over experiment	
Instrument	Bs 240
Test Name	UREA

Srl No	sample	mg/dL
1	High1	135.81
2	High2	137.35
3	High3	139.22
4	Low1	8.2
5	Low2	8.25
6	Low3	7.88

CARRYOVER % 0.008

Carry over experiment	
Instrument	Bs 240
Test Name	ALB

Srl No	sample	g/dl
1	High1	5.1
2	High2	5.2
3	High3	5.1
4	Low1	0.2
5	Low2	0.1
6	Low3	0.2

CARRYOVER % 0.196

Carry over experiment

Instrument	Bs 240
Test Name	Cho H

Srl No	sample	mg/dL
1	High1	300.03
2	High2	301.86
3	High3	304.19
4	Low1	20.28
5	Low2	19.28
6	Low3	18.63

CARRYOVER %

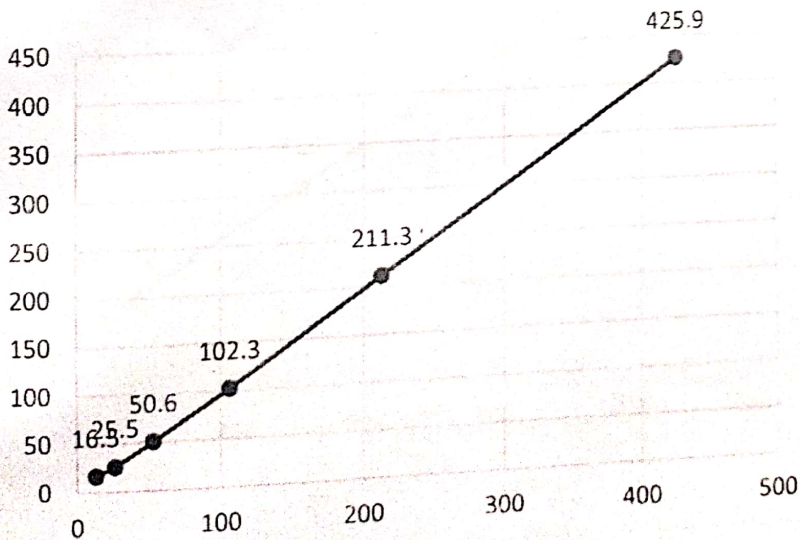
0.003



Mindray

N°	Method	Samp ID	Type	Dil.	Status	Result
1	UreaUV	sample1:64	N	1.0 0		
2	UreaUV	sample1:32	N	1.0 0	13.309375	16.5
3	UreaUV	sample1:16	N	1.0 0	26.61875	25.5
4	UreaUV	sample1:8	N	1.0 0	53.2375	50.6
5	UreaUV	sample1:4	N	1.0 0	106.475	102.3
6	UreaUV	sample1:2	N	1.0 0	212.95	211.3
7	UreaUV	sample1	N	1.0 0	425.9	425.9
8	UreaUV	sample1	N	1.0 0		429.4
9	UreaUV	sample1	N	1.0 0		423.8

Urea

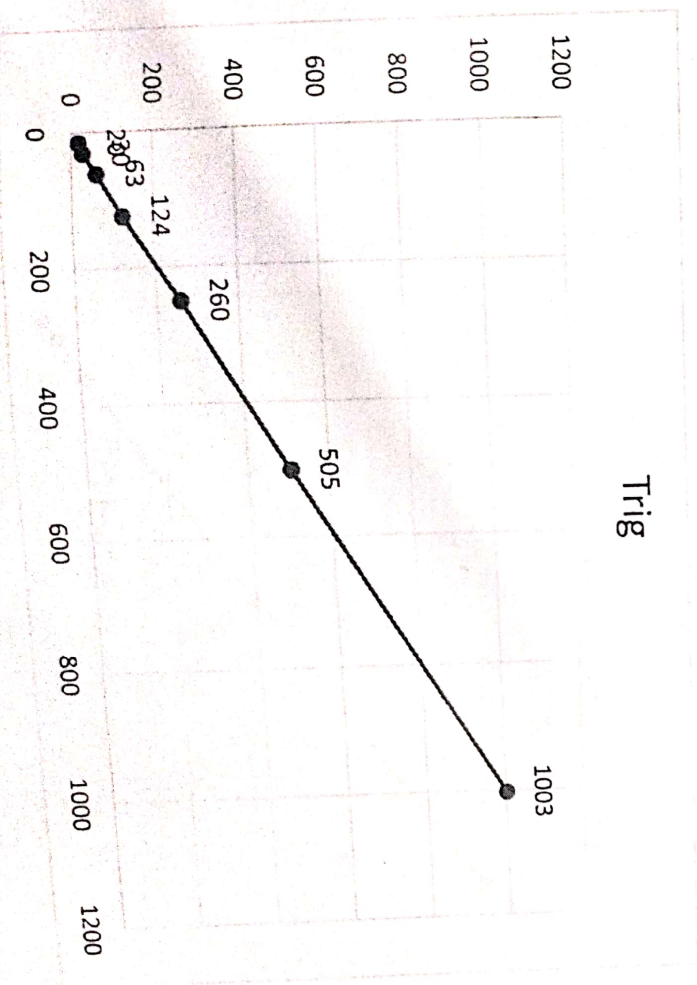


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Mindray

Mindray

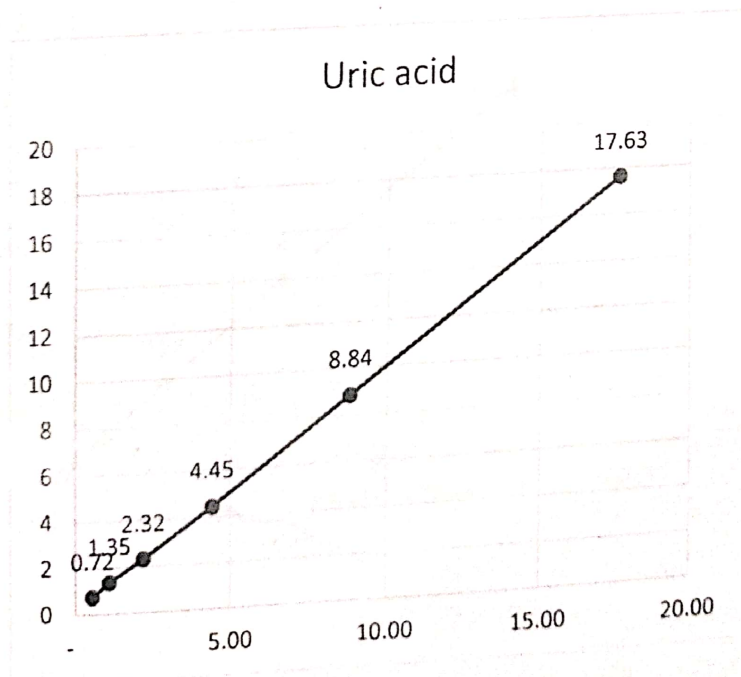
N°	Method	Samp ID	Type	Dil.	Status	Result
1	Trig	sample1:64	N	1.00	15.671875	20
2	Trig	sample1:32	N	1.00	31.34375	30
3	Trig	sample1:16	N	1.00	62.6875	63
4	Trig	sample1:8	N	1.00	125.375	124
5	Trig	sample1:4	N	1.00	250.75	260
6	Trig	sample1:2	N	1.00	501.5	505
7	Trig	sample1	N	1.00	1003	1003
8	Trig	sample1	N	1.00		1007
9	Trig	sample1	N	1.00		997



Mindray

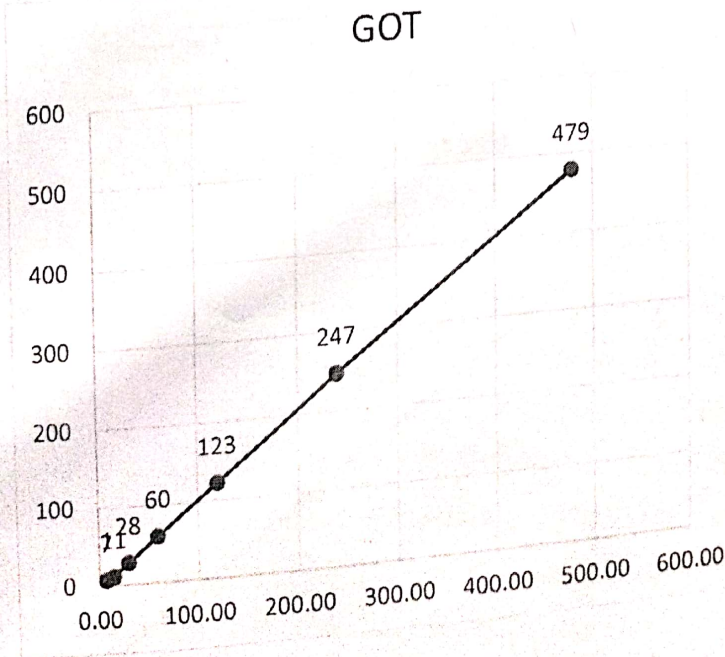
Mindray

Method	Samp ID	Type	Dil.	Status	Result
UA	sample1:32	N	1.00	0.55	0.72
UA	sample1:16	N	1.00	1.10	1.35
UA	sample1:8	N	1.00	2.20	2.32
UA	sample1:4	N	1.00	4.41	4.45
UA	sample1:2	N	1.00	8.82	8.84
UA	sample1	N	1.00	17.63	17.63
UA	sample1	N	1.00		17.39
UA	sample1	N	1.00		17.14



Mindray

N°	Method	Samp ID	Type	Dil.	Status	Result
1	GOT	sample1:64	N	1.00	7.48	7
2	GOT	sample1:32	N	1.00	14.97	11
3	GOT	sample1:16	N	1.00	29.94	28
4	GOT	sample1:8	N	1.00	59.88	60
5	GOT	sample1:4	N	1.00	119.75	123
6	GOT	sample1:2	N	1.00	239.50	247
7	GOT	sample1	N	1.00	479.00	479
8	GOT	sample1	N	1.00		485
9	GOT	sample1	N	1.00		490



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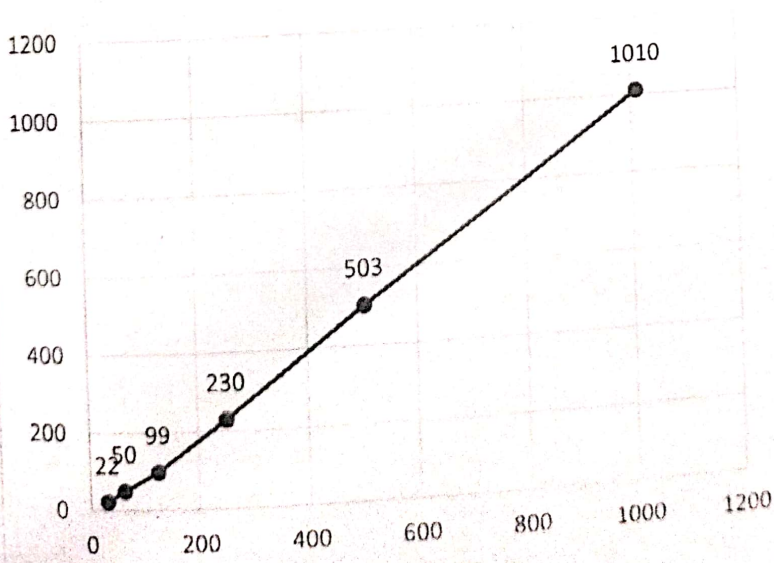
Mindray

Work
sheet
report

Mindray

N°	Method	Samp ID	Type	Dil.	Status	Result	
1	ALP	sample1:64	N	1.00			
2	ALP	sample1:32	N	1.00	31.5625	22	
3	ALP	sample1:16	N	1.00	63.125	50	
4	ALP	sample1:8	N	1.00	126.25	99	
5	ALP	sample1:4	N	1.00	252.5	230	
6	ALP	sample1:2	N	1.00	505	503	
7	ALP	sample1	N	1.00	1010	1010	
8	ALP	sample1	N	1.00		1006	
9	ALP	sample1	N	1.00		1007	

Alkaline Phosphatase





Date:24/04/2024

CALIBRATION CERTIFICATE OF BS-240

CUSTOMERNAME--**SOOD DIAGNOSTICS**

Serial Number -

YX-24005344

User Software = V

5.4.2 Initialization Motor

Vertical Motors - S /R1 /R2 in

HomePolar Motors - S /R1 /R2 in

HomeReactionRotor in home

Sample/ReagentrotorinHome

Ceramic Dispensing pump - S/ R1 /R2 in

HomeOpticsInitialization: Ok

Auto adjustment of the probe is

donePeltiercells and driverstest

Rotor Peltier/ Reagent Rotor peltier driver test:

OkTemperaturesystem initialized

LEDtest:ok

Hardwarecompletelyinitialized

Parameters	Currentvalue	Minimum	Maximum
ReadingreferencePosition-Well 1	7896	7860	7905
WashingSolution Tank 0	0	-5	5
WashingSolution Tank 50	46	40	60
WashingSolution Tank 100	98	95	105
WasteTank0	-1	-5	5
WasteTank50	43	40	60
WasteTank100	100	95	105
Thermaladjustmentofreactionr otor	37.0	36.0	39.0
Thermal adjustment of Washstation	44.9	44	50
Thermaladjustmentofreagenttip1	37.0	36	39

25-B/7, W.E.A. New Rohtak Road, Near Liberty Cinema, Karol Bagh, New Delhi-110005
Tel. : 9643207024, 20, 9810028448 • Email : starbiomed@rediffmail.com, info@starbiomed.com





STAR BIOMED PVT. LTD.

Thermaladjustmentofreagenttip2	37.0	36	39
PhotometricDarkCurrent Adjustment	3885	3941	4500
Main PhotoDiodeCounts340NM	8,82,490	2,16,086	950000
Main PhotoDiodeCounts405NM	8,99,288	7,40,174	950000
Main PhotoDiodeCounts505NM	9,01,338	7,03,853	950000
Main PhotoDiodeCounts535NM	8,89,214	5,97,627	950000
Main PhotoDiodeCounts560NM	8,99,482	7,10,590	950000
Main PhotoDiodeCounts600NM	9,01,891	5,82,890	950000
Main PhotoDiodeCounts635NM	9,00,649	5,91,854	950000
Main PhotoDiodeCounts670NM	8,99,062	7,39,773	950000

Next calibrationdueon:23/04/2025

ForSOOD DIAGNOSTICS



AuthorizedSignatory

25-B/7, W.E.A. New Rohtak Road, Near Liberty Cinema, Karol Bagh, New Delhi-110005
Tel. : 9643207024, 20, 9810028448 • Email : starbiomed@rediffmail.com, info@starbiomed.com

